

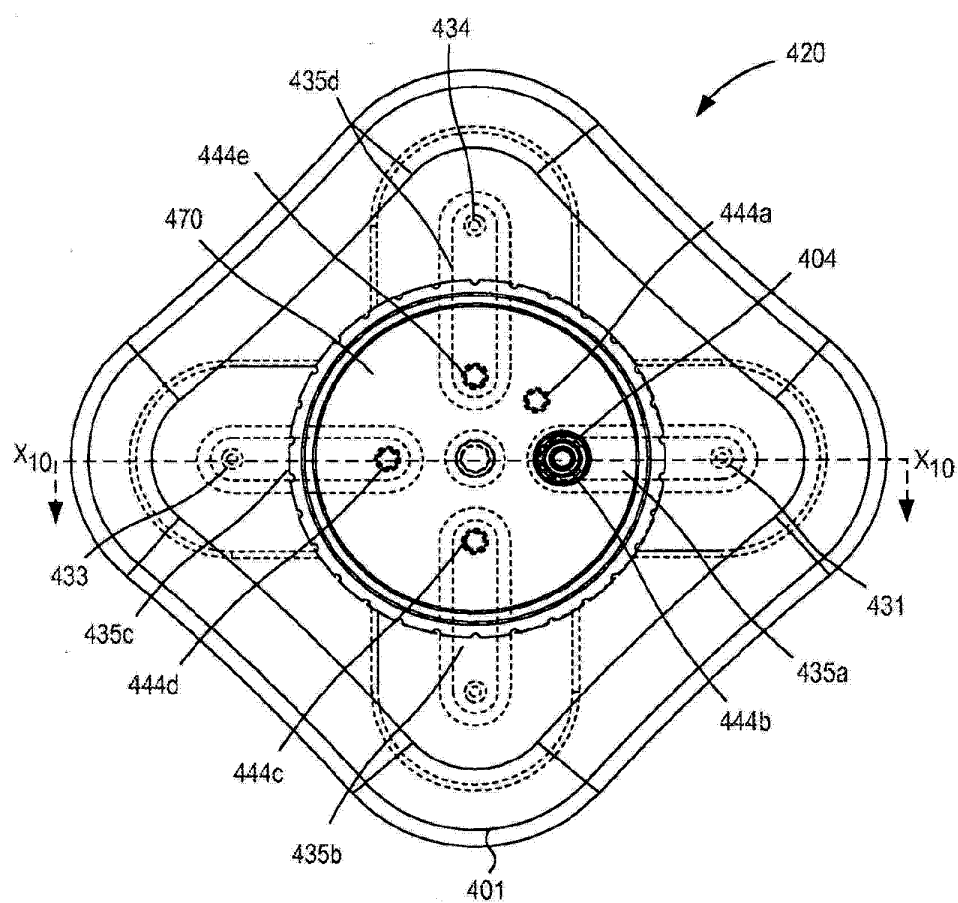


图 21

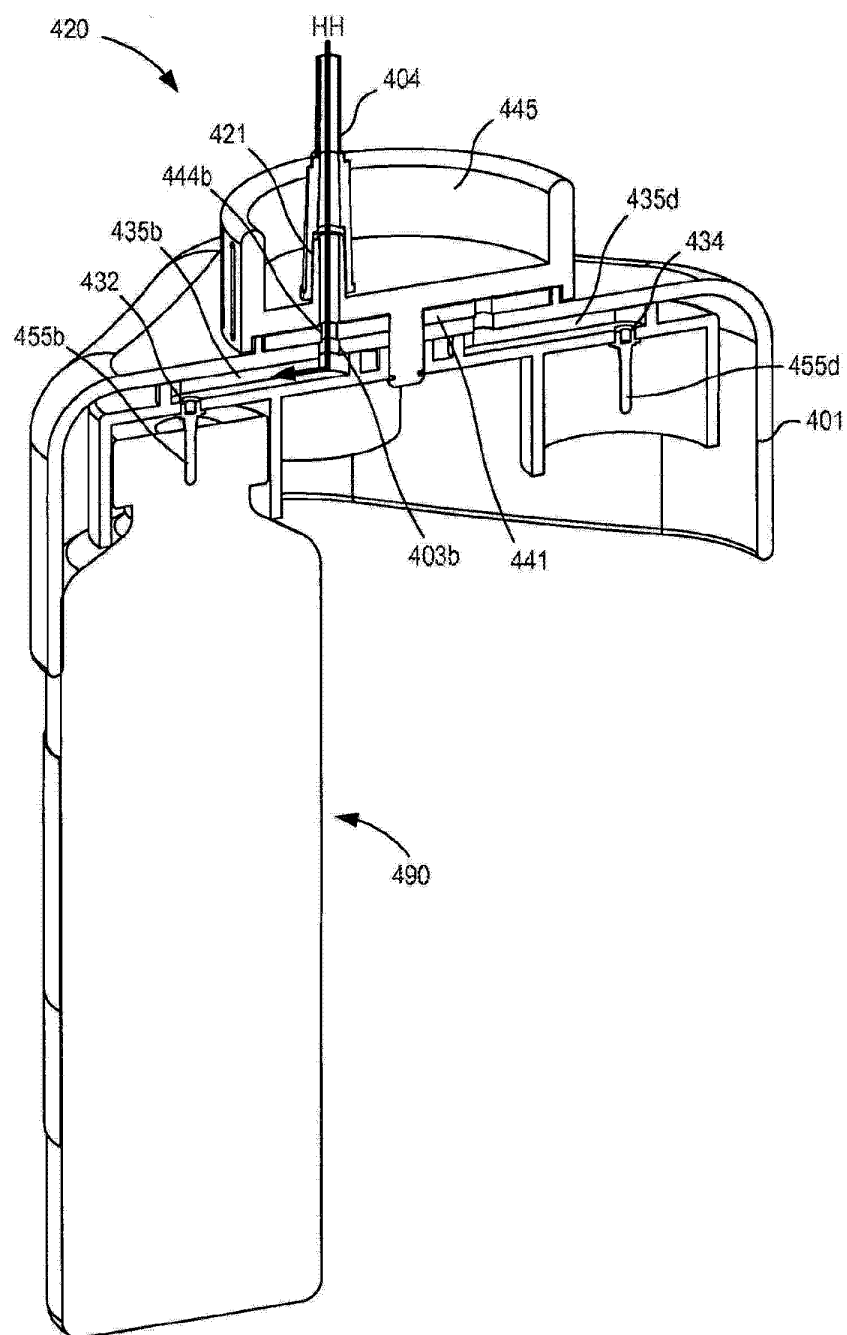


图 22

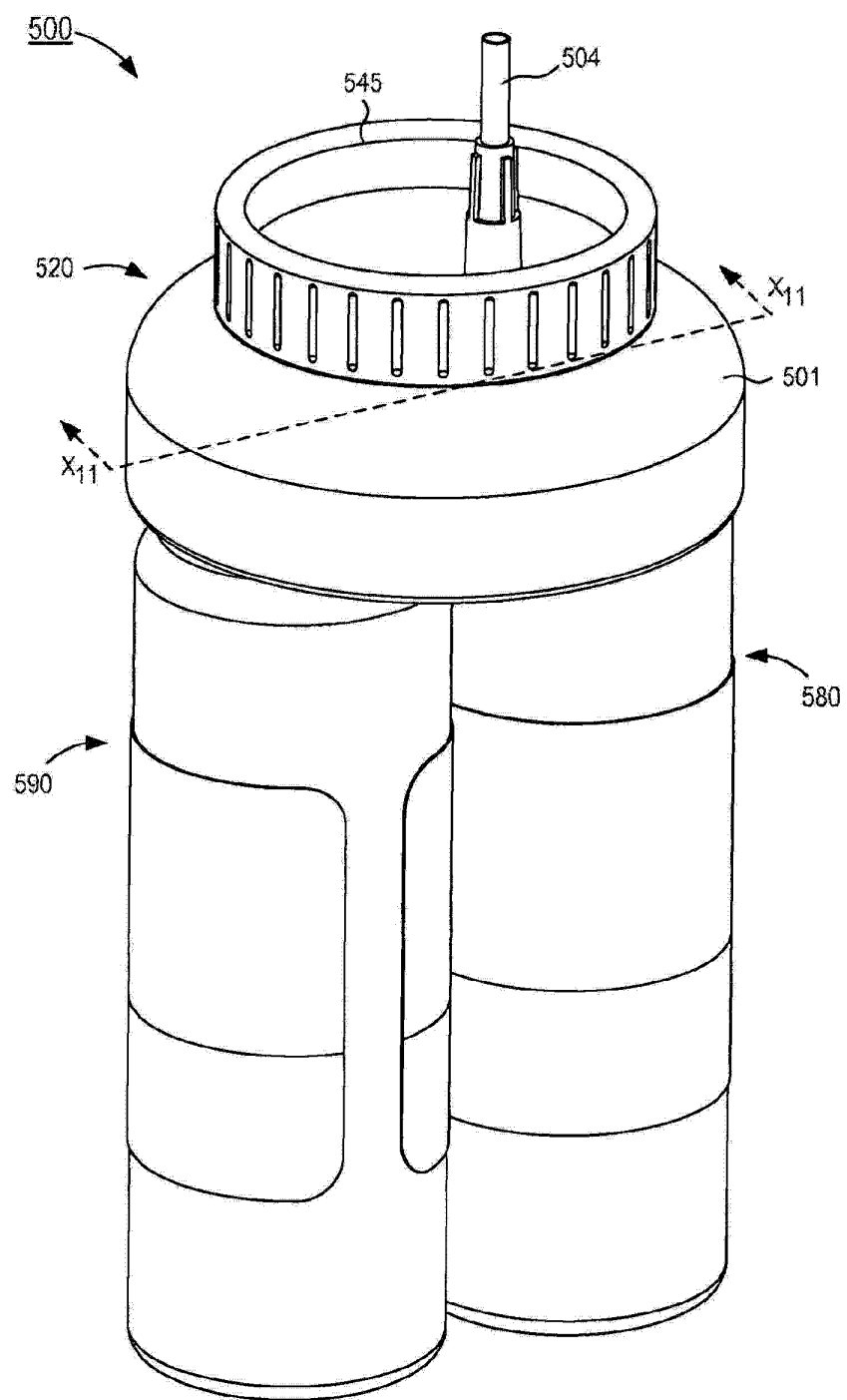


图 23

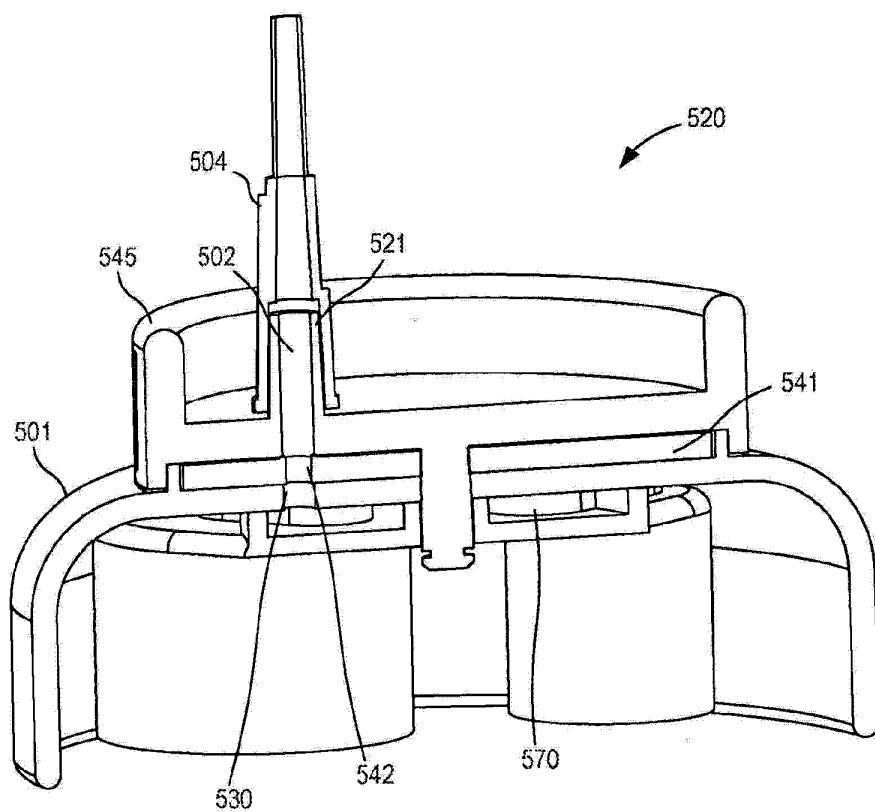


图 24

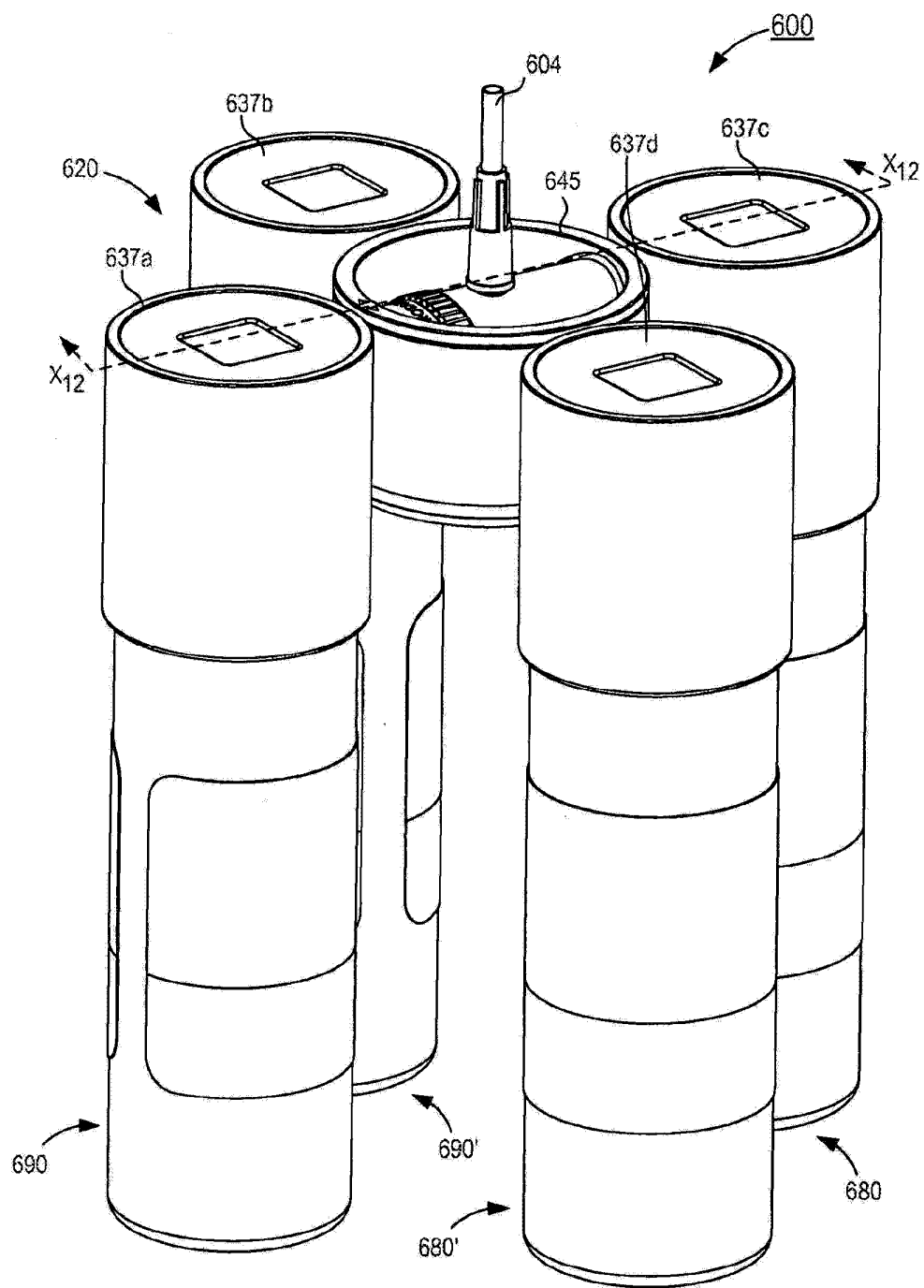


图 26

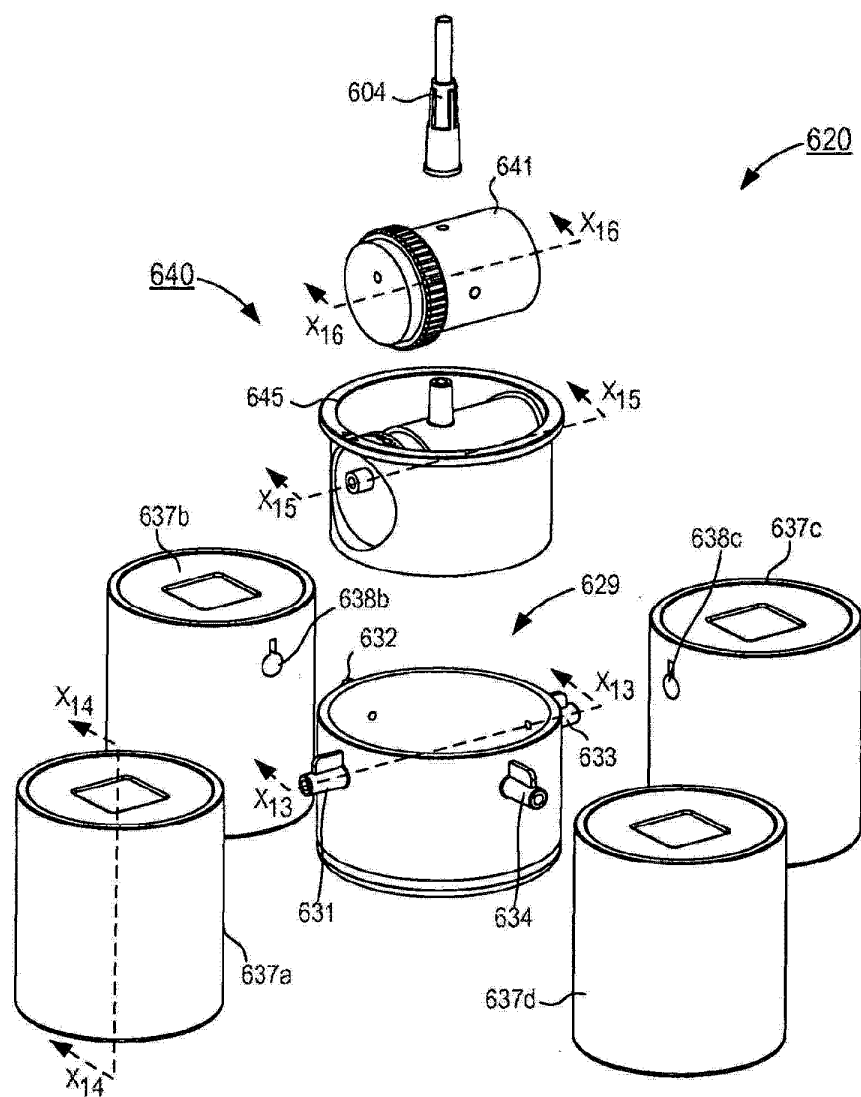


图 27

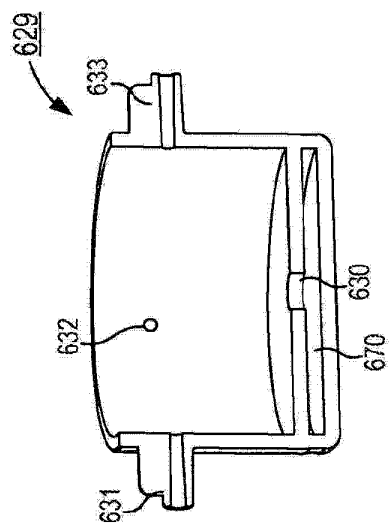


图 28

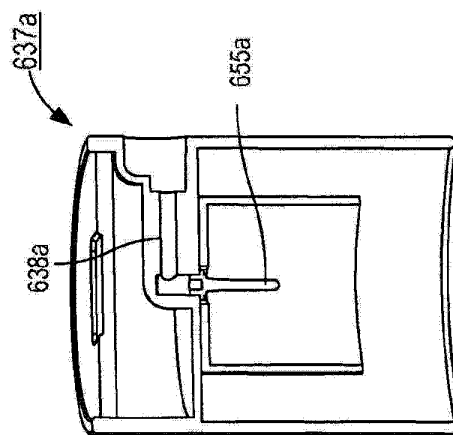


图 29

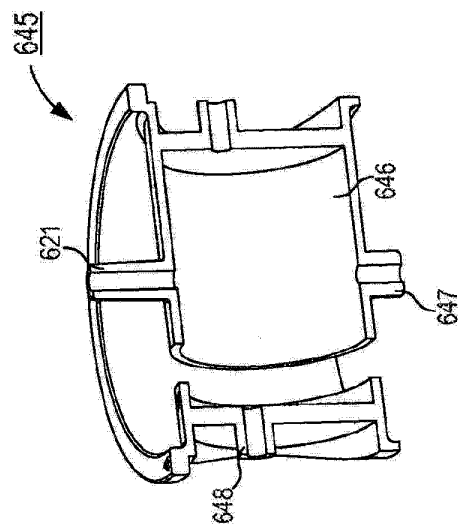


图 30

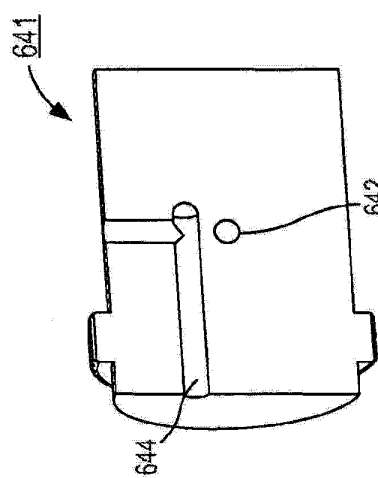


图 31

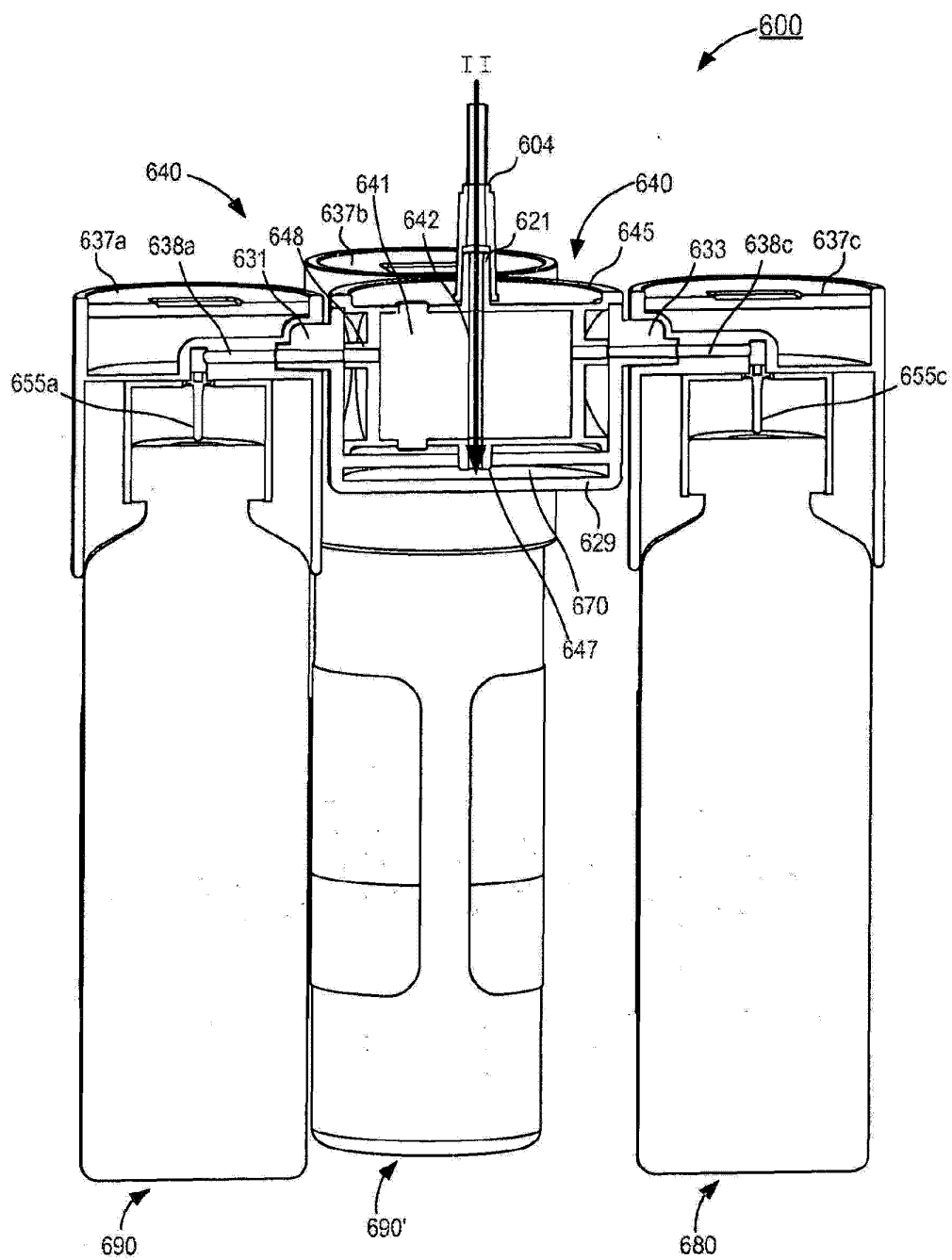


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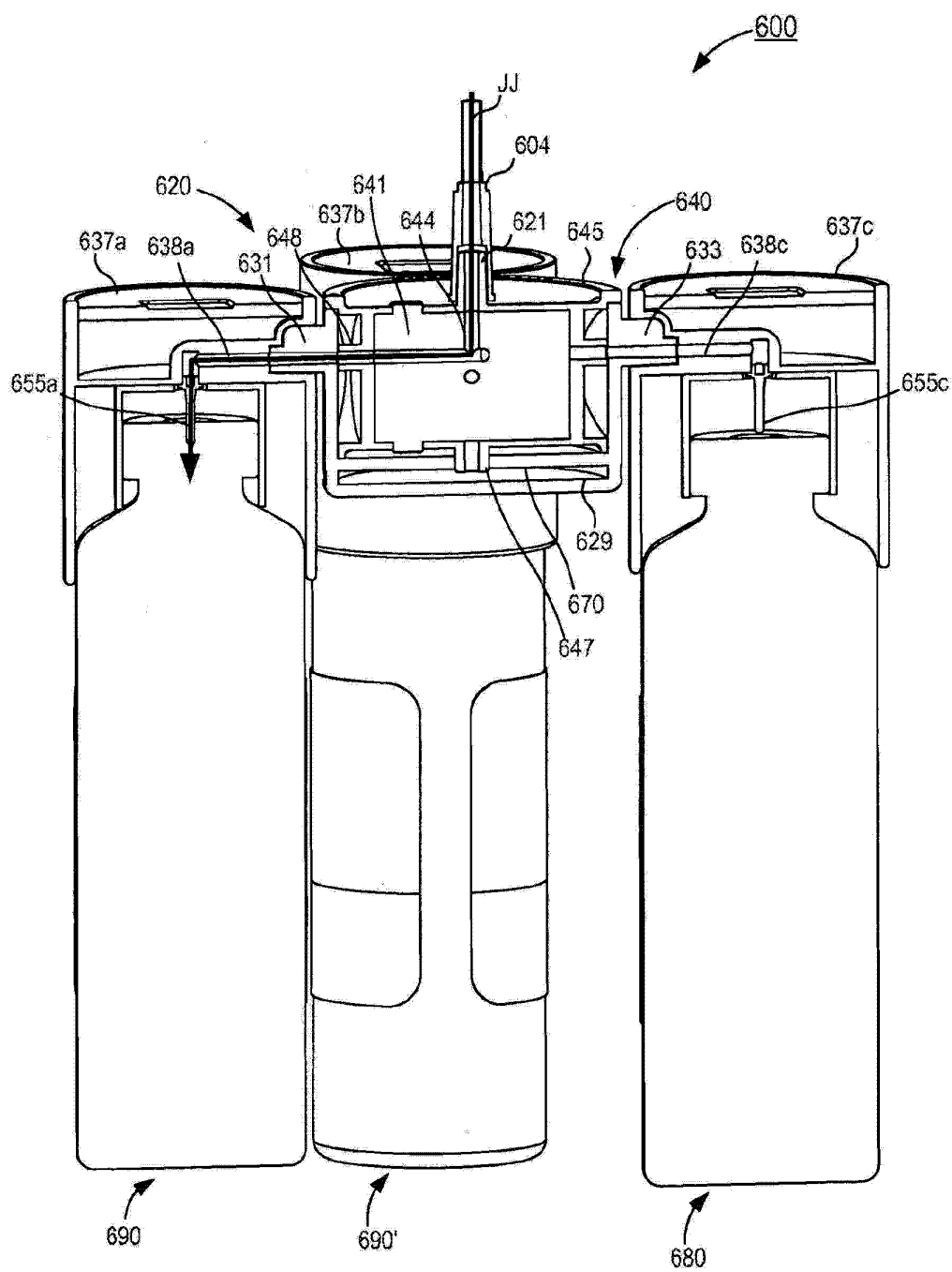


图 33

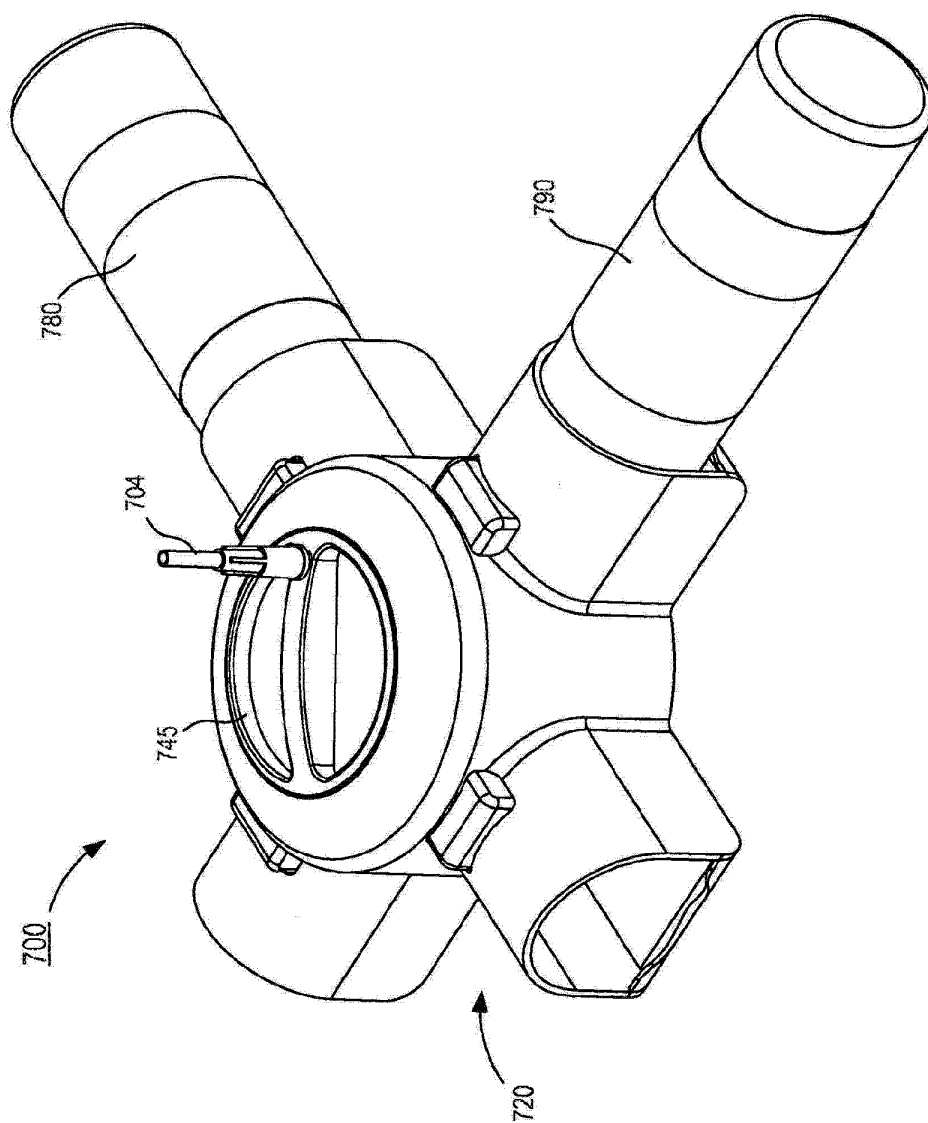


图 31

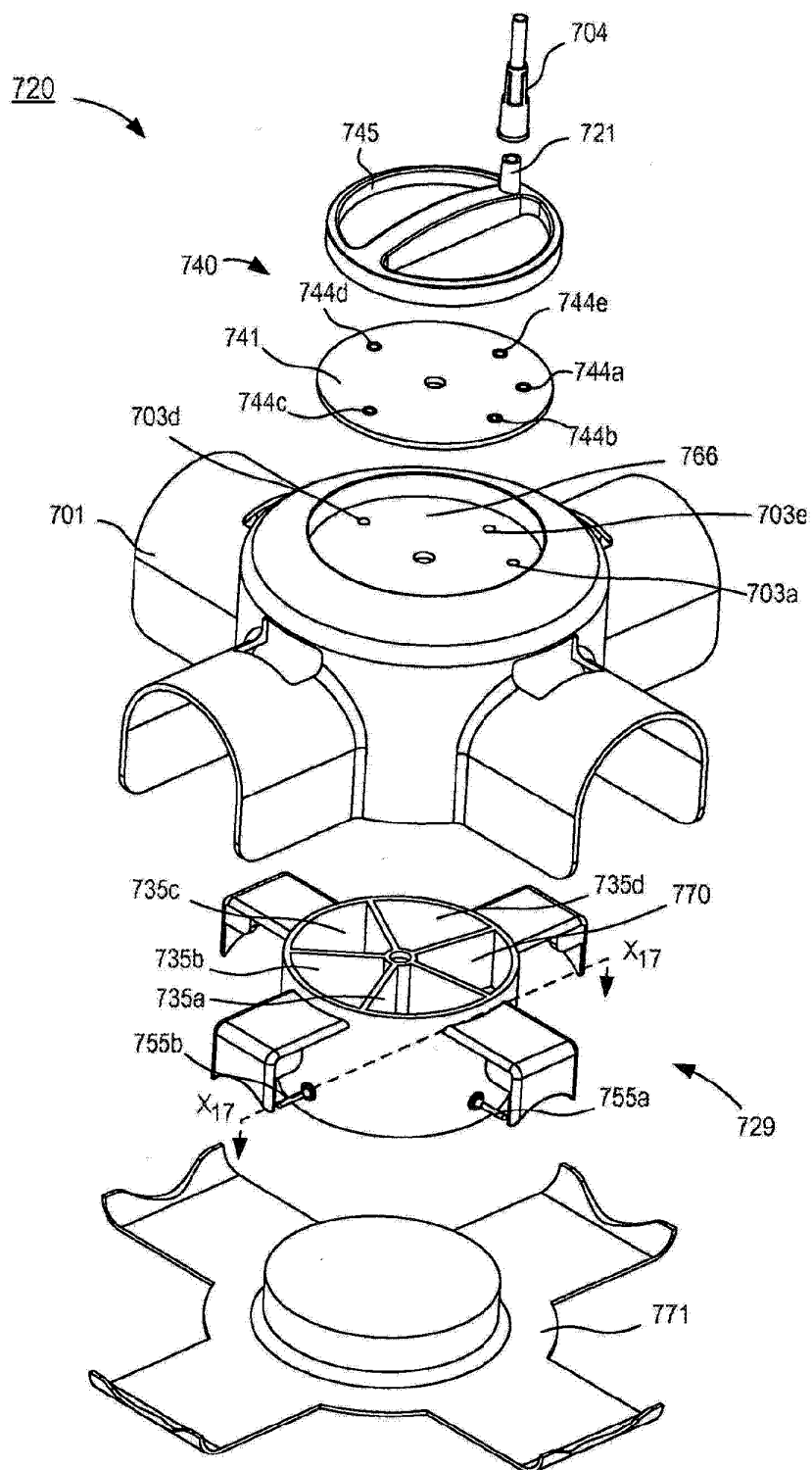


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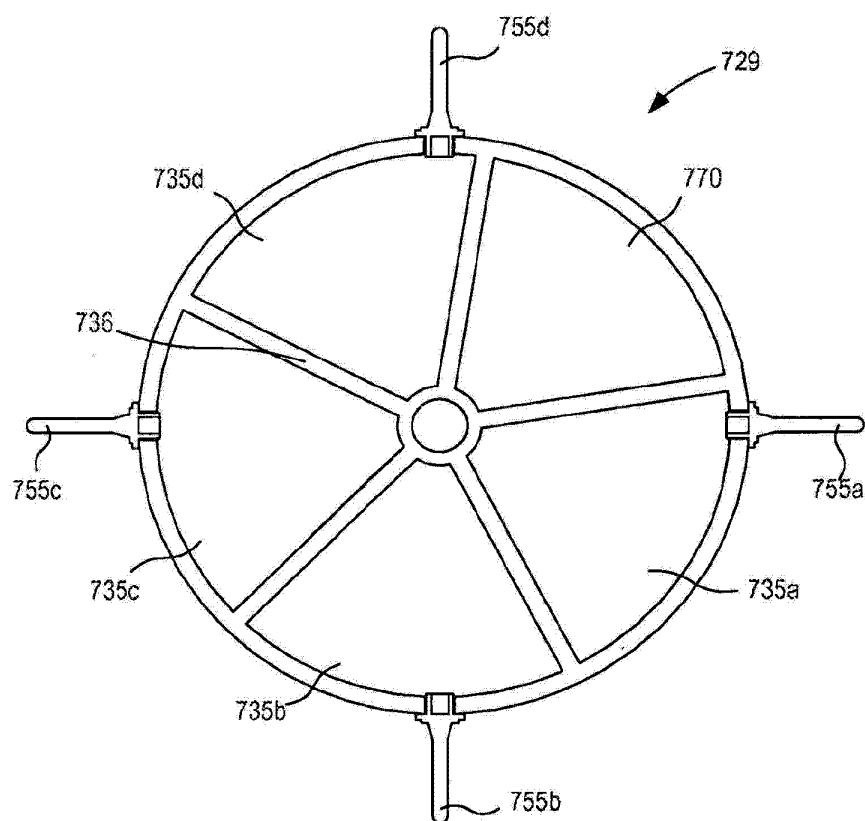


图 36

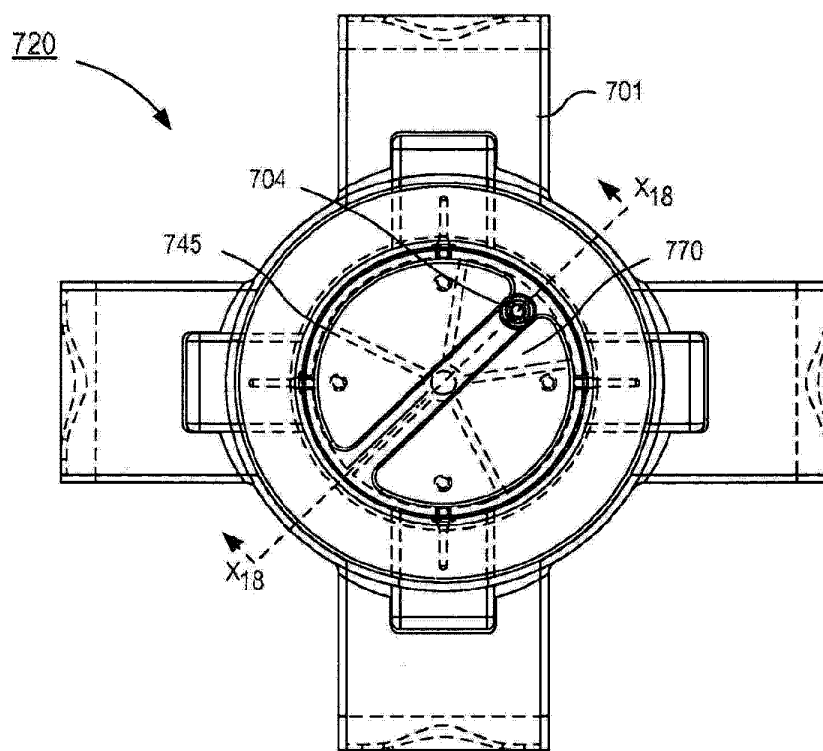


图 37

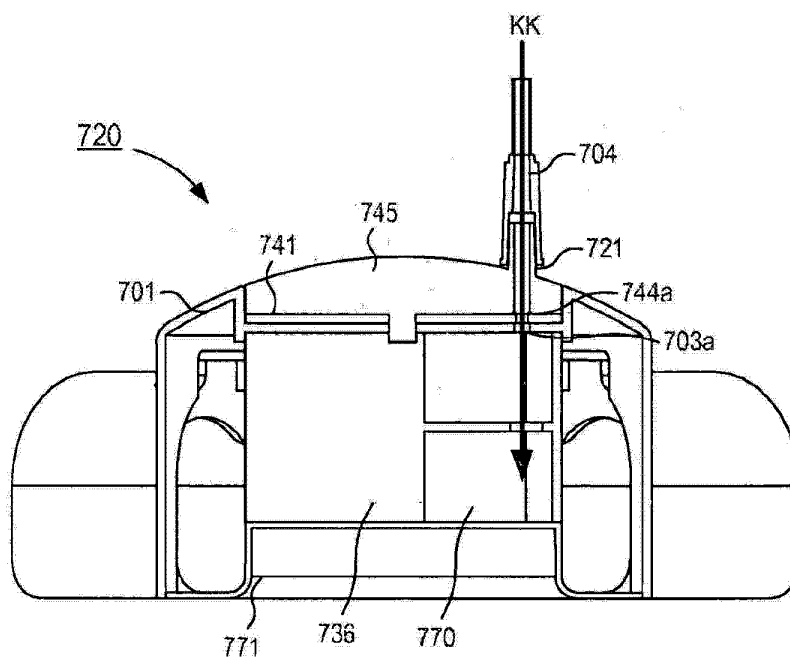


图 38

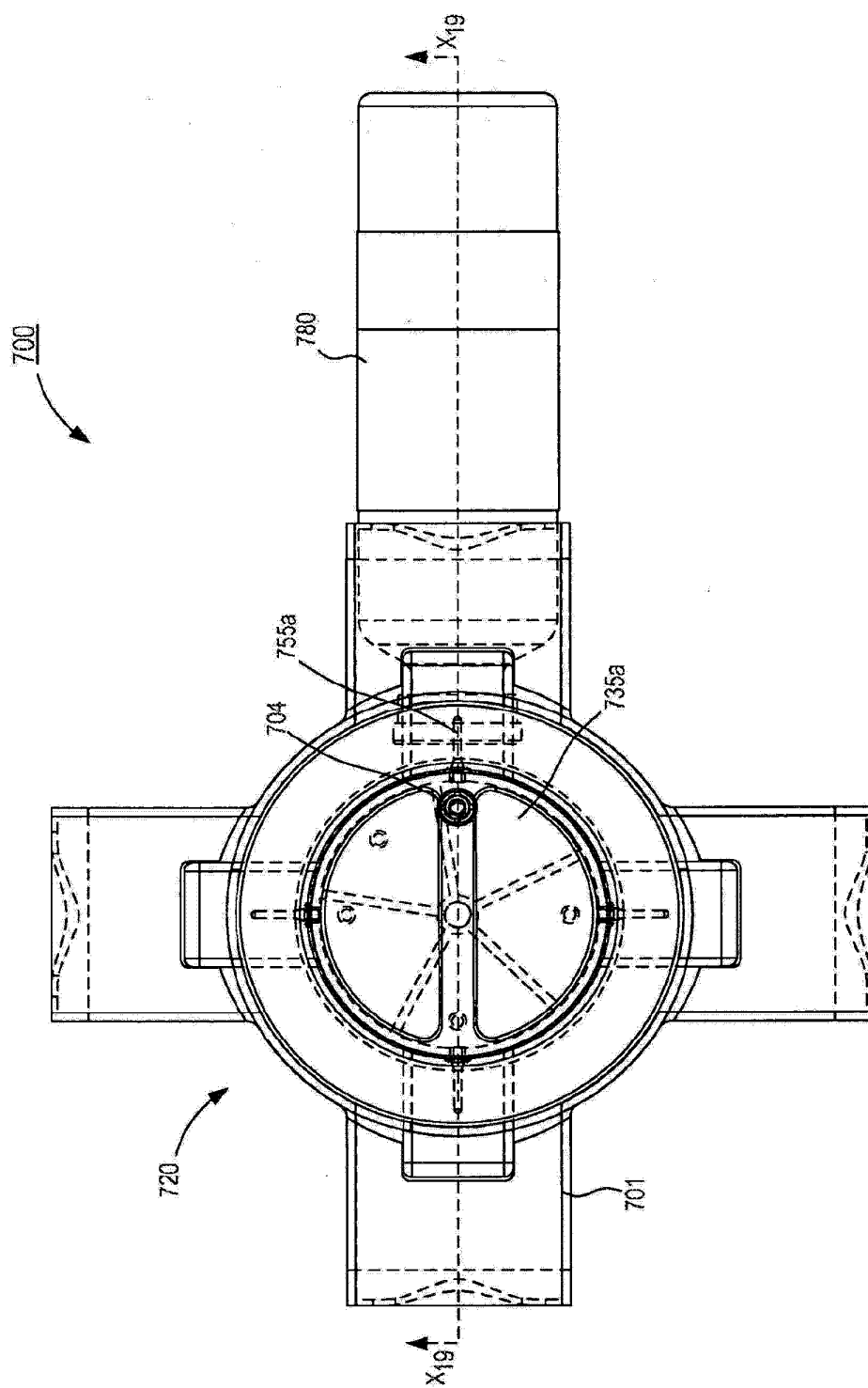


图 39

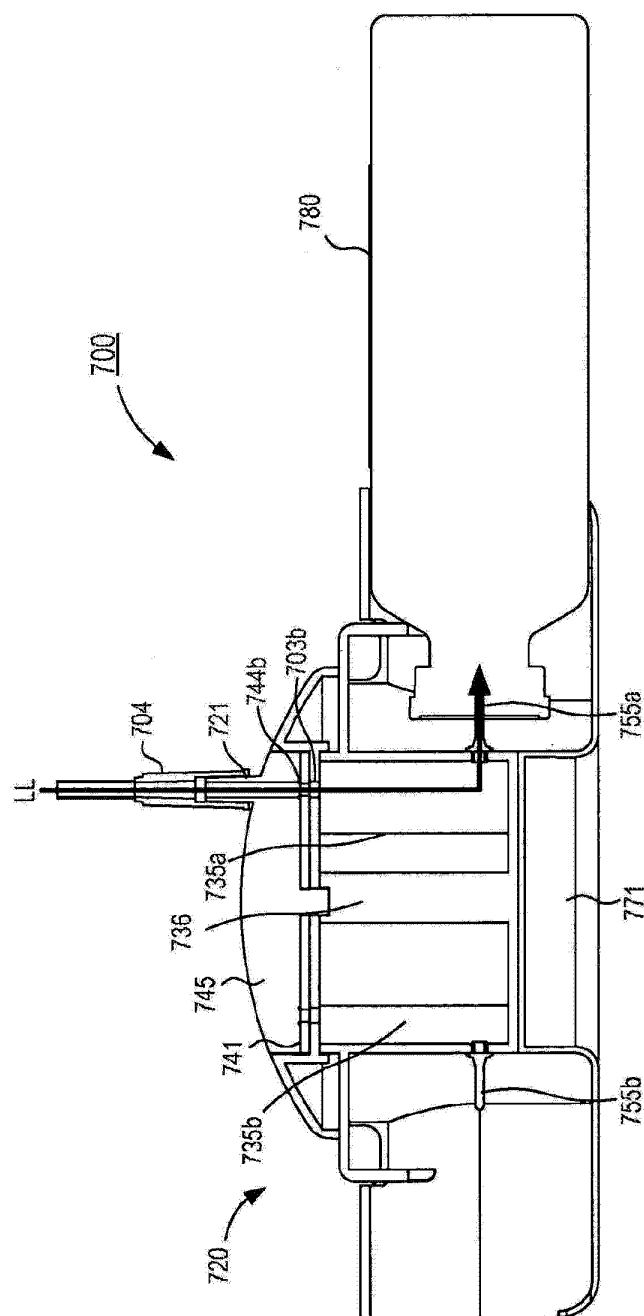


图 10

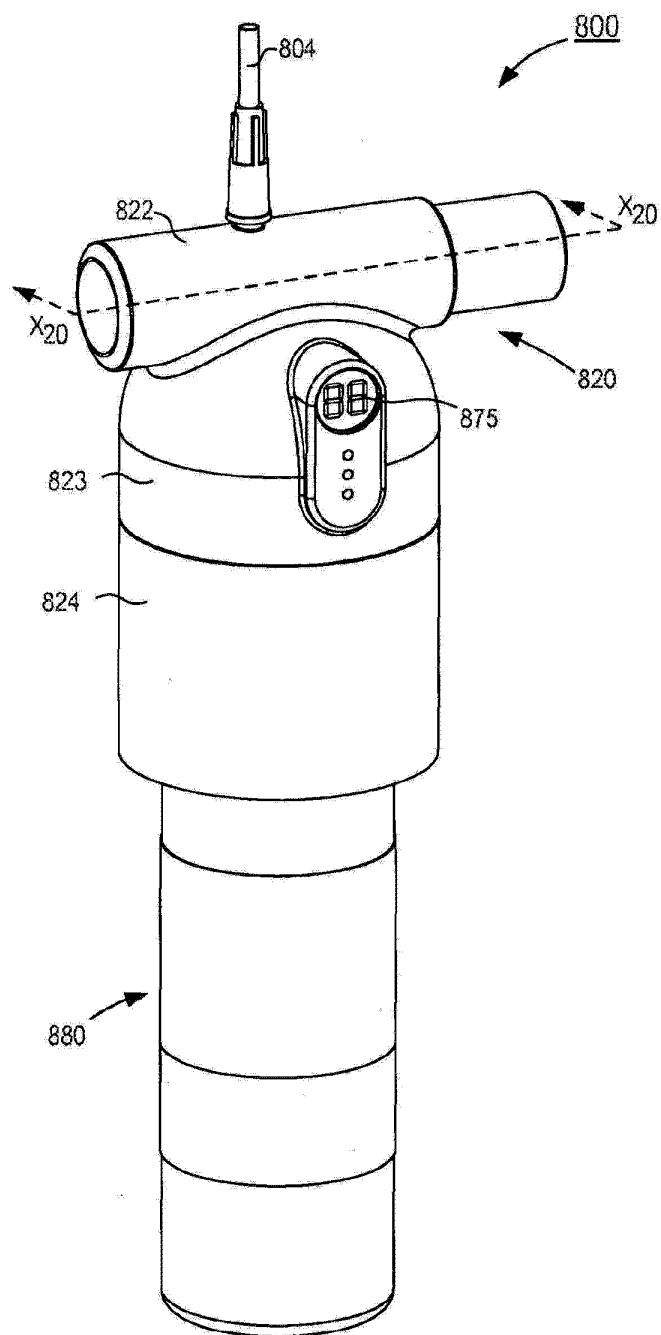


图 41

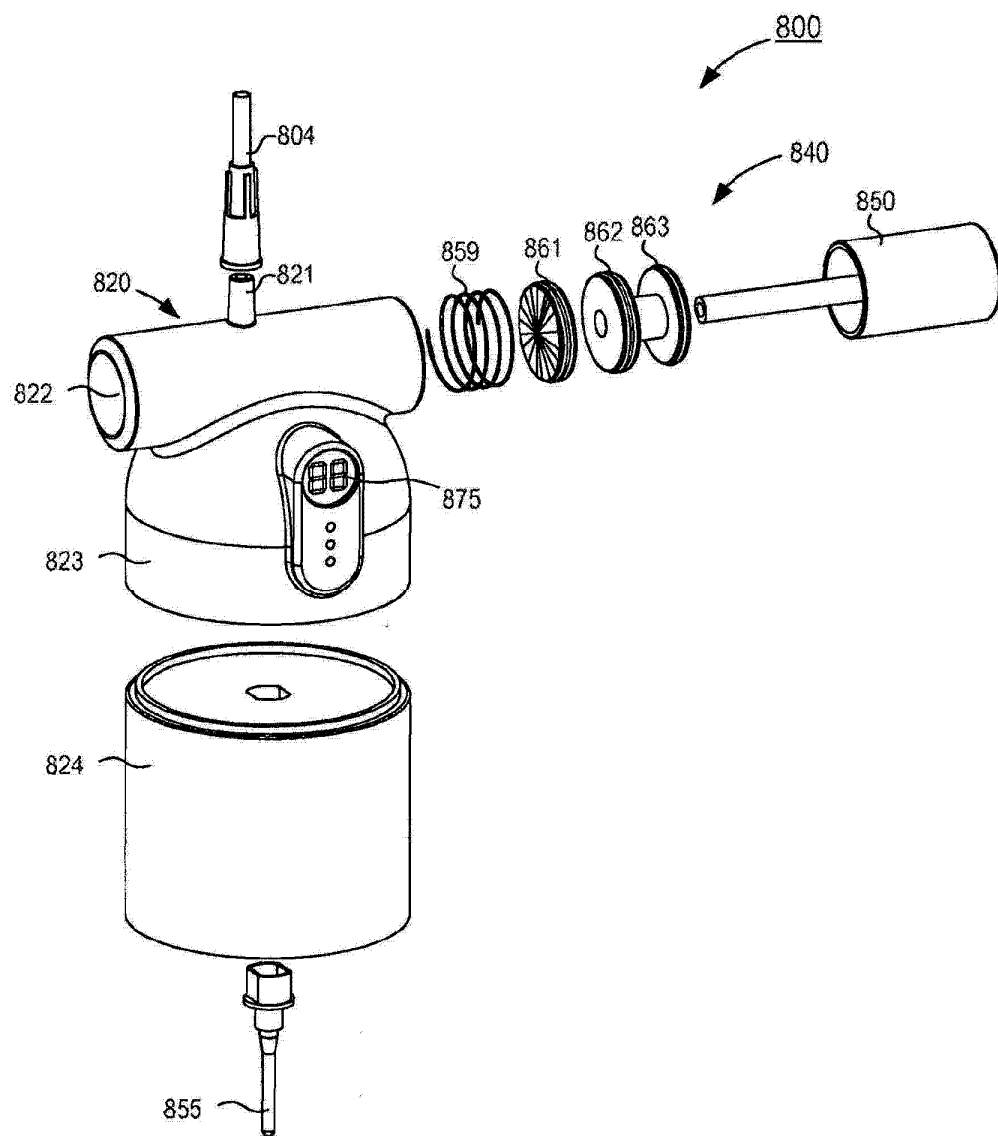


图 42

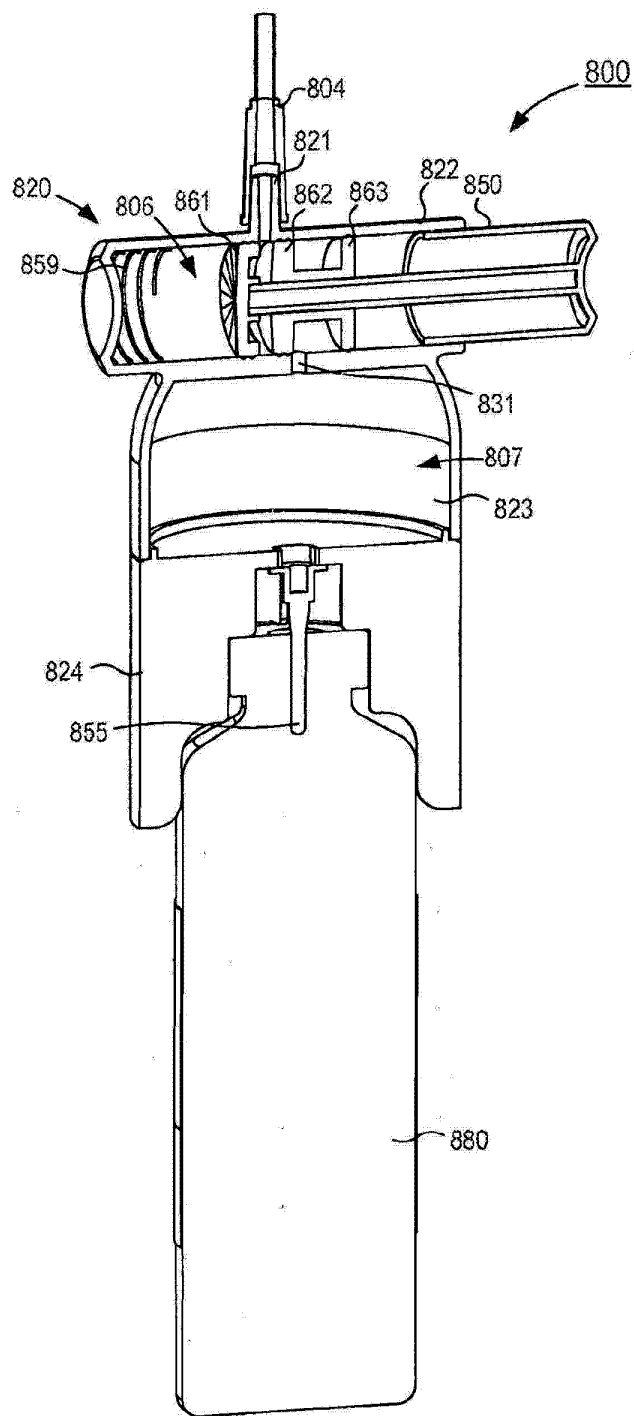


图 13

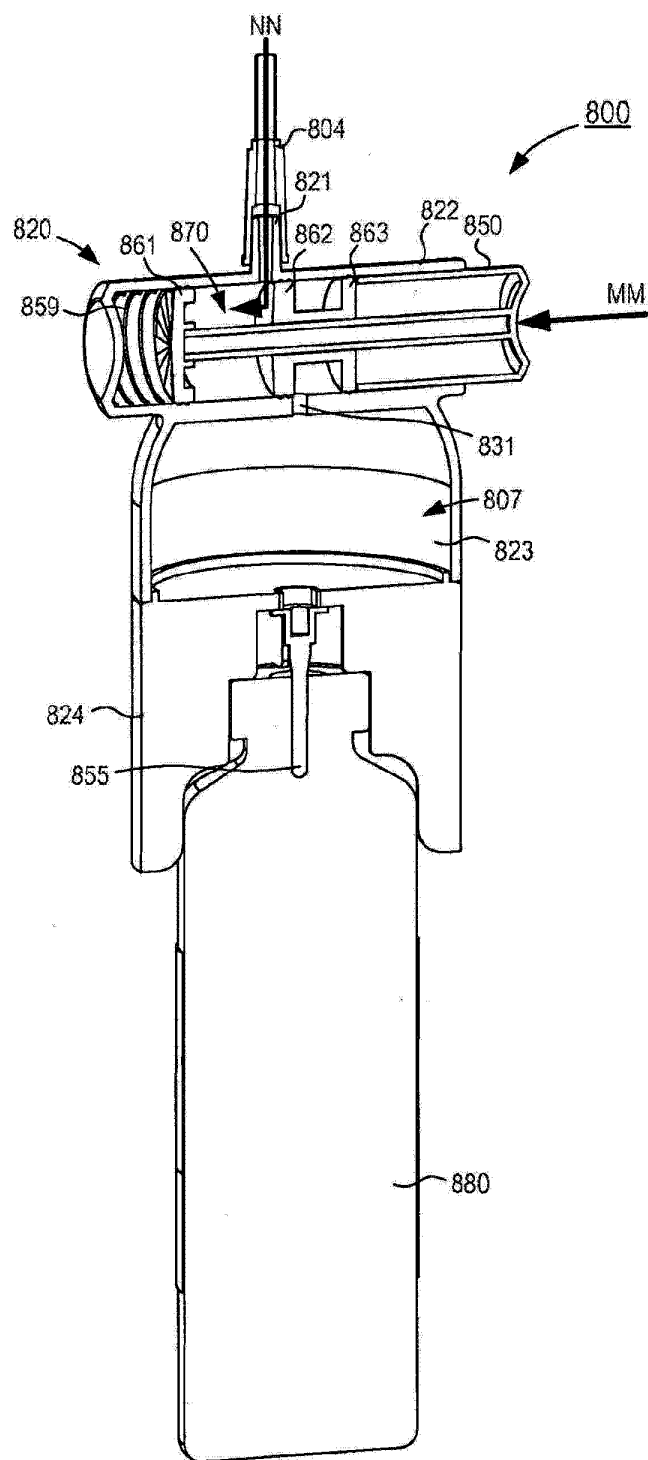


图 44

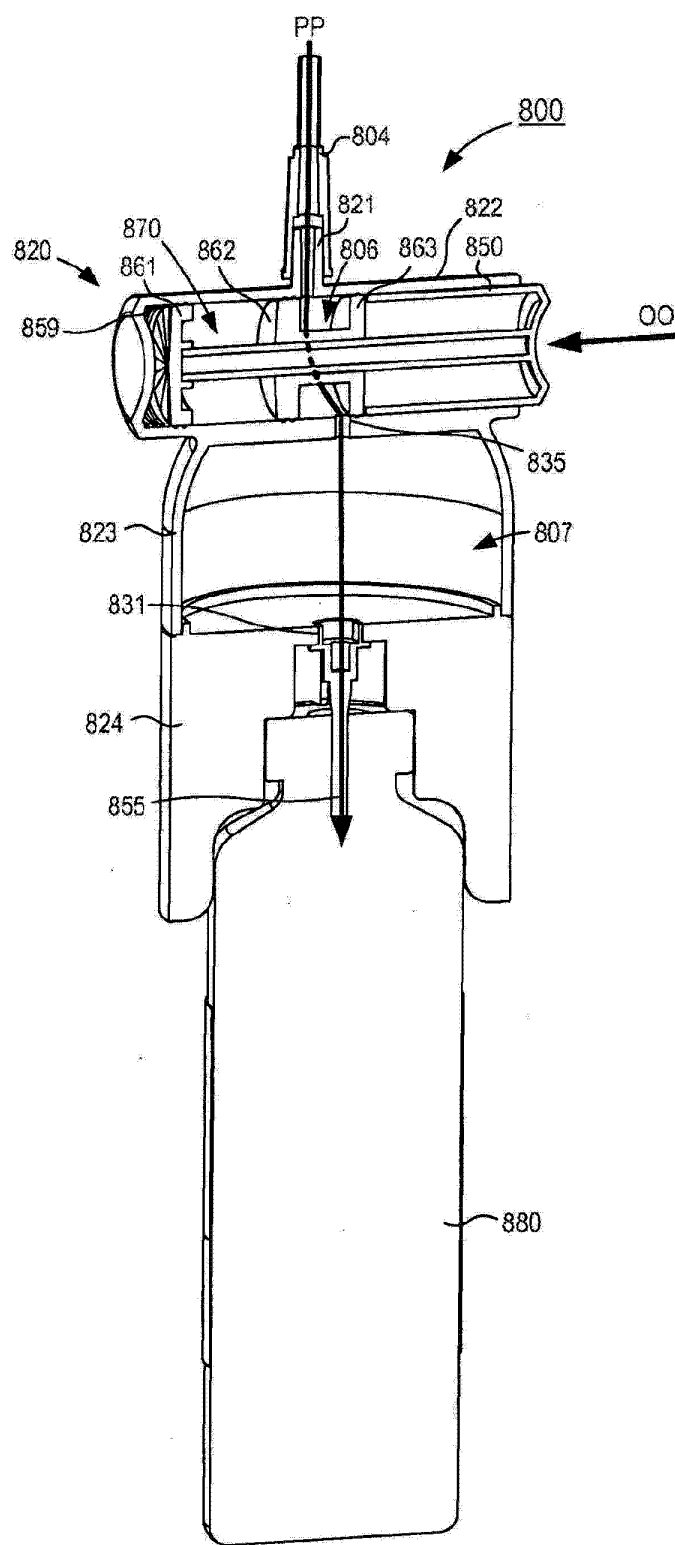


图 45

80

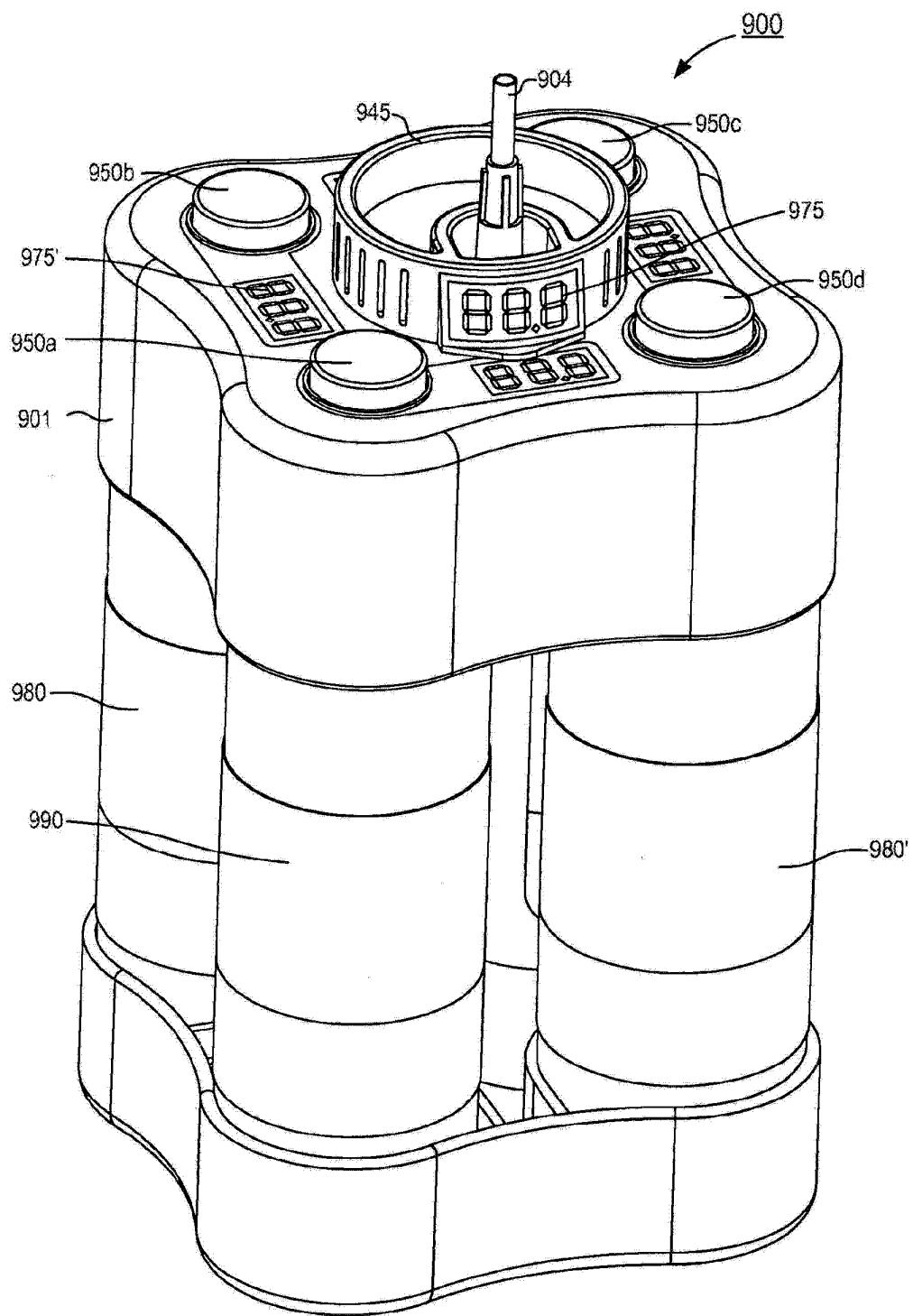


图 46

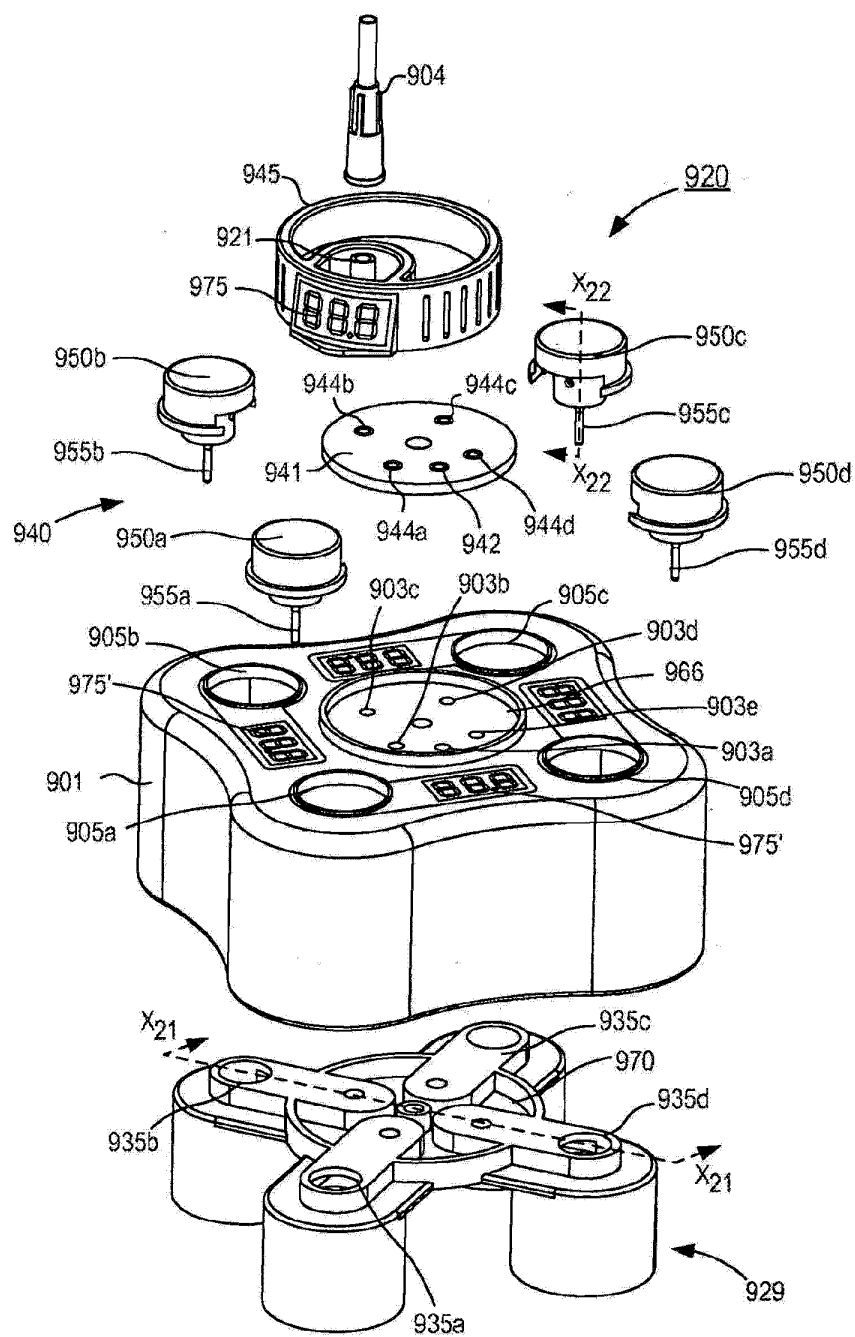


图 47

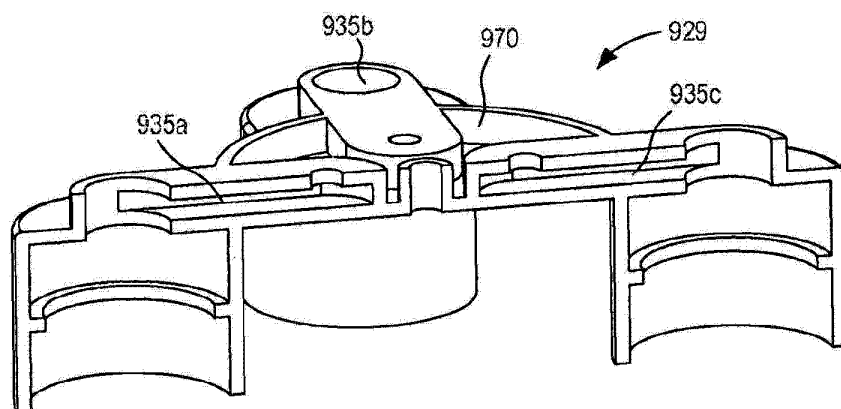


图 48

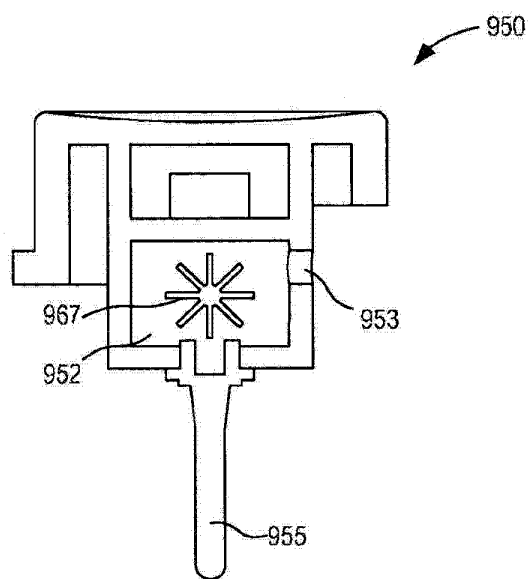


图 49

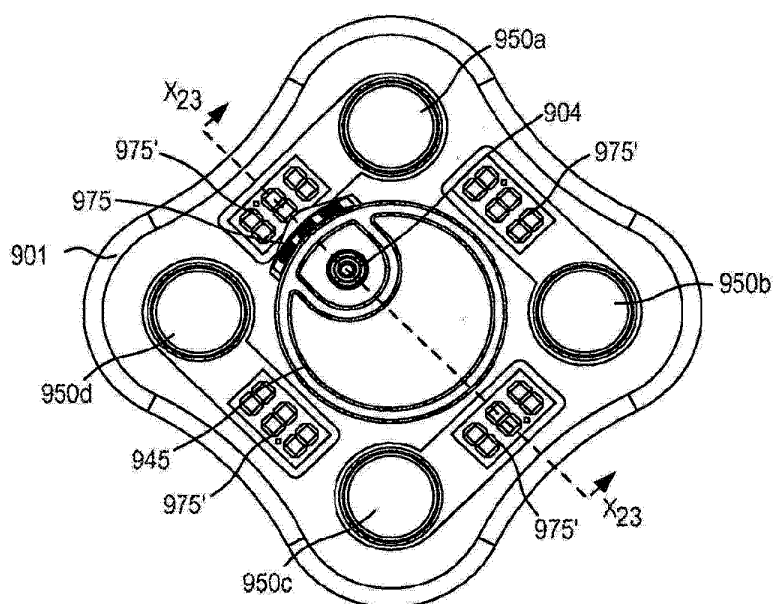


图 50

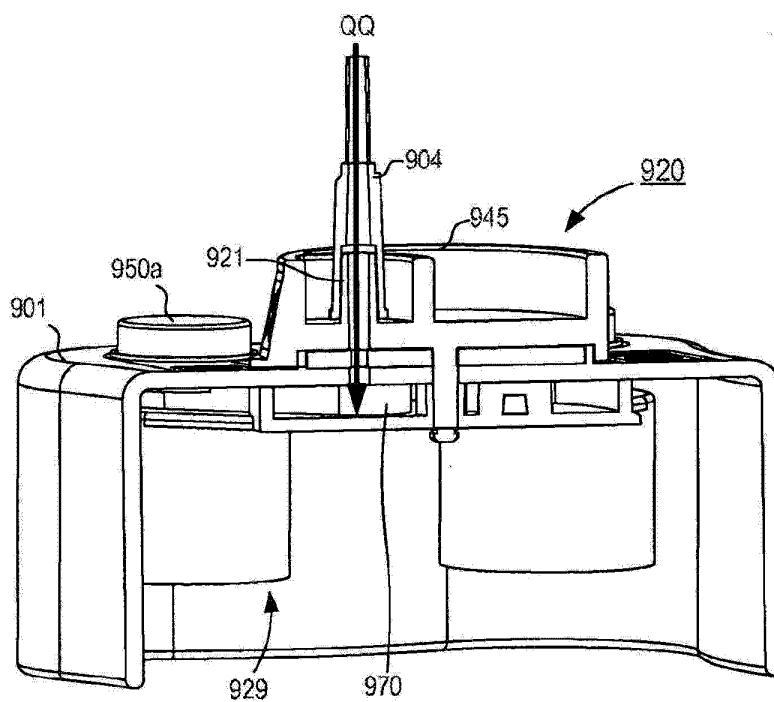


图 51

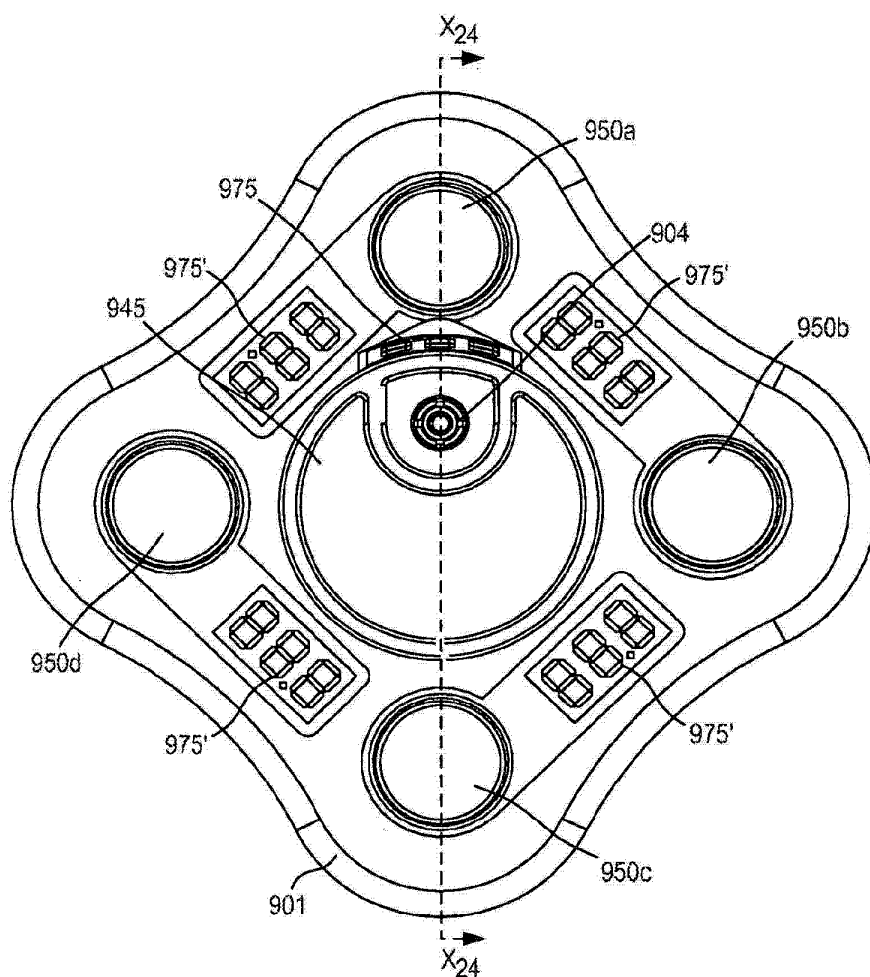


图 52

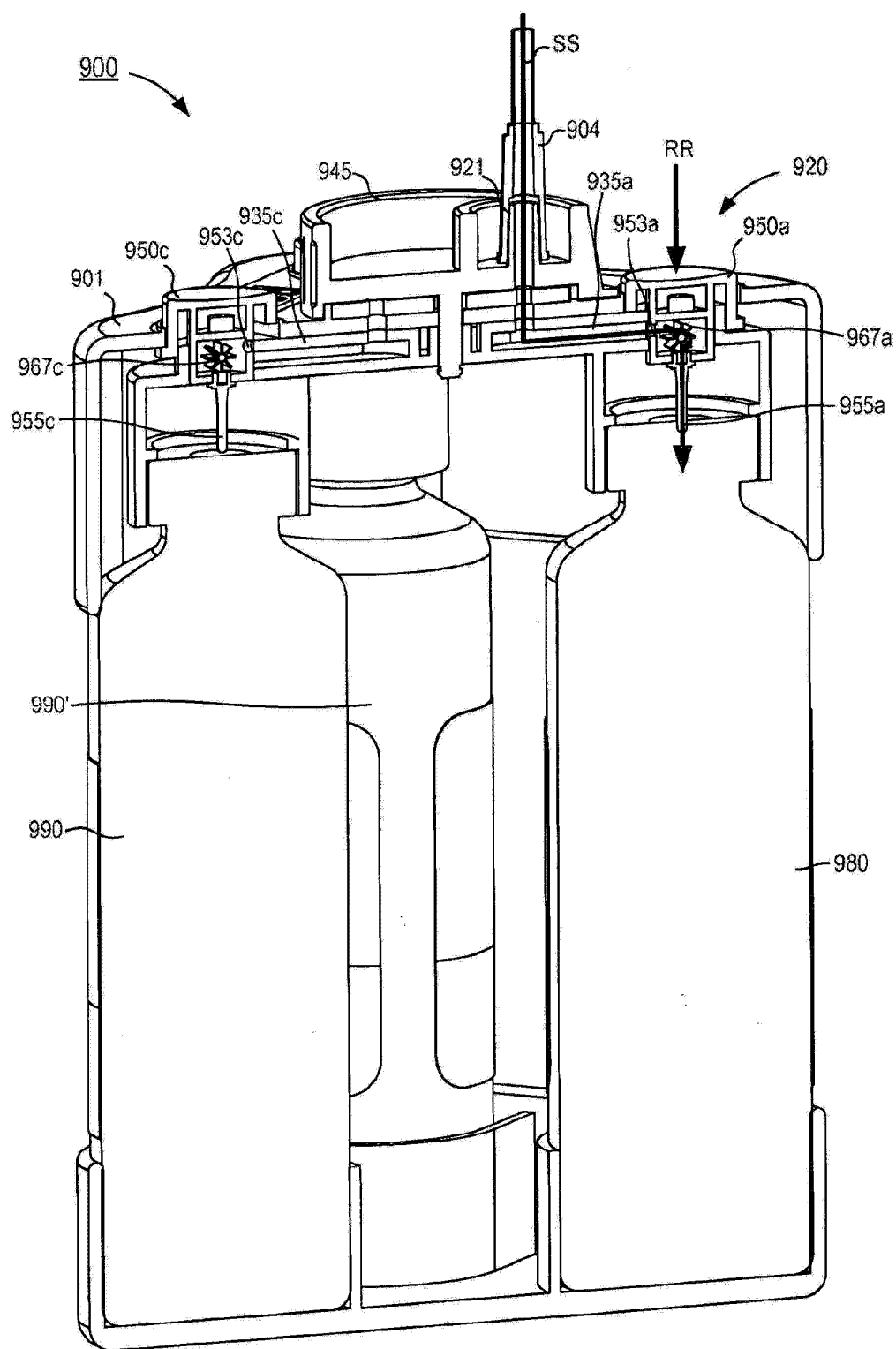


图 53

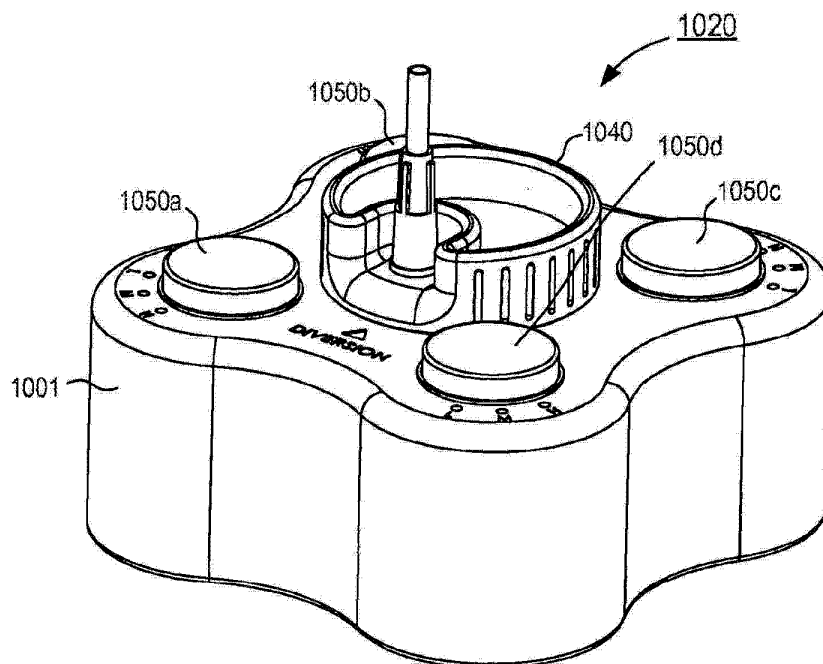


图 54

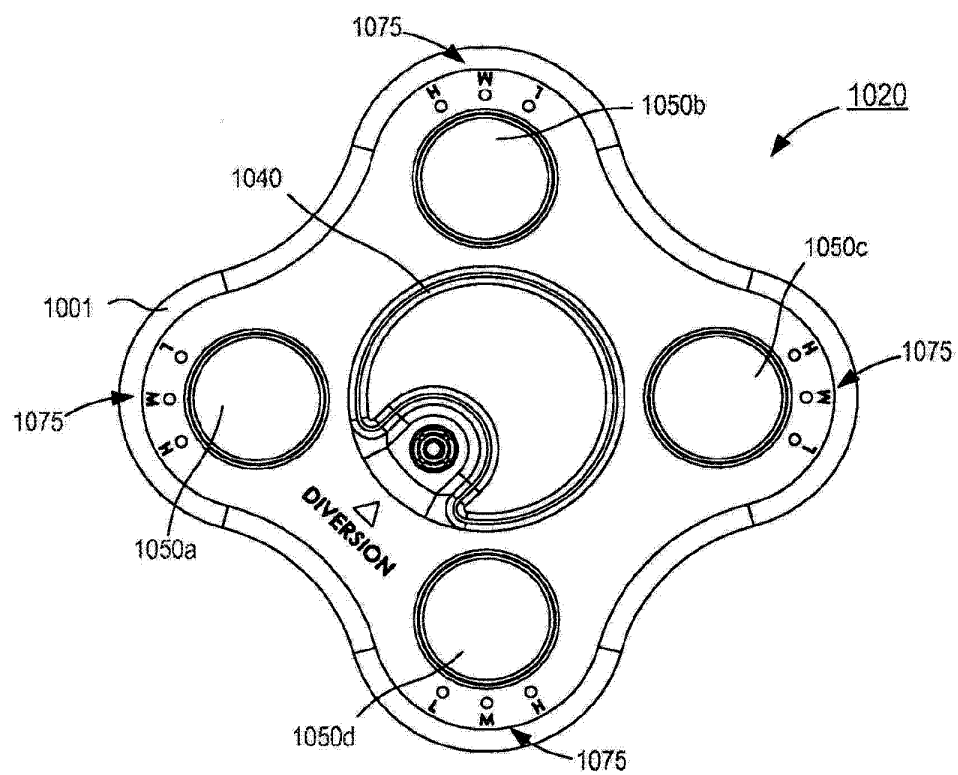


图 55

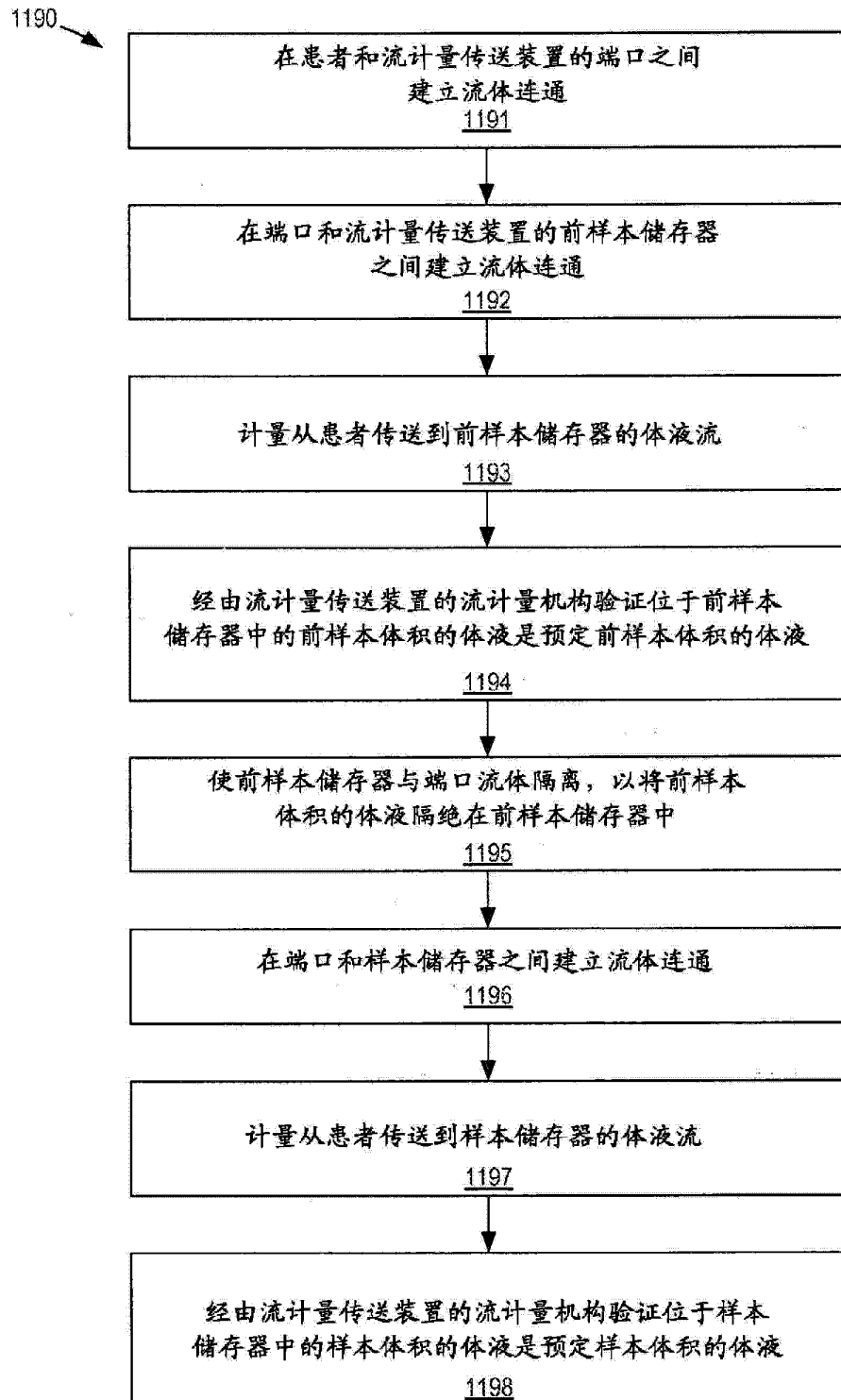


图 56



国家知识产权局

100088

北京市朝阳区安定路5号院8号楼1至21层101五层503室 北京世峰
知识产权代理有限公司
卓霖(010-82800919) 许向彤(010-82800919)

发文日:

2024年04月28日



申请号: 202080000666.0

发文序号: 2024042801618990

申请人: 酷睿有限公司

发明创造名称: 非排气机体流体样品优化装置和系统

第二次审查意见通知书

1. ☒ 审查员已经收到申请人于 2024 年 02 月 05 日提交的意见陈述书, 在此基础上审查员对上述专利申请继续进行实质审查。

☐ 根据国家知识产权局于 _____ 年 _____ 月 _____ 日作出的复审决定, 审查员对上述专利申请继续进行实质审查。

☐ _____

2. ☐ 经审查, 申请人于 _____ 提交的修改文件, 不符合专利法实施细则第 57 条第 3 款的规定, 不予接受。

3. 继续审查是针对下列申请文件进行的:

☐ 上述意见陈述书中所附的经修改的申请文件。

☒ 前次审查意见通知书所针对的申请文件以及上述意见陈述书中所附的经修改的申请文件替换文件。

☐ 前次审查意见通知书所针对的申请文件。

☐ 上述复审决定所确定的申请文件。

☐ _____

4. ☐ 本通知书未引用新的对比文件。

☒ 本通知书引用下列对比文件(其编号续前, 并在今后的审查过程中继续沿用):

编号	文件号或名称	公开日期 (或抵触申请的申请日)
2	US 2018297303A1	20181018

5. 审查的结论性意见:

关于说明书:

☐ 申请的内容属于专利法第 5 条规定的不授予专利权的范围。

☐ 说明书不符合专利法第 26 条第 3 款的规定。

☐ 说明书的修改不符合专利法第 33 条的规定。

☐ 说明书的撰写不符合专利法实施细则第 20 条的规定。

☐ _____

关于权利要求书:

210403
2023.03

纸件申请, 回函请寄: 100088 北京市海淀区蓟门桥西土城路6号 国家知识产权局专利局受理处收
电子申请, 应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外, 以纸件等其他形式提交的文件视为未提交。



国家知识产权局

- ☐ 权利要求_____不符合专利法第 2 条第 2 款的规定。
- ☐ 权利要求_____不符合专利法第 9 条第 1 款的规定。
- ☐ 权利要求_____不具备专利法第 22 条第 2 款规定的新颖性。
- ☒ 权利要求 1-13 不具备专利法第 22 条第 3 款规定的创造性。
- ☐ 权利要求_____不具备专利法第 22 条第 4 款规定的实用性。
- ☐ 权利要求_____属于专利法第 25 条规定的不授予专利权的范围。
- ☐ 权利要求_____不符合专利法第 26 条第 4 款的规定。
- ☐ 权利要求_____不符合专利法第 31 条第 1 款的规定。
- ☐ 权利要求_____的修改不符合专利法第 33 条的规定。
- ☐ 权利要求_____不符合专利法实施细则第 22 条的规定。
- ☐ 权利要求_____不符合专利法实施细则第 23 条的规定。
- ☐ 权利要求_____不符合专利法实施细则第 24 条的规定。
- ☐ 权利要求_____不符合专利法实施细则第 25 条的规定。
- ☐ _____

- ☐ 申请不符合专利法第 26 条第 5 款或者实施细则第 29 条的规定。
- ☐ 申请不符合专利法第 19 条第 1 款的规定。
- ☐ 申请不符合专利法实施细则第 11 条的规定。
- ☐ 分案申请不符合专利法实施细则第 49 条第 1 款的规定。

上述结论性意见的具体分析见本通知书的正文部分。

6. 基于上述结论性意见, 审查员认为:

- ☐ 申请人应当按照通知书正文部分提出的要求, 对申请文件进行修改。
- ☐ 申请人应当在意见陈述书中论述其专利申请可以被授予专利权的理由, 并对通知书正文部分中指出的不符合规定之处进行修改, 否则将不能授予专利权。
- ☒ 专利申请中没有可以被授予专利权的实质性内容, 如果申请人没有陈述理由或者陈述理由不充分, 其申请将被驳回。
- ☐ _____

7. 申请人应注意下列事项:

(1) 根据专利法第 37 条的规定, 申请人应在收到本通知书之日起的 2 个月内陈述意见, 如果申请人无正当理由逾期不答复, 其申请被视为撤回。

(2) 申请人对其申请的修改应当符合专利法第 33 条的规定, 不得超出原说明书和权利要求书记载的范围, 同时申请人对专利申请文件进行的修改应当符合专利法实施细则第 57 条第 3 款的规定, 按照本通知书的要求进行修改。

(3) 申请人的意见陈述书和/或修改文本应当邮寄或递交国家知识产权局专利局受理处, 凡未邮寄或递交给受理处的文件不具备法律效力。

(4) 未经预约, 申请人和/或代理师不得前来国家知识产权局与审查员举行会晤。

8. 本通知书正文部分共有 2 页, 并附有下列附件:

- ☐ 引用的对比文件的复印件共_____份_____页。
- ☐ _____

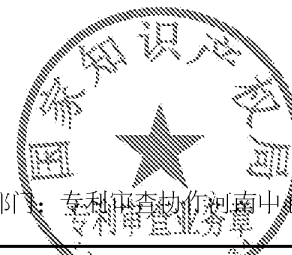
审查员: 李媛媛

联系电话: 0371-87791927

审查部门: 专利审查协作河南中心

210403
2023.03

纸件申请, 回函请寄: 100088 北京市海淀区蓟门桥西土城路 6 号 国家知识产权局专利局受理处收。
电子申请, 应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外, 以纸件等其他形式提交的文件视为未提交。





第二次审查意见通知书

申请号:2020800006660

申请人于 2024 年 2 月 5 日提交了意见陈述书和经过修改的申请文件,审查员在阅读了上述文件后,对本案继续进行审查,再次提出如下审查意见。

一、针对修改后的权利要求书

1. 权利要求 1 不符合专利法第 22 条第 3 款的规定

权利要求 1 请求一种用于优化由流体收集装置从流体源收集的流体样品的装置,对比文件 1(US2018/0271425A1)公开了一种流体样品优化装置,具体的用于优化由流体收集装置从流体源收集流体样品(相当于一种用于优化由流体收集装置从流体源收集的流体样品的装置),并具体公开了(参见说明书第 0141-0149 段,说明书附图 23A-23B):

血液隔离装置 2300 的又一实施方式,其具有与患者针连接的入口端 2302(相当于被配置为与所述流体源连接的入口)、与血液样本收集装置连接的出口端 2304(相当于被配置为与流体收集装置接触的出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于腔室)被填充至待隔离的潜在污染血液的初始等分部分,则隔离室 2306 被填充。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于腔室在所述出口附近具有流阻器)。

从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306,其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于当入口和出口之间施加压差时,所述腔室被布置为从所述流体源接收所述流体样品的第一部分)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物。

少量血液可以进入采样通道 2308,采样通道 2308 最初被阀 2308 关闭。

当释放阀 2308 时,并且在进一步的真空力或其他力的作用下(相当于施加后续压差),后续量的血液(相当于流体样品)将流入入口端 2302,绕过隔离室 2306,并且流入并穿过采样通道 2308(相当于连接在所述入口和所述出口之间的样品路径)朝向出口端 2304 并至收集装置(相当于使得当腔室接收到流体样品的第一部分时,所述流体样品的后续部分能够由所述样品路径从所述入口传送到所述出口)。

少量血液可以进入采样通道 2308(相当于样品路径),采样通道 2308 最初被阀 2310(相当于阻力塞)关闭(相当于样品路径还具有阻力塞)。

权利要求 1 请求保护的技术方案与对比文件 1 相比,其区别技术特征为:(1)流阻器为透气的,通过所述透气的流阻器和所述出口置换其中的空气;(2)所述阻力塞包括可刺穿的膜和刺穿构件,该刺穿构件被配置为刺穿所述膜,其中,所述装置被配置为使得一旦所述腔室填充有所述流体样品的所述第一部分,则在所



述膜上施加压力使得所述膜拉伸并接触所述刺穿构件。

针对上述区别技术特征(1): 对比文件 1 中已经记载了从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306, 其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻隔器; 因此为了使得血液能在真空的作用下使得被吸入隔离室 2306, 具体的疏水塞 2312 为透气的, 通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

针对上述区别技术特征(2): 对比文件 2 (US2018297303A1, 20181018) 公开了一种刺破修补液盛装容器, 并具体记载了(参见权利要求书, 说明书第 0024-0041 段, 说明书附图 1-5)管设置有阻挡所述穿孔修复液流入所述第二流动通道的密封膜(相当于膜), 并且其中密封膜阻塞(相当于阻力塞包括可刺穿的膜)第二流动通道的闭合状态可以切换到其中密封膜被容器内部压力破坏使得第二流动通道打开的打开状态。包括刺穿机构, 所述刺穿机构用于破坏所述管的内部部分上的所述密封膜。刺穿机构 63a(相当于刺穿构件)在储存期间也不接触密封膜 61, 但是当在刺穿修复工作期间容器内部压力增加并且密封膜 61 朝向管 60 的内部凸出时, 刺穿部分 63b 接触密封膜 61(相当于在膜上施加压力使得所述膜拉伸并接触所述刺穿构件), 使得密封膜 61 破裂(相当于该刺穿构件被配置为刺穿所述膜, 阻力塞包括可刺穿的膜和刺穿构件)。因此, 对比文件 2 给出了在压力增加时, 可以使得密封膜拉伸或凸出, 进而使得穿刺机构接触密封膜, 进而使得密封膜破裂, 第二流动通道打开。这与本申请的作用相同, 在面对相同的技术问题时, 本领域技术人员能够想到将其应用于对比文件 1 中。具体的应将该手段应用于对比文件 1 中时, 装置被配置为使得一旦腔室填充有流体样品的第一部分, 则在膜上施加压力使得膜拉伸并接触刺穿构件对于本领域技术人员来说是有能力做到的。

因此, 在对比文件 1 的基础上结合对比文件 2 及本领域常规的技术手段, 得出该权利要求的技术方案对本技术领域的技术人员来说是显而易见的, 因此该权利要求所要求保护的技术方案不具有突出的实质性特点和显著的进步, 该权利要求不具备专利法第二十二条第三款规定的创造性。

2. 权利要求 2-4 不符合专利法第 22 条第 3 款的规定

权利要求 2-4 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要, 设置外壳, 该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述腔室中的一个或多个是本领域技术人员有能力选择的;

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312, 从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306, 其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料);

在对比文件 1 的基础上, 根据需要可以选择腔室包括曲折路径;



因此，当其引用的权利要求不具备创造性时，权利要求 2-4 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

3. 权利要求 5 不符合专利法第 22 条第 3 款的规定

权利要求 5 请求一种用于优化由流体收集装置从流体源收集的流体样品的装置，对比文件 1 公开了一种流体样品优化装置，具体的用于优化由流体收集装置从流体源收集流体样品(相当于一种用于优化由流体收集装置从流体源收集的流体样品的装置)，并具体公开了(参见说明书第 0141-0149 段，说明书附图 23A-23B)：

血液隔离装置 2300 的又一实施方式，其具有与患者针连接的入口端 2302(相当于被配置为与所述流体源连接的入口)、与血液样本收集装置连接的出口端 2304(相当于被配置为与流体收集装置接触的出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于腔室)被填充至待隔离的潜在污染血液的初始等分部分，则隔离室 2306 被填充，结合说明书附图 23A 可以明确隔离室 2306 设置在入口和出口之间(相当于连接在所述入口和所述出口之间的腔室)。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于流阻器，相当于腔室在所述出口附近还具有流阻器)。

从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306，其中血液的初始等分试样(相当于流体样品的第一部分)将接触疏水塞 2312(相当于流阻器)并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于腔室被布置为从所述流体源接收所述流体样品的第一部分)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物。可以确定对比文件 1 中接收到流体样品的第一部分并将污染物容纳在所述污染物容纳储库中。

少量血液可以进入采样通道 2308(相当于样品路径)，采样通道 2308 最初被阀 2310(相当于阻力塞)关闭(相当于样品路径还具有阻力塞，该阻力塞被配置为抑制所述流体样品的第一部分的至少一部分和污染物进入所述样品路径中)。

当释放阀 2310 时，并且在进一步的真空力或其他力的作用下，后续量的血液(相当于流体样品)将流入入口端 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于连接在所述入口和所述出口之间的样品路径)朝向出口端 2304 并至收集装置(相当于使得当在所述腔室中接收到所述流体样品的所述第一部分时，流体样品的后续部分能够被迫通过所述阻力塞，并由所述样品路径从所述入口传送到所述出口)。

权利要求 5 请求保护的技术方案与对比文件 1 相比，其区别技术特征为：(1)流阻器为透气的，以通过所述透气的流阻器和所述出口置换其中的空气；(2)所述阻力塞包括可刺穿的膜和刺穿构件，该刺穿构件被配置为刺穿所述膜，其中，所述装置被配置为使得一旦所述腔室填充有所述流体样品的所述第一部分，则在所述膜上施加压力使得所述膜拉伸并接触所述刺穿构。

针对上述区别技术特征(1)：对比文件 1 中已经记载了从出口端 2304(例如从真空采血管等)施加的真空



或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻器；因此为了使得血液能在真空的作用下使得被吸入隔离室 2306，具体的疏水塞 2312 为透气的，通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

针对上述区别技术特征(2)：对比文件 2 (US2018297303A1, 20181018) 公开了一种刺破修补液盛装容器，并具体记载了(参见权利要求书，说明书第 0024-0041 段，说明书附图 1-5)管设置有阻挡所述穿孔修复液流入所述第二流动通道的密封膜(相当于膜)，并且其中密封膜阻塞(相当于阻力塞包括可刺穿的膜)第二流动通道的闭合状态可以切换到其中密封膜被容器内部压力破坏使得第二流动通道打开的打开状态。包括刺穿机构，所述刺穿机构用于破坏所述管的内部部分上的所述密封膜。刺穿机构 63a(相当于刺穿构件)在储存期间也不接触密封膜 61，但是当在刺穿修复工作期间容器内部压力增加并且密封膜 61 朝向管 60 的内部凸出时，刺穿部分 63b 接触密封膜 61(相当于在膜上施加压力使得所述膜拉伸并接触所述刺穿构件)，使得密封膜 61 破裂(相当于该刺穿构件被配置为刺穿所述膜，阻力塞包括可刺穿的膜和刺穿构件)。因此，对比文件 2 给出了在压力增加时，可以使得密封膜拉伸或凸出，进而使得穿刺机构接触密封膜，进而使得密封膜破裂，第二流动通道打开。这与本申请的作用相同，在面对相同的技术问题时，本领域技术人员能够想到将其应用于对比文件 1 中。具体的应将该手段应用于对比文件 1 中时，装置被配置为使得一旦腔室填充有流体样品的第一部分，则在膜上施加压力使得膜拉伸并接触刺穿构件对于本领域技术人员来说是有能力做到的。

在对比文件 1 的基础上结合对比文件 2 和本领域常规技术手段以获得该权利要求所要求保护的技术方案，对所属技术领域的人员来说是显而易见的，因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步，因而不具第 22 条第 3 款规定的创造性。

4. 权利要求 6-9 不符合专利法第 22 条第 3 款的规定

权利要求 6-9 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要，设置外壳，该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述腔室中的一个或多个是本领域技术人员有能力选择的；

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312，从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料)；

在对比文件 1 的基础上，根据需要可以选择污染物容纳储库包括曲折路径；

对比文件 1 中记载了当释放阀 2308 时，并且在进一步的真空力或其他力的作用下，后续量的血液将流入入口端 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308；



对比文件 1 中已经公开了采样通道 2308 最初被阀 2310(相当于阻力塞)关闭;在对比文件 1 的基础上,关于阻力塞的设置方式是根据需要可以选择的,具体的阻力塞包括具有可溶解材料的网,该可溶解材料在与流体样品的后续第一部分接触时溶解也是不难确定出的一种方式。

因此,当其引用的权利要求不具备创造性时,权利要求 6-9 不具有突出的实质性特点和显著的进步,不符合专利法第 22 条第 3 款有关创造性的规定。

5. 权利要求 10 不符合专利法第 22 条第 3 款的规定

权利要求 10 请求保护一种用于优化流体样品的流体样品优化装置,对比文件 1 公开了一种流体样品优化装置,具体的为一种优化流体样品的优化装置(相当于一种用于优化流体样品的优化装置),并具体公开了(参见说明书第 0141-0149 段,说明书附图 23A-23B):

血液隔离装置 2300 的又一实施方式,其具有与患者针连接的入口端 2302(相当于入口)、与血液样本收集装置连接的出口端 2304(相当于出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于腔室)被填充至待隔离的潜在污染血液的初始等分部分,则隔离室 2306 被填充,结合说明书附图 23A 可以明确隔离室 2306 设置在入口和出口之间(相当于连接在所述入口和所述出口之间的腔室);样品路径设置在入口和出口之间(相当于连接在所述入口和所述出口之间的样品路径)。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于流阻器,腔室在所述出口附近具有透气的流阻器)。

从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306,其中血液的初始等分试样(相当于流体样品的第一部分)将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于腔室被布置为接收所述流体样品的第一部分)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物。可以确定对比文件 1 中腔室中接收到流体样品的第一部分。

少量血液可以进入采样通道 2308(相当于样品路径),采样通道 2308 最初被阀 2310 关闭。

当释放阀 2310 (相当于阻力塞,样品路径还包括阻力塞)时,并且在进一步的真空力或其他力的作用下(相当于施加后续压差),后续量的血液(相当于流体样品)将流入入口端 2302,绕过隔离室 2306,并且流入并穿过采样通道 2308 朝向出口端 2304 并至收集装置(相当于当在所述腔室中接收到所述流体样品的所述第一部分时,所述流体样品的后续部分能够由所述样品路径从所述入口传送到所述出口)。本领域技术人员可以确定对比文件 1 中公开了所述阻力塞被配置为,当在所述腔室中接收了所述流体样品的第一部分时,抑制所述流体样品的所述第一部分的至少一部分进入所述样品路径。

权利要求 10 请求保护的技术方案与对比文件 1 相比,其区别技术特征为:(1)流阻器为透气的,以通过所述透气的流阻器和所述出口置换其中的空气;(2)所述阻力塞包括可刺破的膜;和刺穿构件,该刺穿构件被配置为刺穿所述膜,其中,所述装置被配置为使得一旦所述腔室填充有所述流体样品的所述第一部分,则在



所述膜上施加压力使得所述膜拉伸并接触所述刺穿构件。

针对上述区别技术特征(1): 对比文件 1 中已经记载了从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306, 其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻隔器; 因此为了使得血液能在真空的作用下使得被吸入隔离室 2306, 具体的疏水塞 2312 为透气的, 通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

针对上述区别技术特征(2): 对比文件 2 (US2018297303A1, 20181018) 公开了一种刺破修补液盛装容器, 并具体记载了(参见权利要求书, 说明书第 0024-0041 段, 说明书附图 1-5)管设置有阻挡所述穿孔修复液流入所述第二流动通道的密封膜(相当于膜), 并且其中密封膜阻塞(相当于阻力塞包括可刺穿的膜)第二流动通道的闭合状态可以切换到其中密封膜被容器内部压力破坏使得第二流动通道打开的打开状态。包括刺穿机构, 所述刺穿机构用于破坏所述管的内部部分上的所述密封膜。刺穿机构 63a(相当于刺穿构件)在储存期间也不接触密封膜 61, 但是当在刺穿修复工作期间容器内部压力增加并且密封膜 61 朝向管 60 的内部凸出时, 刺穿部分 63b 接触密封膜 61(相当于在膜上施加压力使得所述膜拉伸并接触所述刺穿构件), 使得密封膜 61 破裂(相当于该刺穿构件被配置为刺穿所述膜, 阻力塞包括可刺穿的膜和刺穿构件)。因此, 对比文件 2 给出了在压力增加时, 可以使得密封膜拉伸或凸出, 进而使得穿刺机构接触密封膜, 进而使得密封膜破裂, 第二流动通道打开。这与本申请的作用相同, 在面对相同的技术问题时, 本领域技术人员能够想到将其应用于对比文件 1 中。具体的应将该手段应用于对比文件 1 中时, 装置被配置为使得一旦腔室填充有流体样品的第一部分, 则在膜上施加压力使得膜拉伸并接触刺穿构件对于本领域技术人员来说是有能力做到的。

在对比文件 1 的基础上结合对比文件 2 和本领域常规技术手段以获得该权利要求所要求保护的技术方案, 对所属技术领域的技术人员来说是显而易见的, 因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步, 因而不具第 22 条第 3 款规定的创造性。

6. 权利要求 11-13 不符合专利法第 22 条第 3 款的规定

权利要求 11-13 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要, 设置外壳, 该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述腔室中的一个或多个是本领域技术人员有能力选择的;

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312, 从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306, 其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料);

在对比文件 1 的基础上, 根据需要可以选择腔室包括曲折路径;



因此，当其引用的权利要求不具备创造性时，权利要求 11-13 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

二、针对申请人的意见陈述书

申请人主要认为：

对比文件 1 没有公开穿刺构件，该穿刺构件被配置为穿刺所述膜。

本发明参照图 9A-9C 详细描述了上述技术特征及其运作原理。可穿刺的膜 702 与穿刺构件 704 间隔开，膜 702 可以是弹性材料片，例如橡胶或其他弹性材料。如图 9C 所示，一旦污染物容纳容器中充满了流体，便在膜片 702 上施加一定的压力以使其进一步拉伸，从而与穿刺构件 704 接触。一旦在膜片 702 与穿刺构件 704 之间形成接触，膜 702 被穿刺构件 704 穿刺或以其他方式破裂，以打开较大的区域，以便随后的一定量或部分的流体流入样品路径（[0086]段）。由此，权利要求 1 所述的装置避免了收集的血液样品中污染物的积累，从而避免了由血液样品中的污染物导致的假阳性的检查结果

审查员充分考虑了其意见陈述，答复如下：

虽然对比文件 1 没有公开穿刺构件，穿刺构件被配置为穿刺膜；然而，对比文件 2（US2018297303A1，20181018）公开了一种刺破修补液盛装容器，并具体记载了（参见权利要求书，说明书第 0024-0041 段，说明书附图 1-5）管设置有阻挡所述穿孔修复液流入所述第二流动通道的密封膜，并且其中密封膜阻塞第二流动通道的闭合状态可以切换到其中密封膜被容器内部压力破坏使得第二流动通道打开的打开状态。包括穿刺机构，所述穿刺机构用于破坏所述管的内部部分上的所述密封膜。穿刺机构 63a 在储存期间也不接触密封膜 61，但是当在刺穿修复工作期间容器内部压力增加并且密封膜 61 朝向管 60 的内部凸出时，刺穿部分 63b 接触密封膜 61，使得密封膜 61 破裂。因此，对比文件 2 给出了在压力增加时，可以使得密封膜拉伸或凸出，进而使得穿刺机构接触密封膜，进而使得密封膜破裂，第二流动通道打开。这与本申请的作用相同，在面对相同的技术问题时，本领域技术人员能够想到将其应用于对比文件 1 中。

基于上述理由，本申请的独立权利要求以及从属权利要求都不具备创造性，同时说明书中也没有记载其他任何可以授予专利权的实质性内容，因而即使申请人对权利要求进行重新组合和/或根据说明书记载的内容作进一步的限定，本申请也不具备被授予专利权的前景。如果申请人不能在本通知书规定的答复期限内提出表明本申请具有创造性的充分理由，本申请将被驳回。

审查员姓名:李媛媛

审查员代码:30110854



国家知识产权局

检索报告

申请号：2020800006660	申请日：2020 年 04 月 01 日	补充检索			
申请人：酷睿有限公司	最早的优先权日：2019 年 04 月 01 日				
权利要求项数：13	说明书段数：95				
审查员确定的 IPC 分类号：G01N1/10,G01N1/02,A61B5/15					
检索记录信息：US2018271425A1: 参见他局检索报告					
US2018297303A1: ENTXTC 语义检索,语义基准:流体或血液或液体充满后，对膜上施加一定的压力以使其进一步拉伸，从而与刺穿构件接触。膜被刺穿构件刺穿或...					
WO2015150742A1: ENTXTC 语义检索,语义基准:污染物容纳容器中充满了流体，便在膜片 702 上施加一定的压力以使其进一步拉伸，从而与刺穿构件 704 接触...					
US9764891B1: ENTXTC 语义检索,语义基准:流体或血液或液体充满后，对膜施加压力，从而使得膜与刺穿构件接触。膜被刺穿构件刺穿或刺破，流体或液体或...					
相 关 专 利 文 献					
类型	国别以及代码[11] 给出的文献号	代码[43]或[45] 给出的日期	IPC 分类号	相关的段落 和 / 或图号	涉及的权 利要求
Y	US2018271425A1	2018-09-27	A61B5/15	说明书第 0141-0149 段，说明书 附图 23A-23B	1-13
Y	US2018297303A1	2018-10-18	B29C73/16	权利要求书， 说明书第 0024-0041 段，说明书 附图 1-5	1-13
A	WO2015150742A1	2015-10-08	B01L3/00	全文	1-13
A	US9764891B1	2017-09-19	B65D85/804	全文	1-13



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相 关 非 专 利 文 献					
类型	书名（包括版本号和卷号）	出版日期	作者姓名和出版者名称	相关页数	涉及的权利要求
类型	期刊或文摘名称 （包括卷号和期号）	发行日期	作者姓名和文章标题	相关页数	涉及的权利要求
类型	网址	网络发布日 或公开日	作者姓名和网页标题	相关部分	涉及的权利要求

表格填写说明事项：

- 1. 审查员实际检索领域的 IPC 分类号应当填写到大组和 / 或小组所在的分类位置。
- 2. 期刊或其它定期出版物的名称可以使用符合一般公认的国际惯例的缩写名称。
- 3. 相关文件的类型说明：
 - X：单独影响权利要求的新颖性或创造性的文件；
 - Y：与本检索报告中其他 Y 类文件组合后影响权利要求的创造性的文件；
 - A：背景技术文件，即反映权利要求的部分技术特征或者有关的现有技术的文件；
 - R：任何单位或个人在申请日向专利局提交的、属于同样的发明创造的专利或专利申请文件。
 - P：中间文件，其公开日在申请的申请日与所要求的优先权日之间的文件，或者会导致需要核实该申请优先权的文件；
 - E：单独影响权利要求新颖性的抵触申请文件；
 - T：申请日或优先权日当天或之后公布的，可以对所要求保护发明的理论或原理提供清楚解释的文件，或者可显示出所要求保护发明的推理或事实不成立的文件；
 - L：除 X、Y、A、R、P、E 和 T 类文件之外的文件。

审 查 员：李媛媛
2024 年 04 月 26 日

审查部门：专利审查协作河南中心



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240
27500 7590 09/29/2023 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER NGUYEN, HUONG Q	
			ART UNIT 3791	PAPER NUMBER
			NOTIFICATION DATE 09/29/2023	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Advisory Action Before the Filing of an Appeal Brief	Application No. 17/893,079	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 September 2023 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☒ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires ____ months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires ____ months from the mailing date of the prior Advisory Action or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.

Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because

a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);

b) ☐ They raise the issue of new matter (see NOTE below);

c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____ (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): (a) ☐ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____

9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____

13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

14. ☒ Other: See Continuation Sheet.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-4, 6-7 and 32-41.

Claim(s) withdrawn from consideration: _____.

/DEVIN B HENSON/ Primary Examiner, Art Unit 3791	
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Continuation of REQUEST FOR RECONSIDERATION/OTHER 14. Other: Applicant contends that Cinqualbre et al does not disclose a housing “that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel” because the test tubes are removable from the body of the device, as well as being external to the device. It is submitted that applicant is reading limitations into the claims. The term “houses” and “defines” is not limited to structural “enclosure.” The claims do not require that the chamber resides “completely within the housing.”

<https://www.merriam-webster.com/dictionary/housing> defines the term as simply “something that covers or protects, such as a support, e.g. frame, for mechanical parts.” It is submitted that this reading of the term “houses” is a broad but reasonable interpretation to one of ordinary skill in the art. The term “defines” is even broader than “houses” and requires/implies even less structure. Therefore, it is submitted that because housing 1 structurally provides the recesses 4 in which test tubes 5 are disposed, the housing absolutely “houses” and “defines” the chamber (defined as test tube), in addition to the inlet, outlet, and sampling channel, as broadly as has been claimed. Though applicant contends that Cinqualbre et al is not a “blood separation device,” said term does not imply any particular structure or function that the prior art cannot support, as broadly as has been claimed. Therefore, the rejection is maintained.

In regard to the drawing objections and 112 rejections, it is submitted that the junction needs to be shown with element numbers in Figure 24, which provides for the other structures of the invention as claimed. Providing said drawing would obviate the 112 rejection.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240
27500 7590 07/19/2023 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER NGUYEN, HUONG Q	
			ART UNIT 3791	PAPER NUMBER
			NOTIFICATION DATE 07/19/2023	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

DETAILED ACTION

This office action is responsive to the amendment filed 5/22/2023. Claims 1-4, 6-7, and 32-41 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “junction” in **Claims 3-4 and 40-41** must be shown *with element numbers* or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the

filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

- (A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;
- (B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g., “means for”) or another linking word or phrase, such as “configured to” or “so that”; and
- (C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step”) in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as

otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL. — The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 40-41 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims recite a junction connecting the inlet port, sampling channel, and the chamber. However, as the instant invention appears to be drawn to the embodiment in Figure 24 and said junction has not been identified in Figure 24 per the drawing objection above, it is unclear that applicant has proper support for the embodiment of Figure 24 with the moving part having a first and second position along with said junction as claimed. If support exists for said junction, applicant is requested to point out portions of the disclosure showing said support.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 1-4, 6-7, 32, 34-38, and 40-41 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al (US Pat No. 3848581) in view of Eldridge (US Pat No. 4207870).

In regard to Claim 1, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood, thus bypassing the first test tube/chamber as defined; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

2. Eldridge discloses the material is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

3. Cinqualbre et al disclose a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

4. Cinqualbre et al disclose wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

6. Cinqualbre et al disclose wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

7. Cinqualbre et al disclose the moving part 11 as defined further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled, the user can close the valve 11 to move it into the closed position so that the next test tube in the series can be

filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

32. Cinqualbre et al disclose wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

In regard to Claim 34, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

35. Eldridge discloses the device in accordance with claim 34, wherein the air permeable blood barrier is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

36. Cinqualbre et al disclose the device in accordance with claim 34, wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling

channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

37. Cinqualbre et al disclose the device in accordance with claim 36, the moving part further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled with blood, the user can close the valve 11 to move it into closed position so that the next test tube in the series can be filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

38. Cinqualbre et al disclose the device in accordance with claim 36, wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

40. Cinqualbre et al disclose the device in accordance with claim 34, further comprising a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

41. Cinqualbre et al disclose the device in accordance with claim 40, wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

Claim(s) 33 and 39 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al in view of Eldridge, further in view of Vaillancouert (US Pat No. 6126643).

Cinqualbre et al in view of Eldridge disclose the inventio above but do not expressly disclose a locking mechanism configured to maintain the moving part in the first position until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Vaillancouert teach that it is well-known in the art to provide an analogous blood sampling device comprising a locking mechanism 24 that enables plunger 21 to be releasably locked relative to barrel 11 so that blood is selectively introduced into the syringe, best seen in Figure 4-5 (Col.4: 63-Col.5: 53). Vaillancouert also teaches that other suitable releasable locking means may also be used to secure the plunger 21 relative to the barrel 11 (Col.5: 8-9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the invention of Cinqualbre et al in view of Eldridge such that there is a locking mechanism configured to selectively maintain the moving part in the first position until the chamber is filled, as taught by Vaillancouert, to effectively prevent the moving part (valve 11 of Cinqualbre et al) from prematurely closing the window 12 before blood sufficiently fills chamber 5 (defined as first test tube on left), which when combined with the user, would thus provide force to overcome the locking mechanism to enable movement of the moving part to the second position as desired. It is noted that the disclosure does not provide any detail into how force would overcome the locking mechanism other than as broadly as has been claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or impropertimewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used.

Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 3, and 20-21 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a

housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 and 8-9 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Response to Arguments

Applicant's arguments with respect to claim(s) above have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

The previous Drawing objections and 112 rejections are moot in light of applicant's amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.Q. NGUYEN
Examiner
Art Unit 3791

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791



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ATTENTION: DOCKETING DEPARTMENT			ABOUELELA, MAY A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 05/16/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 1 is objected to because of the following informalities: the phrase "blood" in lines 8 and 10 should be amended to read –the blood--. Appropriate correction is required.

4. Claim 1 is objected to because of the following informalities: the phrase "the junction being sized" in lines 7-8 should be amended to read –wherein the junction being sized--. Appropriate correction is required.

5. Claim 2 is objected to because of the following informalities: the phrase "blood" in line 3 should be amended to read –the blood--. Appropriate correction is required.

6. Claim 11 is objected to because of the following informalities: the phrase “an curved channel” in line 2 should be amended to read –the curved channel--.

Appropriate correction is required.

7. Claim 12 is objected to because of the following informalities: the phrase “an air permeable blood barrier” in line 2 should be amended to read –the air permeable blood barrier--. Appropriate correction is required.

8. Claim 13 is objected to because of the following informalities: the phrase “the chamber” in line 9 should be amended to read –wherein the chamber--. Appropriate correction is required.

9. Claim 13 is objected to because of the following informalities: the phrase “bodily fluid” in lines 9-10, 12 and 13 should be amended to read –the bodily fluid--.

Appropriate correction is required.

10. Claim 13 is objected to because of the following informalities: the phrase “from the inlet to bypass the chamber” in line 13 should be amended to read –to be directed from the inlet to bypass the chamber--. Appropriate correction is required.

11. Claim 16 is objected to because of the following informalities: the phrase “bodily fluid” in line 3 should be amended to read –the bodily fluid--. Appropriate correction is required.

Claim Interpretation

12. The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

- (A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;
- (B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g.,

“means for”) or another linking word or phrase, such as “configured to” or “so that”; and

- (C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step”) in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word “means,” but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

Limitation “junction” in claims 1, 6 and 13, the claims does not recite enough structure that corresponds to the claimed “junction”, the specification disclose (junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A-17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608, par.0109) which can be interpreted as the structure that corresponds to the claimed “junction”.

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the

claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

13. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

14. Claim 1 recites the limitation "the patient" in line 2. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 6 recites the limitation "the blood control device" in line 2. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 6 recites the limitation "the sequestration chamber" in line 10. There is insufficient antecedent basis for this limitation in the claim. Examiner respectfully notes that the phrase "the sequestration chamber" is also recite in claim 7.

17. Claim 8 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 9 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

19. The statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a statutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of

activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used.

Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1-20 are non-provisionally rejected on the ground of statutory double patenting as being unpatentable over claims 1-20 of U.S Patent Application No.11311219, claims 1-16 of U.S Patent Application No. 9820682, claims 1-23 of U.S Patent Application No.10143412, and claims 1-26 of U.S Patent Application No.11185266.

Also, claim 1-20 are provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-20 of U.S pending Application No.17/730118, and claims 1-18 and 20 of U.S pending Application No.17/094692.

Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent applications, pending applications and the instance application are claiming a common subject matter including: a blood sample device comprising; an inlet, an outlet; a chamber having a vent that includes an air permeable blood barrier; a sampling channel; and a junction connected between the inlet, the

chamber and the sampling channel, wherein the junction being sized and configured such that a first portion of blood conveyed from the patient flows into the chamber to displace air therein through the air permeable blood barrier, and such that a second portion of blood is allowed to bypass the chamber and the first portion of blood at least temporarily contained therein to be directed into the sampling channel toward the outlet.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

<i>Notice of References Cited</i>	Application/Control No. 17/538,990		Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA		Art Unit 3791	Page 1 of 4

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	Examiner MAY A ABOUELELA		Art Unit 3791	Page 2 of 4

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Doc description: Information Disclosure Statement (IDS) Filed

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	Filing Date	2021-11-30
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

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Application Number	17538990
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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

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Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Examiner Name	CENTRAL, DOCKET
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21	9022950		2015-05-05	BULLINGTON GREGORY	
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17538990
Filing Date	2021-11-30
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

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Attorney Docket Number	069366-0572201_KUR2C03US

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If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	07/05/2023
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17538990
Filing Date	2021-11-30
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Attorney Docket Number	069366-0572201_KUR2C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/838,017	04/01/2020	Bobby E. ROGERS	069366-0572158_KUR7001US	1044
27500 7590 04/16/2024 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER PORTILLO, JAIRO H	
			ART UNIT 3791	PAPER NUMBER
			NOTIFICATION DATE 04/16/2024	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/05/2024 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 1-3, 6-8, 14, and 16-17 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Bullington et al (US 2019/0365303) ("Bullington")**.

Regarding Claim 1, while Bullington teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet configured to connect with the fluid source ([0135] Figs. 9 and 10, inlet 512);

an outlet configured to connect with the fluid collection device ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), the sample path further having a resistive plug ([0141] Figs. 9 and 10, barrier 574); and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet),

the resistive plug including a membrane that is pierceable ([0141] Figs. 9 and 10, barrier 574, pierceable by the piercing member); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the membrane causing the membrane to stretch and contact the piercing member.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda*, 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.)].

Regarding Claim 2, Bullington teaches the device in accordance with claim 1, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 1 Rejection*, housing of fluid control device 500).

Regarding Claim 3, Bullington teaches the device in accordance with claim 1, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Regarding Claim 6, Bullington teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

- an inlet configured to connect with the fluid source ([0135] Figs. 9 and 10, inlet 512);
- an outlet configured to connect with the fluid collection device ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), the sample path further having a resistive plug that is configured to inhibit at least a part of a first portion of the fluid sample from entering the sample path ([0141] Figs. 9 and 10, barrier 574 acts as resistive plug); and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber further having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet, after piercing, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet),

the resistive plug including a membrane that is pierceable ([0141] Figs. 9 and 10, barrier 574); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the membrane causing the membrane to stretch and contact the piercing member.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda*, 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.)].

Regarding Claim 7, Bullington teaches the device in accordance with claim 6, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 6 Rejection*, housing of fluid control device 500).

Regarding Claim 8, Bullington teaches the device in accordance with claim 6, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Regarding Claim 14, Bullington teaches a device for optimizing a fluid sample (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet ([0135] Figs. 9 and 10, inlet 512);

an outlet ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet),

wherein the sample path further includes a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample from entering the sample path during receipt of the first portion of the fluid sample in the chamber ([0141] Figs. 9 and 10, barrier 574 acts as resistive plug),

the resistive plug including a membrane that is pierceable ([0141] Figs. 9 and 10, barrier 574); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the membrane causing the membrane to stretch and contact the piercing member.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda*, 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.)].

Regarding Claim 16, Bullington teaches the device in accordance with claim 14, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 14 Rejection*, housing of fluid control device 500).

Regarding Claim 17, Bullington teaches the device in accordance with claim 14, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Claim(s) 4, 9, and 18 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Bullington** in view of **Rogers et al (US 2017/0020428) ("Rogers")**.

Regarding Claim 4, while Bullington teaches the device in accordance with claim 1, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Regarding Claim 9, while Bullington teaches the device in accordance with claim 6, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Regarding Claim 18, while Bullington teaches the device in accordance with claim 14, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Response to Arguments

Applicant's amendments filed 4/05/2024 with respect to the 35 USC 103 rejection have been fully considered, and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bullington.

Applicant's arguments filed 4/05/2024 with respect to the 35 USC 103 rejection have been fully considered, but are not persuasive.

Applicant argues that Bullington teaches the opposite of the amended claim by having the needle move to puncture the membrane, rather than the membrane moving to be punctured by the piercing member. Redesigning Bullington to meet the claim language is not obvious as it would require a substantial redesign and change in the operation of Bullington's device. Examiner respectfully disagrees. Changing Bullington to meet the claim limitations merely requires a reversal of which membrane flexes upon receipt of the fluid sample. This does not require a change in operation as the system would still guide a first portion of the sample to a sequestration chamber, leading to a membrane flexing to enable a piercing action, the piercing action allowing the subsequent portion of the fluid sample to flow to the outlet. Further, a

substantial redesign is not needed as the only change required would be which membrane has the flexing property (barrier 574 instead of diaphragm 576).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAIRO H PORTILLO whose telephone number is (571)272-1073. The examiner can normally be reached M-F 9:00 am - 5:15 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/JAIRO H. PORTILLO/
Examiner
Art Unit 3791

Application/Control Number: 16/838,017
Art Unit: 3791

Page 12

/PUYA AGAHI/
Primary Examiner, Art Unit 3791

Receipt date: 04/05/2024

16/838,017 - GAU: 3791

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PTO/SB/08a (01-22)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16838017
	Filing Date		2020-04-01
	First Named Inventor	Bobby E. ROGERS	
	Art Unit	3791	
	Examiner Name	PORTILLO, JAIRO H	
	Attorney Docket Number	069366-0572158_KUR7001US	

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	1	4416291		1983-11-22	KAUFMAN JOSEPH		
	2	10299713		2019-05-28	PATTON RICHARD G		
	3	10265007		2019-04-23	BULLINGTON GREGORY		
	4	11395612		2022-07-26	BULLINGTON GREGORY J		
	5	10881343		2021-01-05	BULLINGTON GREGORY J		
	6	10596315		2020-03-24	BULLINGTON GREGORY J		
	7	11660030		2023-05-30	BULLINGTON GREGORY J		
	8	11259727		2022-03-01	BULLINGTON GREGORY J		

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Application Number	16838017
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Attorney Docket Number	069366-0572158_KUR7001US

	9	11737693		2023-08-29	BULLINGTON GREGORY J	
	10	11439332		2022-09-13	BULLINGTON GREGORY J	
	11	11589843		2023-02-28	BULLINGTON GREGORY J	
	12	11612340		2023-03-28	BULLINGTON GREGORY J	
	13	11234626		2022-02-01	BULLINGTON GREGORY J	
	14	10624977		2020-04-21	BULLINGTON GREGORY J	
	15	11653863		2023-05-23	BULLINGTON GREGORY J	
	16	11419531		2022-08-23	BULLINGTON GREGORY J	
	17	11786155		2023-10-17	BULLINGTON GREGORY J	
	18	11789017		2023-10-17	BULLINGTON GREGORY J	

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U.S.PATENT APPLICATION PUBLICATIONS

Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16838017
	Filing Date	2020-04-01
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	PORTILLO, JAIRO H
	Attorney Docket Number	069366-0572158_KUR7001US

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20220151525		2022-05-19	BULLINGTON GREGORY J	
	2	20220151527		2022-05-19	BULLINGTON GREGORY J	
	3	20200289039		2020-09-17	BULLINGTON GREGORY J	
	4	20210275068		2021-09-09	MIAZGA JAY M	
	5	20220304664		2022-09-29	HAMMER JEREMY	
	6	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	S5825146	JP		1983-02-15	BECTON DICKINSON CO		☒

If you wish to add additional Foreign Patent Document citation information please click the Add button.

NON-PATENT LITERATURE DOCUMENTS

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16838017
	Filing Date		2020-04-01
	First Named Inventor	Bobby E. ROGERS	
	Art Unit	3791	
	Examiner Name	PORTILLO, JAIRO H	
	Attorney Docket Number	069366-0572158_KUR7001US	

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	2	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	3	Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.	☐
	4	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
	5	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/JAIRO H PORTILLO/	Date Considered	04/10/2024
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	16838017
Filing Date	2020-04-01
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	PORTILLO, JAIRO H
Attorney Docket Number	069366-0572158_KUR7001US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-04-05
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



国家知识产权局

100088

北京市朝阳区安定路5号院8号楼1至21层101五层503室 北京世峰
知识产权代理有限公司
卓霖(010-82800919) 许向彤(010-82800919)

发文日:

2023年09月27日



申请号: 202080000666.0

发文序号: 2023092702079090

申请人: 酷睿有限公司

发明创造名称: 非排气机体流体样品优化装置和系统

第一次审查意见通知书

(进入国家阶段的PCT申请)

- ☒ 应申请人提出的实质审查请求, 根据专利法第35条第1款的规定, 国家知识产权局对上述发明专利申请进行实质审查。
☐ 根据专利法第35条第2款的规定, 国家知识产权局决定自行对上述发明专利申请进行实质审查。
- ☒ 申请人要求以其在:
US 专利局的申请日 2019 年 04 月 01 日为优先权日。
- ☐ 经审查, 申请人于_____提交的修改文件, 不符合专利法实施细则第51条第1款的规定, 不予接受。
- ☐ 审查是针对原始提交的国际申请的中文文本或中文译文进行的。
☒ 审查是针对下列申请文件进行的:
办理进入国家阶段手续时提交的权利要求书、说明书、摘要、摘要附图; 2021 年 4 月 6 日提交的说明书附图。
- ☒ 本通知书引用下列对比文献(其编号在今后的审查过程中继续沿用)

编号	文件号或名称	公开日期 (或抵触申请的申请日)
1	US2018271425A1	2018-09-27

6. 审查的结论性意见:

关于说明书:

- ☐ 申请的内容属于专利法第5条规定的不授予专利权的范围。
- ☐ 说明书不符合专利法第26条第3款的规定。
- ☐ 说明书不符合专利法第33条的规定。
- ☐ 说明书的撰写不符合专利法实施细则第17条的规定。

关于权利要求书:

- ☐ 权利要求_____不符合专利法第2条第2款的规定。
- ☐ 权利要求_____不符合专利法第9条第1款的规定。
- ☐ 权利要求_____不具备专利法第22条第2款规定的新颖性。
- ☒ 权利要求 1-20 不具备专利法第22条第3款规定的创造性。
- ☐ 权利要求_____不具备专利法第22条第4款规定的实用性。

210402
2022.10

纸件申请, 回函请寄: 100088 北京市海淀区蓟门桥西土城路6号 国家知识产权局专利局受理处收
电子申请, 应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外, 以纸件等其他形式提交的文件视为未提交。



国家知识产权局

☐	权利要求	属于专利法第 25 条规定的不予授予专利权的范围。
☐	权利要求	不符合专利法第 26 条第 4 款的规定。
☐	权利要求	不符合专利法第 31 条第 1 款的规定。
☐	权利要求	不符合专利法第 33 条的规定。
☐	权利要求	不符合专利法实施细则第 19 条的规定。
☐	权利要求	不符合专利法实施细则第 20 条的规定。
☐	权利要求	不符合专利法实施细则第 21 条的规定。
☐	权利要求	不符合专利法实施细则第 22 条的规定。
☐		
☐	申请不符合专利法第 26 条第 5 款或者实施细则第 26 条的规定。	
☐	申请不符合专利法第 19 条第 1 款的规定。	
☐	分案申请不符合专利法实施细则第 43 条第 1 款的规定。	

上述结论性意见的具体分析见本通知书的正文部分。

7. 基于上述结论性意见, 审查员认为:

☐ 申请人应当按照通知书正文部分提出的要求, 对申请文件进行修改。

☐ 申请人应当在意见陈述书中论述其专利申请可以被授予专利权的理由, 并对通知书正文部分中指出的不符合规定之处进行修改, 否则将不能授予专利权。

☒ 专利申请中没有可以被授予专利权的实质性内容, 如果申请人没有陈述理由或者陈述理由不充分, 其申请将被驳回。

☐

8. 申请人应注意下列事项:

(1) 根据专利法第 37 条的规定, 申请人应在收到本通知书之日起的 4 个月内陈述意见, 如果申请人无正当理由逾期不答复, 其申请被视为撤回。

(2) 申请人对其申请的修改应当符合专利法第 33 条的规定, 不得超出原说明书和权利要求书记载的范围, 同时申请人对专利申请文件进行的修改应当符合专利法实施细则第 51 条第 3 款的规定, 按照本通知书的要求进行修改。

(3) 申请人的意见陈述书和 / 或修改文本应当邮寄或递交国家知识产权局专利局受理处, 凡未邮寄或递交给受理处的文件不具备法律效力。

(4) 未经预约, 申请人和 / 或代理师不得前来国家知识产权局与审查员举行会晤。

(5) 对进入实质审查阶段的发明专利申请, 在第一次审查意见通知书答复期限届满前 (已提交答复意见的除外), 主动申请撤回的, 可以请求退还 50% 的专利申请实质审查费。

9. 本通知书正文部分共有 6 页, 并附有下列附件:

☐ 引用的对比文件的复印件共 _____ 份 _____ 页。

☐

审查员: 李媛媛

联系电话: 0371-87791927

审查部门: 专利审查协作河南中心

210402
2022.10

纸件申请, 回函请寄: 100088 北京市海淀区蓟门桥西土城路 6 号 国家知识产权局专利局受理处收。
电子申请, 应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外, 以纸件等其他形式提交的文件视为未提交。



国家知识产权局

第一次审查意见通知书

(进入国家阶段的 PCT 申请)

申请号:2020800006660

本申请涉及一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置,经审查,现提出如下审查意见。

1. 权利要求 1 不符合专利法第 22 条第 3 款的规定

权利要求 1 请求一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置,对比文件 1(US2018/0271425A1)公开了一种流体样品优化装置,具体的用于优化由流体收集装置从流体源收集流体样品(相当于一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置),并具体公开了(参见说明书第 0141-0149 段,说明书附图 23A-23B):

血液隔离装置 2300 的又一实施方式,其具有与患者针连接的入口端 2302(相当于被配置为与所述流体源连接的入口)、与血液样本收集装置连接的出口端 2304(相当于被配置为与流体收集装置接触的出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于污染物容纳储库)被填充至待隔离的潜在污染血液的初始等分部分,则隔离室 2306 被填充。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于污染物容纳储库在所述出口附近具有流阻器)。

从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306,其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于当入口和出口之间施加压差时,所述污染物容纳储库被布置为从所述流体源接收所述流体样品的第一部分,使得当接收到流体样品的第一部分并将污染物容纳在所述污染物容纳储库中)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物(相当于流体样品的第一部分潜在地具有污染物)。

少量血液可以进入采样通道 2308,采样通道 2308 最初被阀 2308 关闭。

当释放阀 2308 时,并且在进一步的真空力或其他力的作用下(相当于施加后续压差),后续量的血液(相当于流体样品)将流入入口端 2302,绕过隔离室 2306,并且流入并穿过采样通道 2308(相当于连接在所述入口和所述出口之间的样品路径)朝向出口端 2304 并至收集装置(相当于当所述入口和所述出口之间施加后续压差时,所述流体样品的后续部分能够由所述样品路径从所述入口传送到所述出口)。

权利要求 1 请求保护的技术方案与对比文件 1 相比,其区别技术特征为:流阻器为透气的,通过所述透气的流阻器和所述出口置换其中的空气。

针对上述区别技术特征:对比文件 1 中已经记载了从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306,其中血液的初始等分试样将接触疏水塞 2312



并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻器; 因此为了使得血液能在真空的作用下使得被吸入隔离室 2306, 具体的疏水塞 2312 为透气的, 通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

在对比文件 1 的基础上结合本领域常规技术手段以获得该权利要求所要求保护的技术方案, 对所属技术领域的技术人员来说是显而易见的, 因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步, 因而不具第 22 条第 3 款规定的创造性。

2. 权利要求 2-5 不符合专利法第 22 条第 3 款的规定

权利要求 2-5 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要, 设置外壳, 该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述污染物容纳储库中的一个或多个是本领域技术人员有能力选择的;

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312, 从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306, 其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料);

在对比文件 1 的基础上, 根据需要可以选择污染物容纳储库包括曲折路径;

对比文件 1 中记载了当释放阀 2308 时, 并且在进一步的真空力或其他力的作用下(相当于施加后续压差), 后续量的血液将流入入口端 2302, 绕过隔离室 2306, 并且流入并穿过采样通道 2308(相当于每个压差由所述流体收集装置提供的真空压力提供); 因此对比文件 1 公开了权利要求 5 的附加技术特征;

因此, 当其引用的权利要求不具备创造性时, 权利要求 2-5 不具有突出的实质性特点和显著的进步, 不符合专利法第 22 条第 3 款有关创造性的规定。

3. 权利要求 6 不符合专利法第 22 条第 3 款的规定

权利要求 6 请求一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置, 对比文件 1 公开了一种流体样品优化装置, 具体的用于优化由流体收集装置从流体源收集流体样品(相当于一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置), 并具体公开了(参见说明书第 0141-0149 段, 说明书附图 23A-23B):

血液隔离装置 2300 的又一实施方式, 其具有与患者针连接的入口端 2302(相当于被配置为与所述流体源连接的入口)、与血液样本收集装置连接的出口端 2304(相当于被配置为与流体收集装置接触的出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于污染物容纳储库)被填充至待隔离的潜在污染血液的初始等分部分, 则隔离室 2306 被填充, 结合说明书附图 23A 可以明确隔离室 2306 设置在入口和出口之间(相当于连接在所述入口和所述出口之间的污染物容纳储库)。



隔离室 2306 包括在隔离室 2306 的距入 II 2302 最远的远端处的疏水塞 2312(相当于流阻器, 相当于污染物容纳储库在所述出 II 附近还具有流阻器)。

从出 II 端 II 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入 II 端 II 2302 并直接吸入隔离室 2306, 其中血液的初始等分试样(相当于流体样品的第一部分)将接触疏水塞 2312(相当于流阻器)并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于当所述入 II 和所述出 II 之间施加压差时, 所述污染物容纳储库被布置为从所述流体源接收所述流体样品的第一部分)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物。可以确定对比文件 1 中接收到流体样品的第一部分并将污染物容纳在所述污染物容纳储库中。

少量血液可以进入采样通道 2308(相当于样品路径), 采样通道 2308 最初被阀 2310(相当于阻力塞)关闭(相当于样品路径还具有阻力塞, 该阻力塞被配置为抑制所述流体样品的第一部分的至少一部分和污染物进入所述样品路径中)。

当释放阀 2310 时, 并且在进一步的真空力或其他力的作用下(相当于施加后续压差), 后续量的血液(相当于流体样品)将流入入 II 端 II 2302, 绕过隔离室 2306, 并且流入并穿过采样通道 2308(相当于连接在所述入 II 和所述出 II 之间的样品路径)朝向出 II 端 II 2304 并至收集装置(相当于当所述入 II 和所述出 II 之间施加后续压差时, 流体样品的后续部分能够被迫通过所述阻力塞, 并由所述样品路径从所述入 II 传送到所述出 II)。

权利要求 6 请求保护的技术方案与对比文件 1 相比, 其区别技术特征为: 流阻器为透气的, 以通过所述透气的流阻器和所述出 II 置换其中的空气。

针对上述区别技术特征: 对比文件 1 中已经记载了从出 II 端 II 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入 II 端 II 2302 并直接吸入隔离室 2306, 其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻器; 因此为了使得血液能在真空的作用下使得被吸入隔离室 2306, 具体的疏水塞 2312 为透气的, 通过透气的流阻器和所述出 II 置换其中的空气是本领域技术人员不难想到的。

在对比文件 1 的基础上结合本领域常规技术手段以获得该权利要求所要求保护的技术方案, 对所属技术领域的技术人员来说是显而易见的, 因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步, 因而不具第 22 条第 3 款规定的创造性。

4. 权利要求 7-13 不符合专利法第 22 条第 3 款的规定

权利要求 7-13 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要, 设置外壳, 该外壳容纳和/或限定所述入 II、所述出 II、所述样品路径和所述污染物容纳储库中的一个或多个是本领域技术人员有能力选择的;

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入 II 2302 最远的远端处的疏水塞 2312, 从出



入口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306, 其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料);

在对比文件 1 的基础上, 根据需要可以选择污染物容纳储库包括曲折路径;

对比文件 1 中记载了当释放阀 2308 时, 并且在进一步的真空力或其他力的作用下(相当于施加后续压差), 后续量的血液将流入入口端 2302, 绕过隔离室 2306, 并且流入并穿过采样通道 2308(相当于每个压差由所述流体收集装置提供的真空压力提供); 因此对比文件 1 公开了权利要求 5 的附加技术特征;

对比文件 1 中已经公开了采样通道 2308 最初被阀 2310(相当于阻力塞)关闭; 在对比文件 1 的基础上, 关于阻力塞的设置方式是根据需要可以选择的, 具体的阻力塞包括被后续第一压差可刺穿的膜, 阻力塞还包括刺穿构件, 该刺穿构件被配置为当后续第一压差施加在所述膜的相对侧上时刺穿所述膜是可以选择的设置方式; 此外还可以选择其它的设置方式, 具体的阻力塞包括具有可溶解材料的网, 该可溶解材料在与流体样品的后续第一部分接触时溶解也是不难确定出的一种方式。

因此, 当其引用的权利要求不具备创造性时, 权利要求 7-13 不具有突出的实质性特点和显著的进步, 不符合专利法第 22 条第 3 款有关创造性的规定。

5. 权利要求 14 不符合专利法第 22 条第 3 款的规定

权利要求 14 请求保护一种用于优化流体样品的流体样品优化装置, 对比文件 1 公开了一种流体样品优化装置, 具体的为一种优化流体样品的流体样品优化装置(相当于一种用于优化流体样品的流体样品优化装置), 并具体公开了(参见说明书第 0141-0149 段, 说明书附图 23A-23B):

血液隔离装置 2300 的又一实施方式, 其具有与患者针连接的入口端 2302(相当于入口)、与血液样本收集装置连接的出口端 2304(相当于出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于污染物容纳储库)被填充至待隔离的潜在污染血液的初始等分部分, 则隔离室 2306 被填充, 结合说明书附图 23A 可以明确隔离室 2306 设置在入口和出口之间(相当于连接在所述入口和所述出口之间的污染物容纳储库); 样品路径设置在入口和出口之间(相当于连接在所述入口和所述出口之间的样品路径)。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于流阻器, 污染物容纳储库在所述出口附近具有透气的流阻器)。

从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端 2302 并直接吸入隔离室 2306, 其中血液的初始等分试样(相当于流体样品的第一部分)将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于当所述入口和所述出口之间施加压差时, 所述污染物容纳储库被布置为接收所述流体样品的第一部分)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物(相当于流体样品的第一部分潜在地具有污染物)。可以确定对比文件 1 中接收到流体样品的第一部分并将污染物



容纳在所述污染物容纳储库中。

少量血液可以进入采样通道 2308(相当于样品路径)，采样通道 2308 最初被阀 2310 关闭。

当释放阀 2310 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液(相当于流体样品)将流入入口端 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308 朝向出口端 2304 并至收集装置(相当于当所述入口和所述出口之间施加后续压差时，所述流体样品的后续部分能够由所述样品路径从所述入口传送到所述出口)。

权利要求 14 请求保护的技术方案与对比文件 1 相比，其区别技术特征为：流阻器为透气的，以通过所述透气的流阻器和所述出口置换其中的空气。

针对上述区别技术特征：对比文件 1 中已经记载了从出口端 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入口端 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻器；因此为了使得血液能在真空的作用下使得被吸入隔离室 2306，具体的疏水塞 2312 为透气的，通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

在对比文件 1 的基础上结合本领域常规技术手段以获得该权利要求所要求保护的技术方案，对所属技术领域的技术人员来说是显而易见的，因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步，因而不具第 22 条第 3 款规定的创造性。

6. 权利要求 15 不符合专利法第 22 条第 3 款的规定

权利要求 15 对其引用的权利要求作了进一步限定，对比文件 1 中进一步公开了少量血液可以进入采样通道 2308(相当于样品路径)，采样通道 2308 最初被阀 2310(相当于阻力塞)关闭(相当于该阻力塞被配置为在接收到流体样品的第一部分并将污染物容纳在所述污染物容纳储库期间，抑制所述流体样品的第一部分的至少一部分和污染物进入所述样品路径)。

当释放阀 2310 时，并且在进一步的真空力或其他力的作用下，后续量的血液将流入入口端 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308 朝向出口端 2304 并至收集装置。

因此，当其引用的权利要求不具备创造性时，权利要求 15 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

7. 权利要求 16-20 不符合专利法第 22 条第 3 款的规定

权利要求 16-20 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要，设置外壳，该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述污染物容纳储库中的一个或多个是本领域技术人员有能力选择的；

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312，从出



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II 端 II 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入 II 端 II 2302 并直接吸入隔离室 2306, 其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料);

在对比文件 1 的基础上, 根据需要可以选择污染物容纳储库包括曲折路径;

对比文件 1 中记载了当释放阀 2308 时, 并且在进一步的真空力或其他力的作用下(相当于施加后续压差), 后续量的血液将流入 II 端 II 2302, 绕过隔离室 2306, 并且流入并穿过采样通道 2308(相当于每个压差由所述流体收集装置提供的真空压力提供); 因此对比文件 1 公开了权利要求 5 的附加技术特征;

对比文件 1 中已经公开了采样通道 2308 最初被阀 2310(相当于阻力塞)关闭; 在对比文件 1 的基础上, 关于阻力塞的设置方式是根据需要可以选择的, 具体的阻力塞包括被后续第一压差可刺穿的膜, 阻力塞还包括刺穿构件, 该刺穿构件被配置为当后续第一压差施加在所述膜的相对侧上时刺穿所述膜是可以选择的设置方式。

因此, 当其引用的权利要求不具备创造性时, 权利要求 16-20 不具有突出的实质性特点和显著的进步, 不符合专利法第 22 条第 3 款有关创造性的规定。

基于上述理由, 本申请的独立权利要求以及从属权利要求都不具备创造性, 同时说明书中也没有记载其他任何可以授予专利权的实质性内容, 因而即使申请人对权利要求进行重新组合和/或根据说明书记载的内容作进一步的限定, 本申请也不具备被授予专利权的前景。如果申请人不能在本通知书规定的答复期限内提出表明本申请具有创造性的充分理由, 本申请将被驳回。

在第一次审查意见通知书答复期限届满前(已提交答复意见的除外)主动申请撤回的, 可以退还 50% 的专利申请实质审查费。审查员电话 0371-87791927, 或审查值班电话 0371-87792282 代为转达。

审查员姓名:李媛媛
审查员代码:30110854



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检索报告

申请号: 2020800006660	申请日: 2020 年 04 月 01 日	首次检索			
申请人: 酷睿有限公司	最早的优先权日: 2019 年 04 月 01 日				
权利要求项数: 20	说明书段数: 95				
审查员确定的 IPC 分类号: G01N1/10,G01N1/02,A61B5/15					
检索记录信息: US2018271425A1: 参考国际检索报告以及美局通知书 EP3324845A1: 参考同族检索报告 US2014112841A1: 参考同族检索报告 WO2019232196A1: 参考同族检索报告 CN104107054A: CNTXT 语义检索,语义基准:2020800006660 CN104981203A: CNTXT 语义检索,语义基准:CN213588280U CN1717280A: 425 CNTXT, (G01N1/1C) and (((阻隔 or 阻塞 or 流阻 or 阻力塞) and ((流体 or 血 or 样品) s 污染)) and (真空 or 压差 or 负压))					
相 关 专 利 文 献					
类型	国别以及代码[11] 给出的文献号	代码[43]或[45] 给出的日期	IPC 分类号	相关的段落 和 / 或图号	涉及的权 利要求
X	US2018271425A1	2018-09-27	A61B5/15	说明书第 0141-0149 段, 说明书 附图 23A-23B	1-20
A	EP3324845A1	2018-05-30	A61M39/06	全文	1-20
A	US2014112841A1	2014-04-24	B01L3/00	全文	1-20
L	WO2019232196A1	2019-12-05	A61B5/15	全文	1-20



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A	CN104107054A	2014-10-22	A61B5/151	全文	1-20
A	CN104981203A	2015-10-14	A61B5/155	全文	1-20
A	CN1717280A	2006-01-04	B01L3/00	全文	1-20

相 关 非 专 利 文 献					
类型	书名（包括版本号和卷号）	出版日期	作者姓名和出版者名称	相关页数	涉及的权利要求
类型	期刊或文摘名称 （包括卷号和期号）	发行日期	作者姓名和文章标题	相关页数	涉及的权利要求
类型	网址	网络发布日 或公开日	作者姓名和网页标题	相关部分	涉及的权利要求

表格填写说明事项：

1. 审查员实际检索领域的 IPC 分类号应当填写到人组和 / 或小组所在的分类位置。
2. 期刊或其它定期出版物的名称可以使用符合一般公认的国际惯例的缩写名称。
3. 相关文件的类型说明：
X：单独影响权利要求的新颖性或创造性的文件；
Y：与本检索报告中其他 Y 类文件组合后影响权利要求的创造性的文件；
A：背景技术文件，即反映权利要求的部分技术特征或者有关的现有技术的文件；
R：任何单位或个人在申请日向专利局提交的、属于同样的发明创造的专利或专利申请文件。
P：中间文件，其公开日在申请的申请日与所要求的优先权日之间的文件，或者会导致需要核实该申请优先权的文件；



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E: 单独影响权利要求新颖性的抵触申请文件;

T: 申请日或优先权日当天或之后公布的, 可以对所要求保护发明的理论或原理提供清楚解释的文件, 或者可显示出所要求保护发明的推理或事实不成立的文件;

L: 除 X、Y、A、R、P、E 和 T 类文件之外的文件。

审 查 员: 李媛媛
2023 年 09 月 25 日

审查部门: 专利审查协作河南中心



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Application No. 17 840 467.9 - 1132	Ref. EPA-147 134	Date 22.04.2020
Applicant Kurin, Inc.		

Communication under Rule 71(3) EPC

1. Intention to grant

You are informed that the examining division intends to grant a European patent on the basis of the above application, with the text and drawings and the related bibliographic data as indicated below.

A copy of the relevant documents is enclosed.

1.1 In the text for the Contracting States:

AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT
RO RS SE SI SK SM TR

Description, Pages

1, 2, 4-44	as published	
3, 3a	filed in electronic form on	16-12-2019

Claims, Numbers

1-14	filed in electronic form on	16-12-2019
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Drawings, Sheets

1/69-69/69	as published
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With the following amendments to the above-mentioned documents proposed by the division

Description, Pages	1, 20, 23, 27, 40
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Comments

DESCRIPTION

Page 1: Deletion of irrelevant and/or superfluous information (Rule 48(1)(c) EPC, Guidelines F-II, 7.4)

Pages 20, 23, 27, 40: Insertion of SI/metric units (Rule 49(10) EPC)

CLAIMS

Page 1: Deletion of irrelevant and/or superfluous information (Rule 48(1)(c) EPC, Guidelines F-II, 7.4)

1.2 Bibliographic data

The title of the invention in the three official languages of the European Patent Office, the international patent classification, the designated contracting states, the registered name(s) of the applicant(s) and the other bibliographic data are shown on **EPO Form 2056** (enclosed).

2. Invitation

You are invited, **within a non-extendable period of four months** of notification of this communication,

2.1 to EITHER approve the text communicated above and verify the bibliographic data (Rule 71(5) EPC)

(1) by filing a translation of the claim(s) in the other two official languages of the EPO

	Fee code	EUR
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(2a) by paying the fee for grant including the fee for publication:
minus any amount already paid (Rule 71a(5) EPC):

007	960.00
	0.00

Total amount:	960.00
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(3) by paying additional claims fees under Rule 71(4) EPC;
number of claims fees payable: 0
minus any amount already paid (Rule 71a(5) EPC):

016	0.00
	0.00

Total amount:	0.00
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Important: If the translations of the claims and fees have already been filed and paid respectively in reply to a previous communication under Rule 71(3) EPC, e.g. in the case of resumption of examination after approval (see Guidelines C-V, 6), **agreement as to the text to be granted** (Rule 71a(1) EPC) must be expressed within the same time limit (e.g. by approving the text and verifying the bibliographic data, by confirming that grant proceedings can go ahead with the documents on file and/or by stating which translations of the claims already on file are to be used).

Note 1: See "Notes concerning fee payments" below.

Note 2: Any overpaid "minus" amounts will be refunded when the decision to grant (EPO Form 2006A) has been issued.

Note 3: For the calculation of the grant fee under Article 2(2), No. 7, RFees (old fee structure), the number of pages is determined on the basis of a clean copy of the application documents, in which text deleted as a result of any amendments by the examining division is not shown. Such clean copy is made available via on-line file inspection only.

2.2 OR, in the case of disapproval, to request reasoned amendments or corrections to the text communicated above or keep to the latest text submitted by you (Rule 71(6) EPC).

In this case the translations of the claims and fee payments mentioned under point 2.1 above are NOT due.

The terms "amendment(s)" and "correction(s)" refer only to amendments or corrections of the application documents and not of other documents (e.g. bibliographic data, the designation of the inventor, etc.).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the examining division requesting that you correct this deficiency (Rule 137(4) EPC).

2.3 Bibliographic data

Where you request a change or correction of bibliographic data in response to the Rule 71(3) communication, this will **not** cause the sending of a further communication under Rule 71(3) EPC. You will still have to pay the fees and file translations in reply to the Rule 71(3) communication in the case of 2.1 above, unless you also file a reasoned request for amendments or corrections in response to the Rule 71(3) communication (see case 2.2 above).

3. Loss of rights

If neither of the two possible actions above (see points 2.1 or 2.2) is performed in due time, the European patent application will be deemed to be withdrawn (Rule 71(7) EPC).

4. Further procedure

4.1 In the case of point 2.1 above

- 4.1.1** The decision to grant the European patent will be issued, and the **mention of the grant** of the patent will be published in the European Patent Bulletin, if the requirements concerning the translation of the claims and the payment of all fees are fulfilled and there is agreement as to the text to be granted (Rule 71a(1) EPC).

Note on payment of the renewal fee:

If a renewal fee becomes due before the next possible date for publication of the mention of the grant of the European patent, publication will be effected only after the renewal fee and any additional fee have been paid (Rule 71a(4) EPC).

Under Article 86(2) EPC, the obligation to pay renewal fees to the European Patent Office terminates with the payment of the renewal fee due in respect of the year in which the mention of the grant of the European patent is published.

Note on payment of the designation fee(s):

If the designation fee(s) become(s) due after the communication under Rule 71(3) EPC, the mention of the grant of the European patent will not be published until these fees have been paid (Rule 71a(3) EPC).

- 4.1.2** After publication, the **European patent specification** can be downloaded free of charge from the EPO publication server <https://data.epo.org/publication-server>.

4.1.3 Filing of translations in the contracting states

As regards translation requirements prescribed by the contracting states under Article 65(1) EPC, please consult the website of the European Patent Office

www.epo.org → Law & practice → Legal texts, National law relating to the EPC

www.epo.org → Law & practice → All Legal texts → London Agreement

In the case of a valid extension or validation

As regards translation requirements prescribed by the extension or validation states, please consult the website of the European Patent Office

www.epo.org → Law & practice → Legal texts, National law relating to the EPC

Failure to supply a prescribed translation in a contracting state, or in an extension or validation state may result in the patent being deemed to be void *ab initio* in the state concerned (Art. 65(3) EPC).

4.2 In the case of 2.2 above

If the present communication under Rule 71(3) EPC is based on an auxiliary request and, within the time limit, you maintain the main request or a higher ranking request which is not allowable, the application will be refused (Art. 97(2) EPC).

If the examining division gives its consent to the requested amendments or corrections, it will issue a new communication under Rule 71(3) EPC; otherwise, it shall resume the examination proceedings (Rule 71(6) EPC).

5. Filing of a divisional application

Any divisional application relating to this European patent application must be filed directly with the European Patent Office in Munich, The Hague or Berlin and will be in the language of the proceedings for the present application, or if the latter was not in an official language of the EPO, the divisional application may be filed in the language of the present application as filed (see Article 76(1) and Rule 36(2) EPC). Any such divisional application must be filed while the present application is still pending (Rule 36(1) EPC; Guidelines A-IV, 1.1.1).

6. Notes concerning fee payments

6.1 Making payments

For payments made via deposit account, please note that as from 1 December 2017 debit orders will only be carried out if filed in an electronically processable format (xml), using an accepted means of filing as laid down in the Arrangements for deposit accounts (ADA), published in the Supplementary publication in the Official Journal.

All relevant information related to the modes of payment of fees to the EPO can be retrieved from the EPO website at "**Making Payments**".

6.2 Information concerning fee amounts

Procedural fees are usually adjusted every two years, on even years, with effect from 1 April. Therefore, before making a payment, parties should verify the amounts actually due on the date of payment using the applicable version of the Schedule of fees and expenses, published as a Supplement to the Official Journal of the EPO, available on the EPO website (www.epo.org) at www.epo.org/schedule-of-fees. The "Schedule of fees" table allows the viewing, downloading and searching of individual fee amounts, both current and previous.

6.3 Note to users of the automatic debiting procedure

The fee for grant, including the fee for publication, and any additional claims fees due under Rule 71(4) EPC will be debited automatically on the date of filing of the translations of the claims, or on the last day of the period of this communication. However, if the designation fee(s) become(s) due as set out in Rule 71a(3) EPC and/or a renewal fee becomes due as set out in Rule 71a(4) EPC, these should be paid separately by another permitted way of payment in order not to delay the publication of the mention of the grant. The same applies in these circumstances to the payment of extension and validation fees. The same applies in these circumstances to the payment of extension and validation fees.

Note: If a waiver is expressed in response to a Rule 71(3) communication (see OJ EPO 2015, A52), the fee for grant, including the fee for publication/printing, and any additional claims fees will not be debited automatically. These fees must be paid separately by another means of payment allowed under the Rules relating to Fees.

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Enclosures: Text intended for grant

EPO Form 2056

Annex to EPO Form 2004, Communication pursuant to Rule 71(3) EPC

Bibliographical data of European patent application No. 17 840 467.9

For the intended grant of the European patent, the bibliographical data are set out below, for information:

Title of invention:

- BLUTPROBENOPTIMIERUNGSSYSTEM SOWIE VORRICHTUNG ZUR SEQUESTRIERUNG VON BLUTKONTAMINANTEN
- BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE
- SYSTÈME D'OPTIMISATION D'ÉCHANTILLON DE SANG ET DISPOSITIF DE SÉQUESTRATION DE CONTAMINANT DU SANG

Classification: INV. A61B5/15 A61B5/153 A61B5/154 A61B5/157

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Contracting States*

for which fees have been paid:

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Extension States*

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Validation States*

for which fees have been paid:

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*) If the time limit for the payment of designation fees according to Rule 39(1) EPC has not yet expired and the applicant has not withdrawn any designation, **all Contracting States/Extension States/Validation States** are currently still deemed to be designated. See also Rule 71a(3) EPC and, if applicable, the above Note to users of the automatic debiting procedure.

**) If two or more applicants have designated different Contracting States, this is indicated here.

~~BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD~~

BACKGROUND

[0001] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0002] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0003] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0004] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0005] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

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[0006] Blood culture collection kits generally consist of a “butterfly” set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a “Vacutainer,” which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0007] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0008] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0009] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe’s plunger that is drawn too quickly for the patient’s condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0010] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by

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antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0011] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

US 2014/039348 A1 discloses a device including a pre-sample reservoir, an actuator mechanism and a diverter. The pre-sample reservoir can be fluidically coupled to a delivery member to receive and isolate a predetermined volume of bodily-fluid withdrawn from a patient. US 2014/107564 A1 discloses an apparatus including a cannula assembly, a housing, a fluid reservoir, a flow control mechanism and an actuator. US 4 813 433 A discloses a syringe for withdrawing fluids which consists of one-handed operated syringe. The syringe comprises a double compartmented housing, a piston disposed in one of said compartments, a piston rod connected to said piston controlling the movement of said piston in a barrel, and vent means. US 2013/317391 A1 discloses an apparatus including a housing, a flow control mechanism and an actuator. At least a portion of the flow control mechanism is movably disposed within the housing.

SUMMARY

[0012] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0013] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate

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short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0014] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0015] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected

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with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0016] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0017] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0018] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

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[0019] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0020] The blood sequestration device, in one aspect can include an inlet port, an outlet port, a sequestration chamber connected with the inlet port via a junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further includes a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber, and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In certain related aspects, the sequestration chamber, the sampling channel and the junction are sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0021] In another aspect, the sampling channel and the junction is sized and configured such that a first portion of blood flows into and fills the sequestration chamber to displace air therein through the vent, and such that a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0022] The blood sequestration and sampling system sequestration device, in certain aspects can include a blood sampling pathway having a patient needle on a proximal end and a sample collection device on a distal end; and a blood sequestration device attached on the blood sampling pathway between the proximal end and distal end of the blood sampling pathway. The blood sequestration device in one aspect can include an inlet port coupled with the blood sampling pathway toward the patient needle, an outlet port coupled with the blood sampling pathway toward the sample collection device, a sequestration chamber connected with the inlet port via a junction, which chamber has a

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vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In a certain related aspect, the sequestration chamber, the sampling channel and the junction can be sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0023] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0024] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] These and other aspects will now be described in detail with reference to the following drawings.

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- [0026] FIG. 1 illustrates a blood sample optimization system.
- [0027] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.
- [0028] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.
- [0029] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.
- [0030] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.
- [0031] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.
- [0032] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.
- [0033] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.
- [0034] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.
- [0035] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.
- [0036] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.
- [0037] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.
- [0038] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

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[0039] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminants of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0040] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0041] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0042] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0043] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

[0044] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0045] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0046] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0047] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0048] FIGS. 23A – 23E illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0049] FIGS. 24A – 24D illustrate another implementation of a blood optimization system and blood sequestration device.

[0050] FIGS. 25A – 25D illustrate another implementation of a blood optimization system and blood sequestration device.

[0051] FIGS. 26A – 26E illustrate another implementation of a blood optimization system and blood sequestration device.

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[0052] FIGS. 27A – 27D illustrate another implementation of a blood optimization system and blood sequestration device.

[0053] FIGS. 28A – 28F illustrate another implementation of a blood optimization system and blood sequestration device.

[0054] FIGS. 29A – 29C illustrate another implementation of a blood optimization system and blood sequestration device.

[0055] FIGS. 30A – 30G illustrate another implementation of a blood optimization system and blood sequestration device.

[0056] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0057] This document describes blood sample optimization systems and methods for reducing or eliminating contaminants in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0058] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be

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pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0059] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0060] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a

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liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0061] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a “duck bill” or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0062] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0063] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0064] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an

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open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0065] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0066] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a “T” or “Y” connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0067] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood

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pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0068] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0069] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0070] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A “T” or “Y” connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

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[0071] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0072] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0073] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0074] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood

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from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indicator or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0075] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0076] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0077] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that

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includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0078] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0079] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

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[0080] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0081] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0082] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0083] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

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[0084] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0085] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0086] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0087] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which

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about the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0088] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0089] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0090] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0091] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0092] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminants of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0093] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately $\geq 0,1143$ cm (0,045 inches), ~~$\geq 0,045$ inches,~~ but can have a diameter of between $\geq 0,0254$ cm (0,01 inches) ~~$\geq 0,01$ inches~~ or less to $\geq 0,508$ cm (0,2 inches) ~~$\geq 0,2$ inches~~ or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a

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non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0094] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0095] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have

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any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0097] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0098] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0099] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the

patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately $\geq 0,1143$ cm (0,045 inches), $\geq 0,045$ inches, but can have a diameter of between $\geq 0,0254$ cm (0,01 inches) $\geq 0,01$ inches or less to $\geq 0,508$ cm (0,2 inches) $\geq 0,2$ inches or more.

[00100] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[00101] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[00102] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[00103] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some

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implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[00104] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00105] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[00106] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F

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illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[00107] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[00108] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00109] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00110] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent

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material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00111] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the inlet port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00112] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00113] In some instances, as shown in FIG. 15H, an inlet port 1532 can include a male luer connector for connecting to a removable patient needle, and an outlet port 11534 can include a female luer connector for connecting with a syringe. This implementation of the inlet port and outlet port can be used with any device described herein, for avoiding a propensity of a Vacutainer-type device collapsing a patient's vein. In this implementation, a clinician can use the syringe in a modulated fashion to obtain a blood sample. In operation, the syringe is attached to the outlet port 1004, and the needle is attached to the inlet port 1002. A venipuncture is performed with the needle, and without the clinician pulling on the syringe. An initial aliquot of blood fills a sequestration chamber, and then the syringe can be used to draw a sample of blood through the collection channel, bypassing the sequestered blood in the sequestration chamber.

[00114] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an inlet port, and outlet port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00115] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately $\geq 0,1143$ cm (0,045 inches), ~~$\geq 0,045$ inches,~~ but can have a diameter of between $\geq 0,0254$ cm (0,01 inches) ~~$\geq 0,01$ inches~~ or less to $\geq 0,508$ cm (0,2 inches) ~~$\geq 0,2$ inches,~~ or more.

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[00116] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00117] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00118] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

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[00119] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00120] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00121] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17E and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17E illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00122] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00123] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top

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member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00124] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00125] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective member 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00126] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at

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atmospheric pressure, but the sampling channel 1606 is directed to an outlet port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00127] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00128] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00129] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00130] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

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[00131] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00132] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00133] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00134] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B,

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contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00135] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[00136] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel 2308 before the initial aliquot of blood is sequestered in the sequestration chamber 2306. For instance, valve 2308 can also be formed as a flap, door or closable window or barrier within the sampling channel 2308.

[00137] FIGS. 23C – 23E illustrate an alternative implementation of the blood sequestration device 2300', in which a sequestration chamber 2320 branches off from a main collection channel 2322 between an inlet port 2316 to connect with a patient needle and an outlet port 2318 to connect with a blood sample collection device, such as a Vacutainer, a syringe, or the like. The sequestration chamber 2320 includes an air-permeable, blood impermeable blood barrier 2324, such as a hydrophobic plug of material, or a filter formed of one or more layers, for example. A valve 2324 closes off

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and opens the collection channel 2322, and the device 2300' can be used similarly as described above.

[00138] FIG. 24A – 24D illustrate a blood sample optimization system 2400 that includes a patient needle 2402 for vascular access to a patient's bloodstream, a blood sample collection device 2404 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2406 providing a fluid connection between the patient needle 2402 and the blood sample collection device 2404. In some implementations, the blood sample collection device 2404 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2406 from the patient needle 2402.

[00139] The blood sample optimization system 2400 further includes a blood sequestration device 2408, located at any point on the conduit 2406 between the patient needle 2402 and the blood sample collection device 2404. The location of the blood sequestration device 2408 can be based on a length of the conduit between the blood sequestration device 2408 and the patient needle 2402, and the associated volume that length provides.

[00140] The blood sequestration device 2408 includes an inlet port 2412 for being connected to the conduit 2406 toward the patient needle 2402, and an outlet port 2414 for being connected to the conduit 2406 toward the blood sample collection device 2404, and a housing 2416. The housing 2416 can be any shape, although it is shown in FIGS. 24A – D as being substantially cylindrical, and includes the inlet port 2412 and outlet port 2414, which can be located anywhere on the housing although shown as being located on opposite ends of the housing 2416.

[00141] The blood sequestration device 2408 further includes a blood sequestration chamber 2418 connected with the inlet port 2412. The blood sequestration chamber 2418 is defined by an inner chamber housing 2419 that is movable from a first position to receive and sequester a first aliquot of blood, to a second position to expose one or more apertures 2424 at a proximal end of the inner chamber housing 2419 to allow blood to bypass and/or flow around the inner chamber housing 2419 and through a blood sample channel 2422 defined by the outer surface of the inner chamber housing 2419 and the

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inner surface of the housing 2416. The blood sequestration chamber 2418 includes an air permeable blood barrier 2420 at a distal end of the blood sequestration chamber 2418.

[00142] In operation, the inner chamber housing 2419 is in the first position toward the inlet port 2412, such that the one or more apertures 2424 are closed, and the blood sequestration chamber 2418 is in a direct path from the patient needle. Upon venipuncture of a patient, and drawing of blood by way of a syringe or Vacutainer, or other blood collection device 2404, the initial aliquot of blood flows into the blood sequestration chamber 2418. As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position. The inner chamber housing 2419 and/or housing 2416 can include a locking mechanism of one or more small tabs, grooves, detents, bumps, ridges, or the like, to maintain the inner chamber housing 2419 in the first position until the blood sequestration chamber 2418 is filled, providing force to overcome the locking mechanism to enable movement of the inner chamber housing 2419 to the second position. Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.

[00143] As described above, the housing 2416 and/or inner chamber housing 2419 can be formed as cylindrical and concentric, but can be any shape, such as squared, rectangular, elliptical, oval, or other cross-sectional shape. The outer surface of the distal end of the inner chamber housing 2419 can have one or more outwardly projecting tangs 2421 with gaps therebetween. The tangs 2421 contact the inner surface of the housing 2416 to help define the blood sampling channel 2422 therebetween, and to help stop the inner chamber housing 2419 in the second position. The gaps between the tangs 2421 enable blood to flow through the blood sampling channel 2422 and to the outlet port 2414. When the inner chamber housing 2419 is in the second position and the blood sequestration chamber 2418 is filled with the first aliquot of blood, further blood samples will automatically flow through the inlet port 2412, through the one or more apertures 2424, through the blood sampling channel 2422, through the gaps between the tangs 2421, and ultimately through the outlet port 2414 to be collected by a blood sampling device 2404.

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[00144] FIGS. 25A – D show a blood optimization system 2500 and blood sequestration device 2502, formed substantially as described in FIGS. 15, 16, 17, 18 and 19, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2520. Air initially in the blood sequestration chamber 2520 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2520. The air venting mechanism includes an air permeable blood barrier 2506, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2520.

[00145] The air venting mechanism includes an inner wall 2516 that at least partially circumscribes or surrounds the air permeable blood barrier 2506, and an outer wall 2504 spaced apart from the inner wall 2516. The outer wall 2504 can have one or more air vents 2514 formed therein. The outer wall 2504 extends higher upward than the inner wall 2516, such that a lid 2510, such as a cap, plug, cover, etc., can be attached to the outer wall 2504 and be displaced by a small distance from the top of the inner wall 2516. A seal 2508 in the form of a silicone wafer, or other elastomeric material, fits within the outer wall 2504 to cover the air permeable blood barrier 2506 and abut the top of the inner wall 2516. The seal 2508 covers and seals the air permeable blood barrier 2506 and inhibits air from entering the blood sequestration chamber 2520 through the air permeable blood barrier 2506. A fulcrum 2512 on an underside of the lid 2510 allows the seal 2508 to flexibly disconnect from the top of the inner wall 2516 when pushed by air displaced from the blood sequestration chamber 2520, to allow air to vent from the air permeable blood barrier 2506 and through the one or more air vents 2514 in the outer wall 2504.

[00146] FIG. 26A – E illustrate a blood sample optimization system 2600 that includes a patient needle 2602 for vascular access to a patient's bloodstream, a blood sample collection device 2604 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2606 providing a fluid connection between the patient needle 2602 and the blood sample collection device 2604. The conduit 2606 can include flexible tubing. In preferred implementations, the blood sample collection device 2604 includes a protective shield 2605 that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the

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collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2602.

[00147] The blood sample optimization system 2600 further includes a blood sequestration device 2608, located at any point on the conduit 2606 between the patient needle 2602 and the blood sample collection device 2604. The location of the blood sequestration device 2608 can be based on a length of the conduit between the blood sequestration device 2608 and the patient needle 2602, and the associated volume that length provides.

[00148] The blood sequestration device 2608 includes an inlet port 2612 for being connected to the conduit 2606 toward the patient needle 2602, and an outlet port 2614 for being connected to the conduit 2606 toward the blood sample collection device 2604. The blood sequestration device 2608 includes an outer housing 2616 and an inner housing 2617, both having a cylindrical form, and being connected concentrically. The outer housing 2616 includes an outer wall 2618 and an inner conduit 2620 that defines a blood sampling channel 2622 to convey blood through the conduit 2606 to the blood sampling device 2604. The inner housing 2617 fits snugly between the inner conduit 2620 and the outer wall 2618 of the outer housing, and is rotatable in relation to the outer housing 2616. The fit between the outer housing 2616 and the inner housing 2617 can be a friction fit that maintains the housings in a particular position. The inner housing 2617 defines a blood sequestration chamber 2624, preferably a helical or corkscrew channel around the outer surface of inner conduit 2620 of the outer housing 2616, and which terminates at an air vent 2628 having an air permeable blood barrier, as shown in FIG. 26E.

[00149] The blood sequestration chamber 2624 is connected with the blood sampling channel 2622 via diversion junction 2624 formed in the inner conduit 2620, when the blood sequestration device in a first state, illustrated in FIG. 26C. The protective shield 2606 on the collection needle 2604 provides a block for air or blood, enabling a diversion of an initial aliquot of blood into the blood sequestration chamber 2624 as the patient's blood pressure overcomes the ambient air pressure in the blood sequestration channel 2624 to displace air therefrom through air vent 2628.

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[00150] When the inner housing 2617 is rotated relative to the outer housing 2616, or vice versa, to a second state, as illustrated in FIG. 26D, the blood sequestration chamber 2624 is shut off from diversion junction 2624, enabling a direct path from the patient needle through the conduit 2606 to the collection needle 2604, via blood sampling channel 2622. The outer housing 2616 and/or inner housing 2617 can include ridges or grooves formed within a portion of their surfaces, to facilitate relative rotation from the first state to the second state.

[00151] FIGS. 27A – D illustrate a blood optimization system 2700 and blood sequestration device 2702, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, and 25, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2720. Air initially in the blood sequestration chamber 2720 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2720. The air venting mechanism includes an air permeable blood barrier 2706, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2720.

[00152] The air venting mechanism includes an inner wall 2716 that at least partially circumscribes or surrounds the air permeable blood barrier 2706, and an outer wall 2704 spaced apart from the inner wall 2716. A cap 2722 is positioned on the air venting mechanism, preferably by having a lower cap wall 2728 that fits between the inner wall 2716 and the outer wall 2704 of the air venting mechanism, and frictionally abutting either the inner wall 2716 or the outer wall 2704 or both. The cap 2722 further includes one or more vent holes 2724 or slits, apertures, openings, or the like, which extend through an upper surface of the cap 2722 around a downwardly extending plug 2726. The plug 2726 is sized and adapted to fit snugly within the space defined by inner wall 2716.

[00153] In a first position, as illustrated in FIG. 27C, the cap 2722 is extended from the air venting mechanism to allow air from the blood sequestration chamber 2720 to exit through the air permeable blood barrier 2706 and through the one or more vent holes 2724. Once the air from the blood sequestration chamber 2720 has been displaced, i.e., when the blood sequestration chamber 2720 is filled with the first aliquot of potentially tainted blood from the patient, then the cap 2722 can be pushed down on the air venting

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mechanism in a second position as shown in FIG. 27D, so that the plug 2726 fits within the inner wall 2716 over the air permeable blood barrier 2706 to seal the air venting mechanism. In either the first position or the second position, the cap 2722 protects the air permeable blood barrier 2706 from outside air or from being touched by a user.

[00154] FIGS. 28A – F illustrate a blood optimization system 2800 and blood sequestration device 2802, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but utilizing a multi-layered filter, and in some implementations, a filter with trapped reactive material, for an air permeable blood barrier. As shown in FIGS. 28C and D, an air permeable blood barrier 2803 includes a first layer 2804 of an air permeable but blood impermeable material, and a second layer 2806 that includes a reactive material, such as a hydrophobic material, for repelling blood while still allowing air to pass through both layers. As shown in FIGS. 28E and F, the air permeable blood barrier 2803 can include any number of layers, such as a third layer 2808 formed of the same air permeable but blood impermeable material as first layer 2804, while a second layer 2806 includes trapped or embedded blood reactive material.

[00155] FIGS. 29A – C illustrate a blood optimization system 2900 and blood sequestration device 2902, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but in which a blood sequestration chamber 2904 is at least partially filled with a blood-absorptive material 2906. The blood-absorptive material 2906 can act as a wicking material to further draw in blood to be sequestered upon venipuncture of the patient, and prior to use of a blood drawing device such as a Vacutainer™ or a syringe, or the like.

[00156] FIGS. 30A – G illustrate a blood optimization system 3000 and blood sequestration device 3002, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26. The blood sequestration device 3000 includes an inlet port 3002 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 3002 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 3002 defines an opening into the blood sequestration device 3000, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the

opening can be circular with a diameter of approximately $\geq 0,1143$ cm (0,045 inches), but can have a diameter of between $\geq 0,0254$ cm (0,01 inches) or less to $\geq 0,508$ cm (0,2 inches) or more.

[00157] The inlet port 3002 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 3002, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 3000 at the time of blood draw or sampling.

[00158] The blood sequestration device 3000 further includes an outlet port 3004, which defines an opening out of the blood sequestration device 3000 and to the blood sample collection device. The outlet port 3004 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 3000 at the time of blood draw or sampling.

[00159] The blood sequestration device 3000 further includes a sampling channel 3006 between the inlet port 3002 and the outlet port 3004, and a sequestration chamber 3008 that is connected to and split off or diverted from the sampling channel 3006 at any point between the inlet port 3002 and the outlet port 3004. The sampling channel 3006 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 3008. The sampling channel 3006 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 3006 has a substantially similar cross sectional area as the opening of the inlet port 3002. In other implementations, the sampling channel 3006 can gradually widen from the inlet port 3002 to the outlet port 3004. The sequestration chamber 3008 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the

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blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 3006.

[00160] In some exemplary implementations, the diversion between the sampling channel 3006 and the sequestration chamber 3008 is by diverter junction 3007. Diverter junction 3007 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008. The sequestration chamber 3008 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 3008.

[00161] The sequestration chamber 3008 is preferably maintained at atmospheric pressure, and includes a vent 3010 at or near a distal end of the sequestration chamber 3008. The vent 3010 may include an air permeable blood barrier 3012 as described above.

[00162] The blood sequestration device 3000 can include a housing 3001 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated FIG. 30F, the housing 3001 includes a top member 3020 and a bottom member 3022 that are mated together. The blood sequestration device 3000 can also include a gasket or other sealing member (not shown) so that when the top member 3020 is mechanically attached with the bottom member 3022, the interface between the two is sealed by the gasket or sealing member. The bottom member 3022 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 3006, the sequestration chamber 3008, and diverter junction 3007.

[00163] The sequestration chamber 3008 may have a larger cross section than the sampling channel 3006 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 3006.

[00164] In some implementations, the sampling channel 3006 and the sequestration chamber 3008 are formed by grooves, channels, locks or other pathways formed in housing 3001. The housing 3001 can be made of rubber, plastic, metal or any other suitable material. The housing 3001 can be formed of a clear or translucent material, or

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of an opaque or non-translucent material. In other implementations, the housing 3001 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 3006 and/or the sequestration chamber 3008 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 3008 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 3006. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 3012 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00165] The air permeable blood barrier 3012 can be covered with, or surrounded by, a cap 3032. The cap 3032 can be sized and configured to inhibit a user from touching the air permeable blood barrier 3012 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 3012 as the air is displaced from the sequestration chamber 3008. The cap 3032 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00166] The air venting mechanism includes a wall 3030 that at least partially circumscribes or surrounds the air permeable blood barrier 3012. The wall 3030 can have one or more air vents formed therein. The cap 3032 covers wall 3030 and can be snapped, glued, or otherwise attached in place. A seal 3017 in the form of a silicone wafer, or other elastomeric material, fits within the wall 3030 to cover the air permeable blood barrier 3012 and abut the top of the wall 3030. The seal 3017 covers and seals the air permeable blood barrier 3012 and inhibits air from entering the blood sequestration chamber 3008 through the air permeable blood barrier 3012. A fulcrum 3012 on an underside of the cap 3032 allows the seal 3008 to flexibly disconnect from the top of the inner wall 3016 when pushed by air displaced from the blood sequestration chamber 3008, to allow air to vent from the air permeable blood barrier 3012 and through the one or more air vents in the wall 3030 and/or cap 3032.

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[00167] In use, the blood sequestration device 3000 includes a sampling channel 3006 and a sequestration chamber 3008. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 3006 is directed to an outlet port 3004 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 3008 terminates at a vent 3010 to atmosphere that includes an air permeable blood barrier 3012.

[00168] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 3002 of blood sequestration device 3000. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 3008 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 3008 to displace air therein through the air permeable blood barrier 3012, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 3006. In various exemplary embodiments, the sequestration chamber 3008 and sampling channel 3006 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00169] Eventually, the sequestration chamber 3008 fills with blood that displaces air through the air permeable blood barrier 3012. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 3012 material to completely or partially seal the vent 3010. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00170] Upon filling the blood sequestration pathway 3008 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 3006, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 3006, queuing up the uncontaminated blood to be drawn through the sampling channel 3006.

[00171] In yet another aspect, the blood sequestration chamber and/or blood sampling channel, or other component, of any of the implementations described herein,

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can provide a visually discernable warning or result in a component adapted for operative fluid communication with the flash chamber of an introducer for an intravenous catheter into a blood vessel of a patient. The device and method provides a visually discernable alert when blood from the patient communicates with a test component reactive to communicated blood plasma, to visually change. The reaction with the blood or the plasma occurs depending on one or a plurality of reagents positioned therein configured to test for blood contents, substances or threshold high or low levels thereof, to visually change in appearance upon a result.

[00172] In yet other aspects, the blood sequestration chamber and/or blood sampling channel can be sized and adapted to provide a particular volumetric flow of blood, either during the sequestration process and/or the sampling process.

[00173] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

~~Amended~~ claims

1. A blood sequestration device (812, 1000, 1100, 1202, 1302, 1401, 1500, 1600, 2008, 2100, 2200, 2300, 2408, 2502, 2608, 2702, 2802, 2902, 3000) comprising;
- an inlet port (802, 902, 1002, 1102, 1212, 1314, 1402, 1502, 1532, 1602, 2302, 2316, 2412, 2612, 3002);
 - an outlet port (904, 1004, 1104, 1214, 1312, 1404, 1504, 1534, 1604, 2304, 2318, 2414, 2614, 3004) ;
 - a sequestration chamber (55, 104, 204, 304, 822, 1008, 1108, 1218, 1318, 1408, 1508, 1608, 2102, 2306, 2320, 2418, 2520, 2624, 2720, 2904, 3008) connected with the inlet port via a junction, the sequestration chamber having a vent (1510, 1610, 2628, 3010) that includes an air permeable blood barrier (20, 106, 824, 1010, 1110, 1310, 1412, 1512, 1612, 2202, 2420, 2506, 2706, 2803, 3012), the vent being defined by an outer wall (2504, 2618, 2704) that at least partially circumscribes the air permeable blood barrier and includes one or more air vents (2514), the vent further including a cap (1208, 1307, 2722, 3032), that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and
 - a sampling channel (820, 1406, 1508, 1606, 2104, 2308, 2422, 2622, 3006) having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;
 - the sequestration chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.
2. The blood sequestration device in accordance with claim 1, further comprising a housing (40, 50, 818, 1301, 1414, 1501, 1601, 2101, 2416, 2616, 3001) that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

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3. The blood sequestration device in accordance with claim 1, wherein the vent further includes an inner wall (2516, 2716, 3016) within the outer wall and that contains the air permeable blood barrier.

4. The blood sequestration device in accordance with claim 1, wherein the one-way seal is positioned over the inner wall and within the outer wall of the vent.

5. The blood sequestration device in accordance with claim 4, wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum (2512, 3012) against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the sequestration chamber.

6. The blood sequestration device in accordance with claim 1, wherein the air permeable blood barrier includes a sealing material that seals the vent upon contact with blood.

7. The blood sequestration device in accordance with claim 1, wherein the air permeable blood barrier includes a filter having a first layer and a second layer, the second layer of the filter having a hydrophobic material to repel blood.

8. A blood sequestration and sampling system (800, 1200, 1300, 1400, 2000, 2400, 2500, 2600, 2700, 2800, 2900, 3000) comprising:
a blood sampling pathway having a patient needle on a proximal end and a sample collection device on a distal end; and

a blood sequestration device in accordance with any of claims 1 to 7 attached on the blood sampling pathway between the proximal end and distal end of the blood sampling pathway, wherein the inlet port is coupled with the blood sampling pathway toward the patient needle;

the outlet port is coupled with the blood sampling pathway toward the sample collection device.

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9. The blood sequestration system in accordance with claim 8, wherein the blood sequestration device further comprises a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

10. The blood sequestration system in accordance with claim 8, wherein the vent of the blood sequestration device further includes an inner wall within the outer wall and that contains the air permeable blood barrier.

11. The blood sequestration system in accordance with claim 8, wherein the one-way seal of the vent is positioned over the inner wall and within the outer wall of the vent.

12. The blood sequestration system in accordance with claim 11, wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the sequestration chamber.

13. The blood sequestration system in accordance with claim 8, wherein the air permeable blood barrier of the blood sequestration device includes a sealing material that seals the vent upon contact with blood.

14. The blood sequestration system in accordance with claim 8, wherein the air permeable blood barrier of the blood sequestration device includes a filter having a first layer and a second layer, the second layer of the filter having a hydrophobic material to repel blood.

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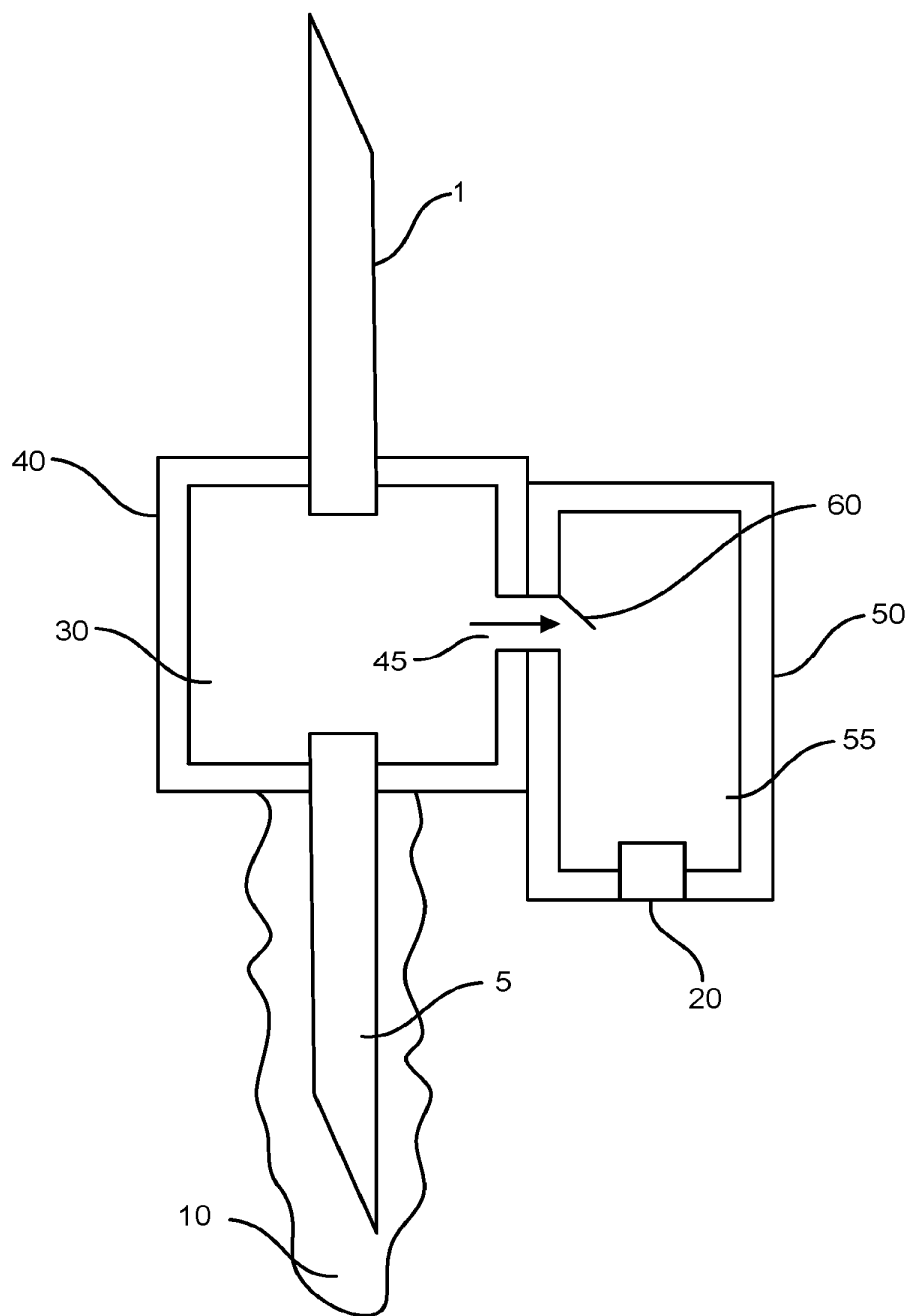


FIG. 1

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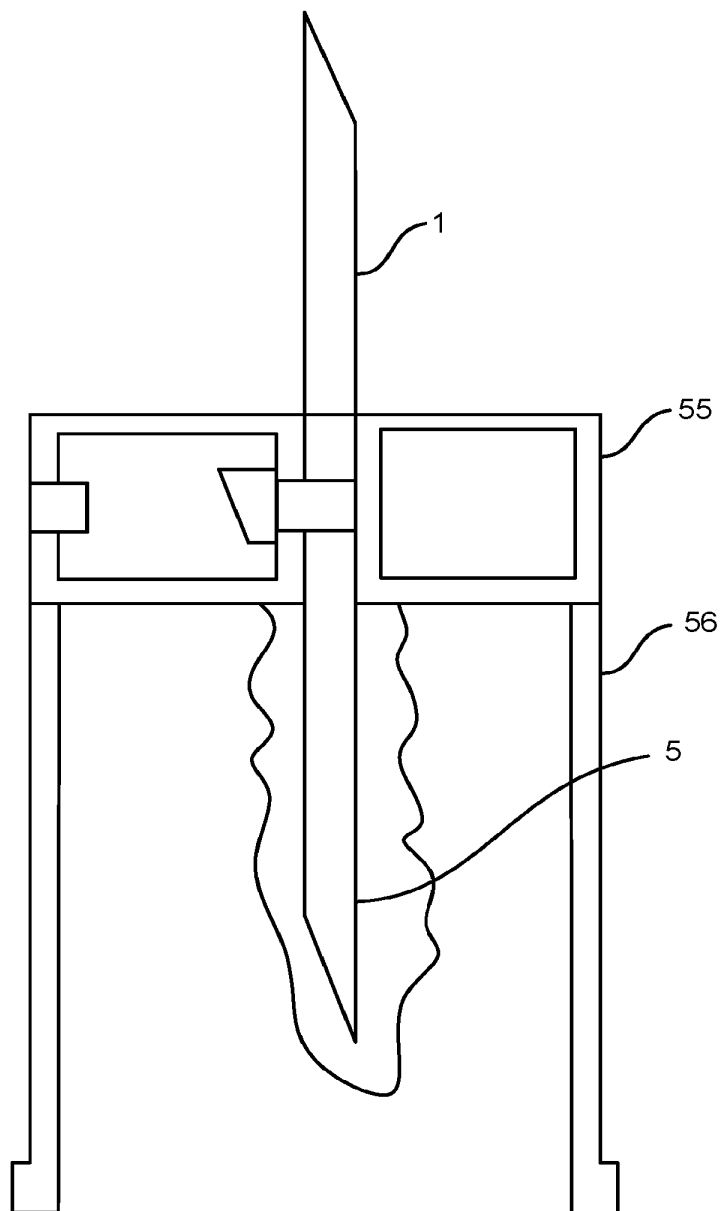


FIG. 2

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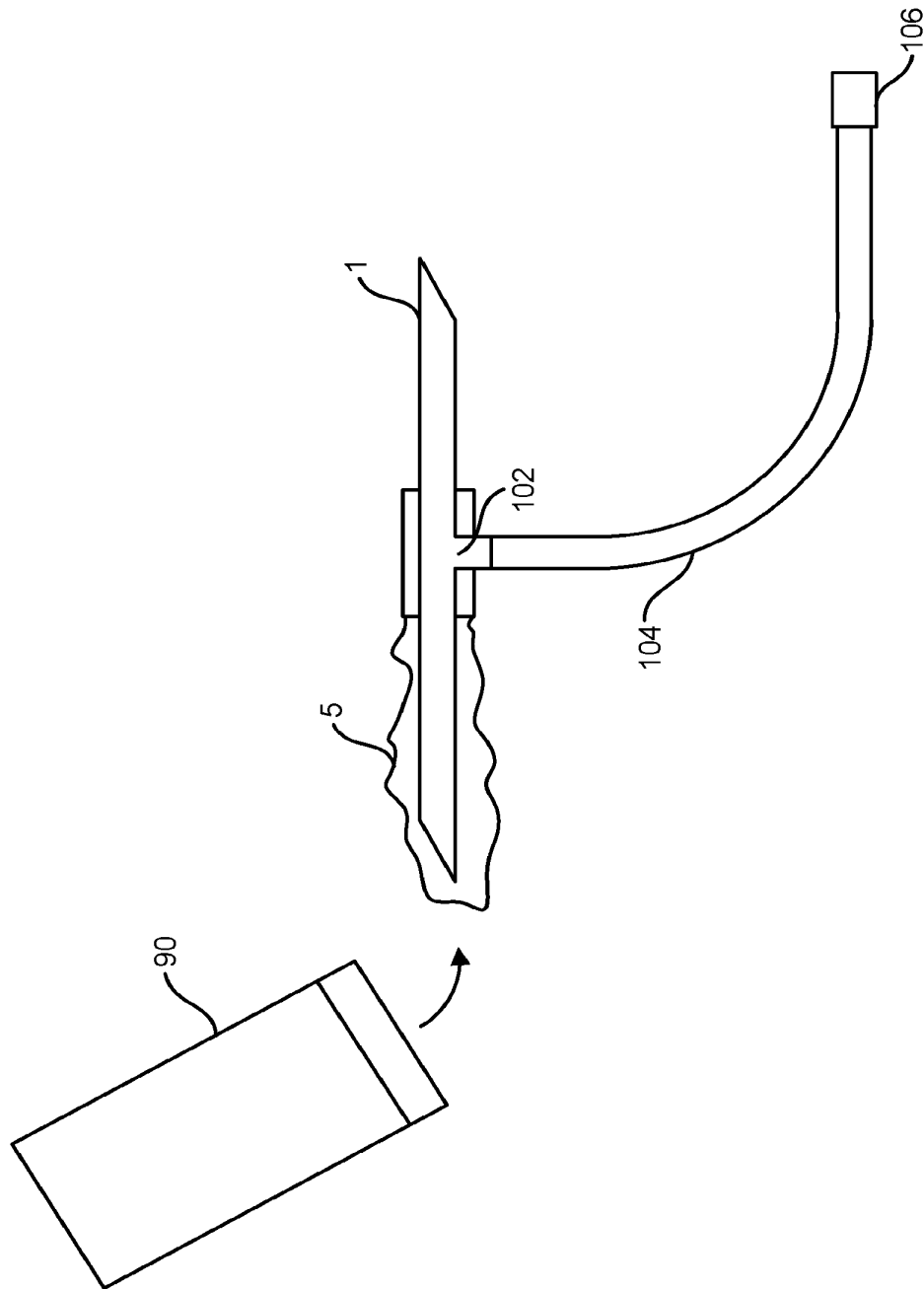


FIG. 3

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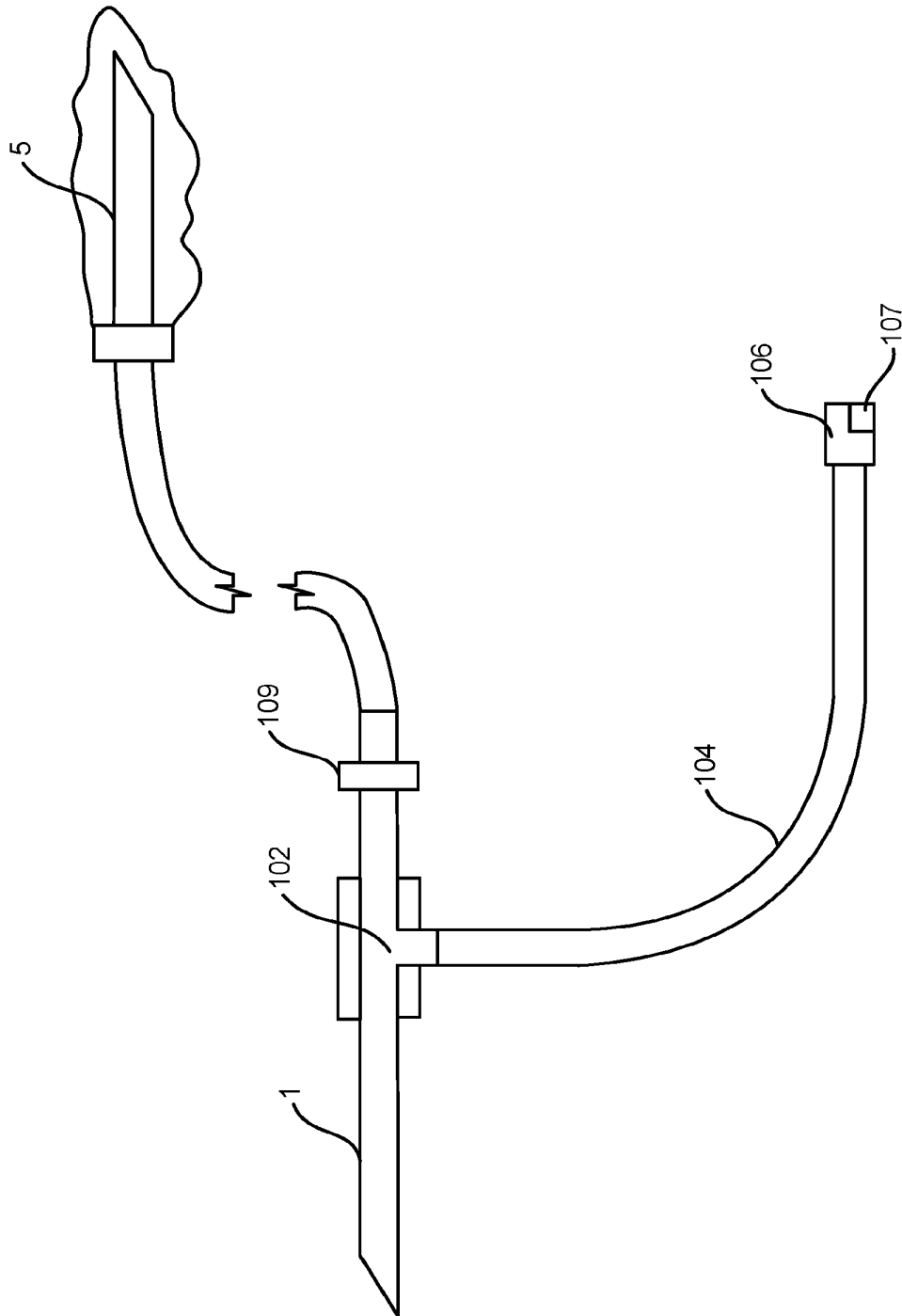


FIG. 4

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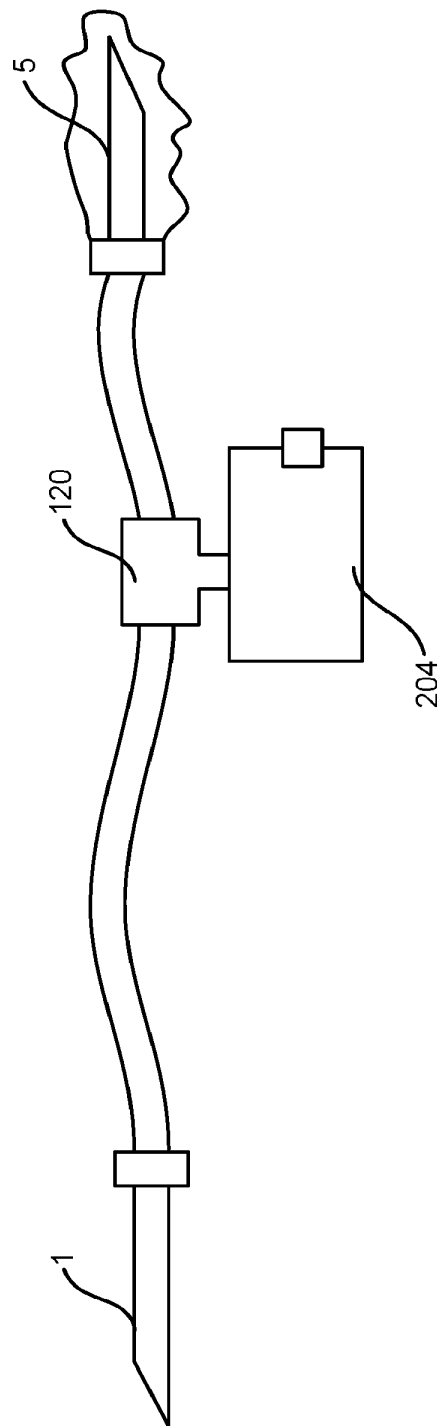


FIG. 5

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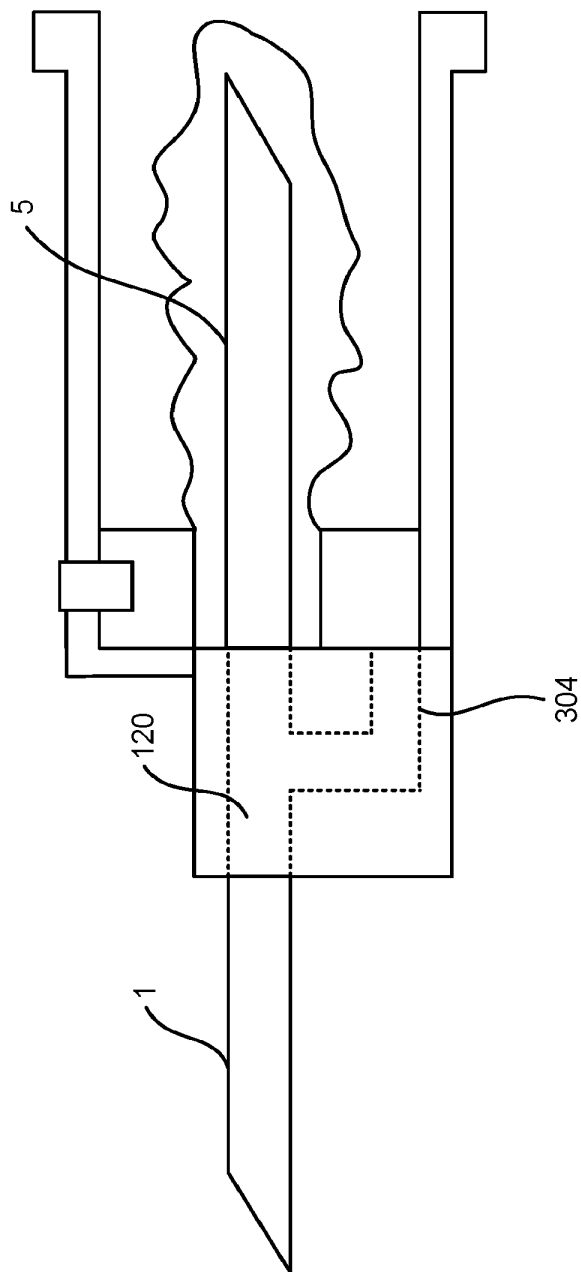


FIG. 6

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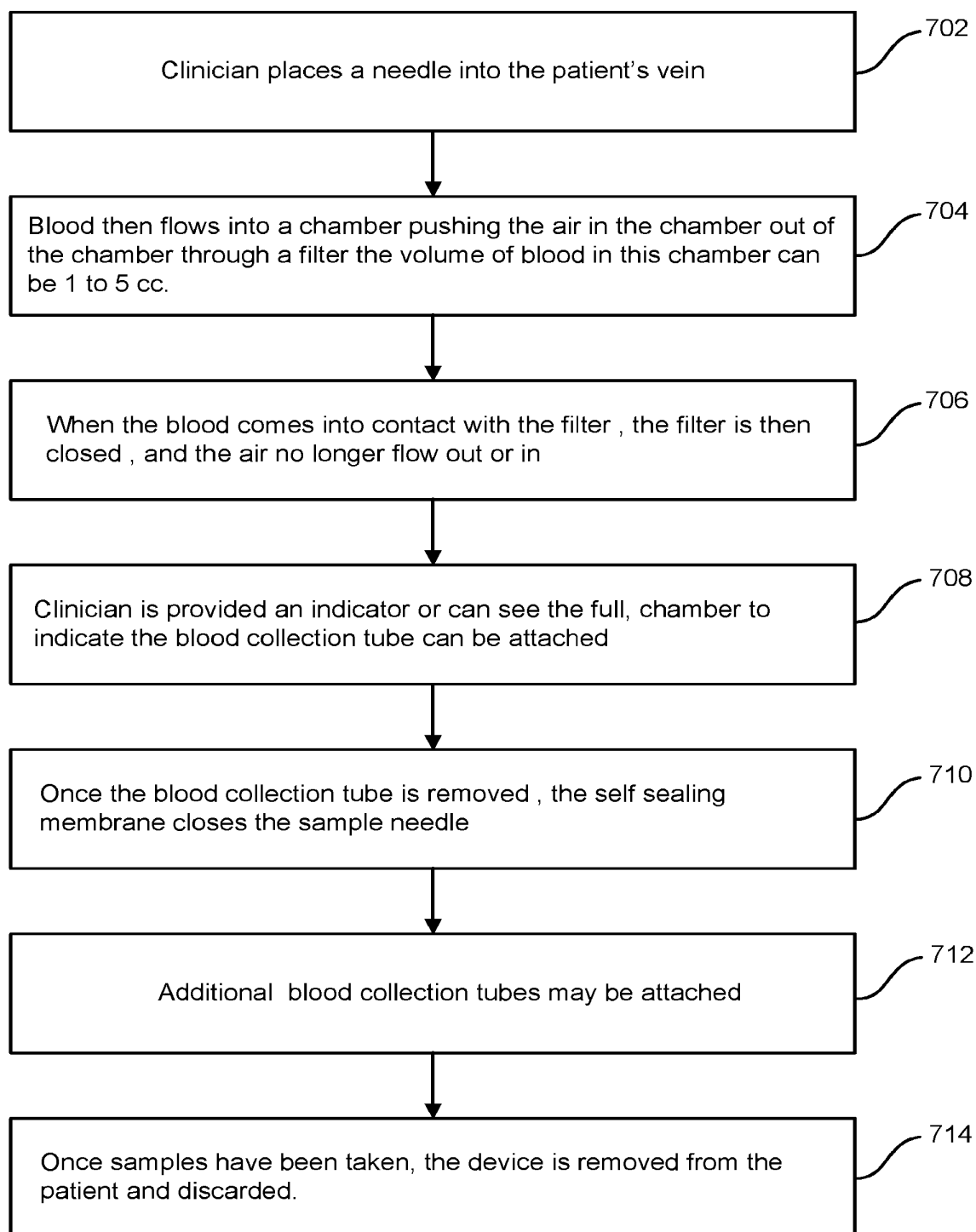
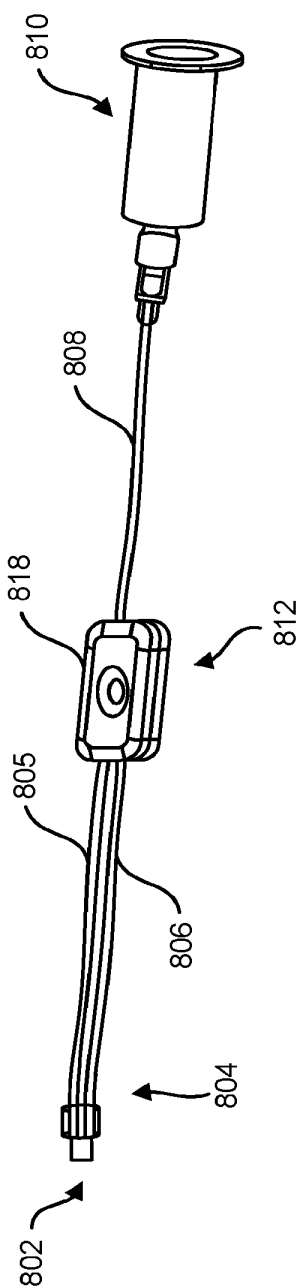
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FIG. 7

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800

FIG. 8A

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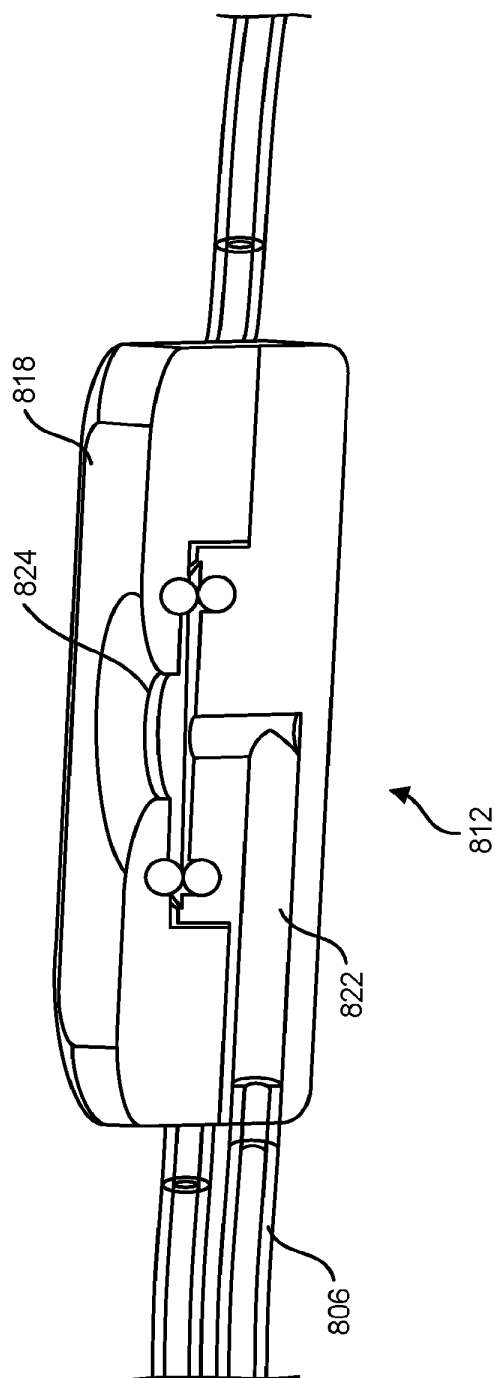


FIG. 8B

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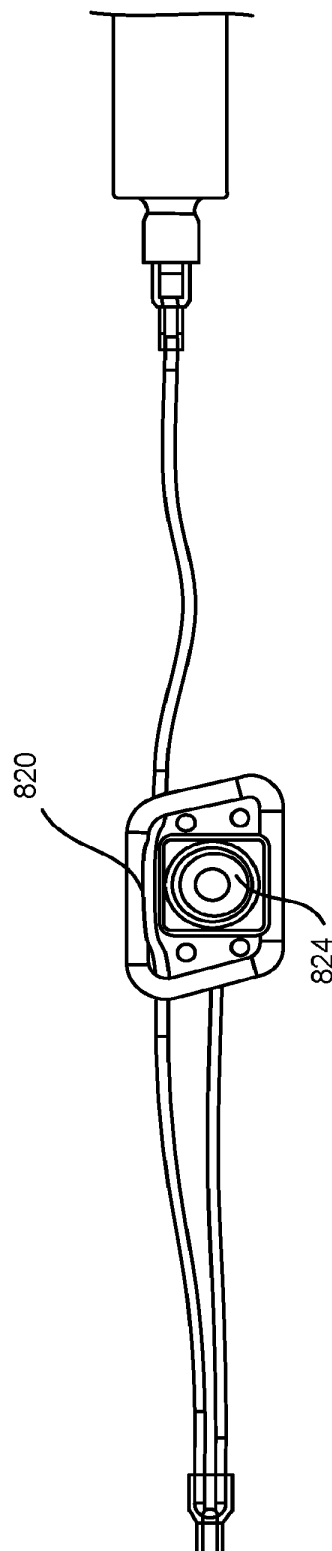


FIG. 8C

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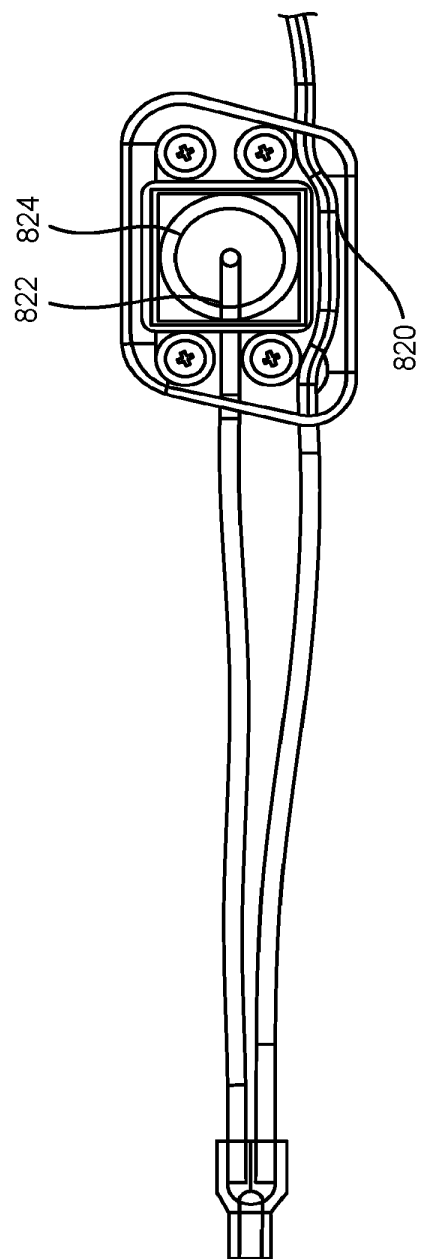


FIG. 8D

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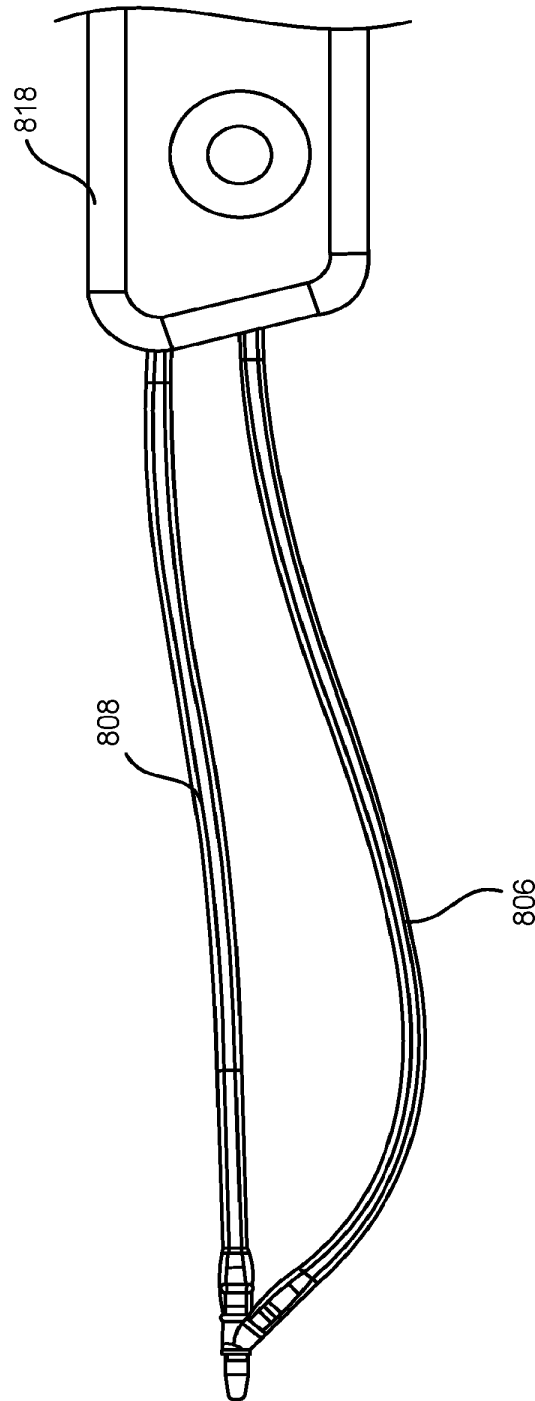


FIG. 8E

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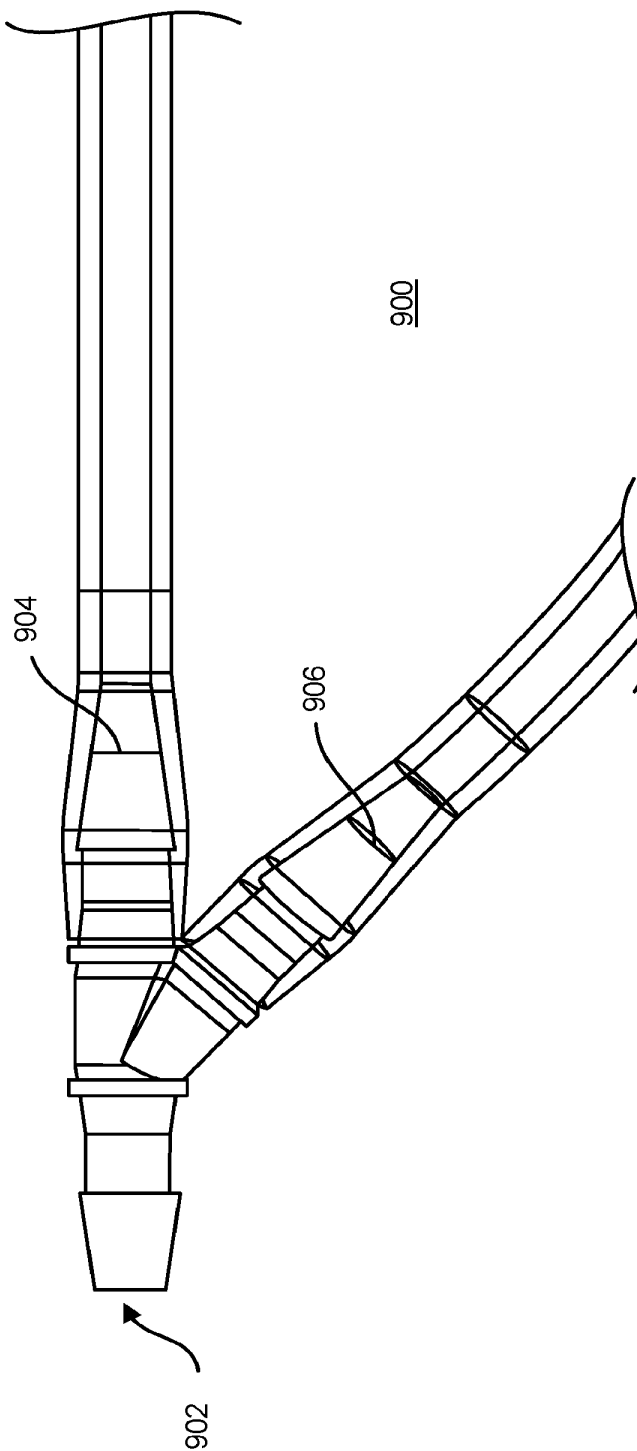


FIG. 9

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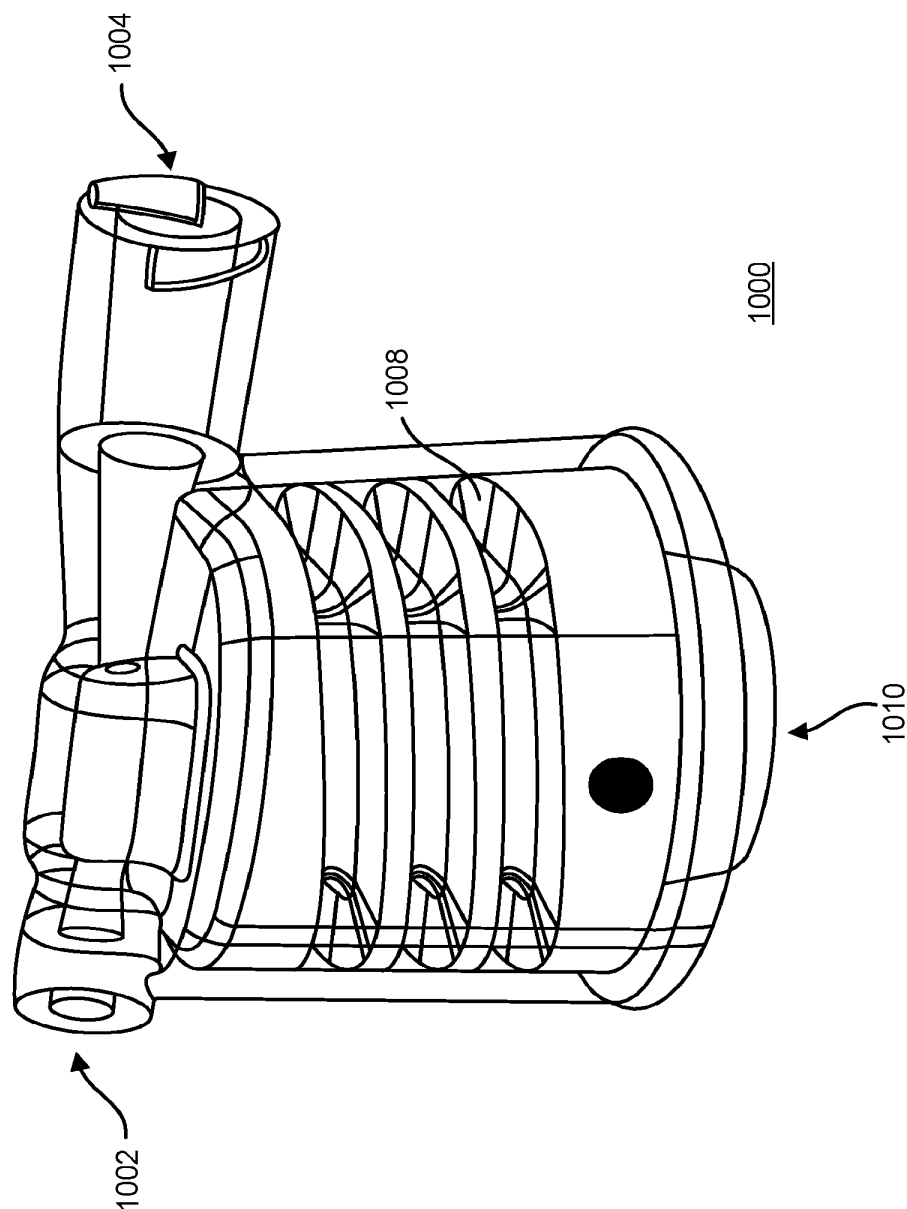


FIG. 10A

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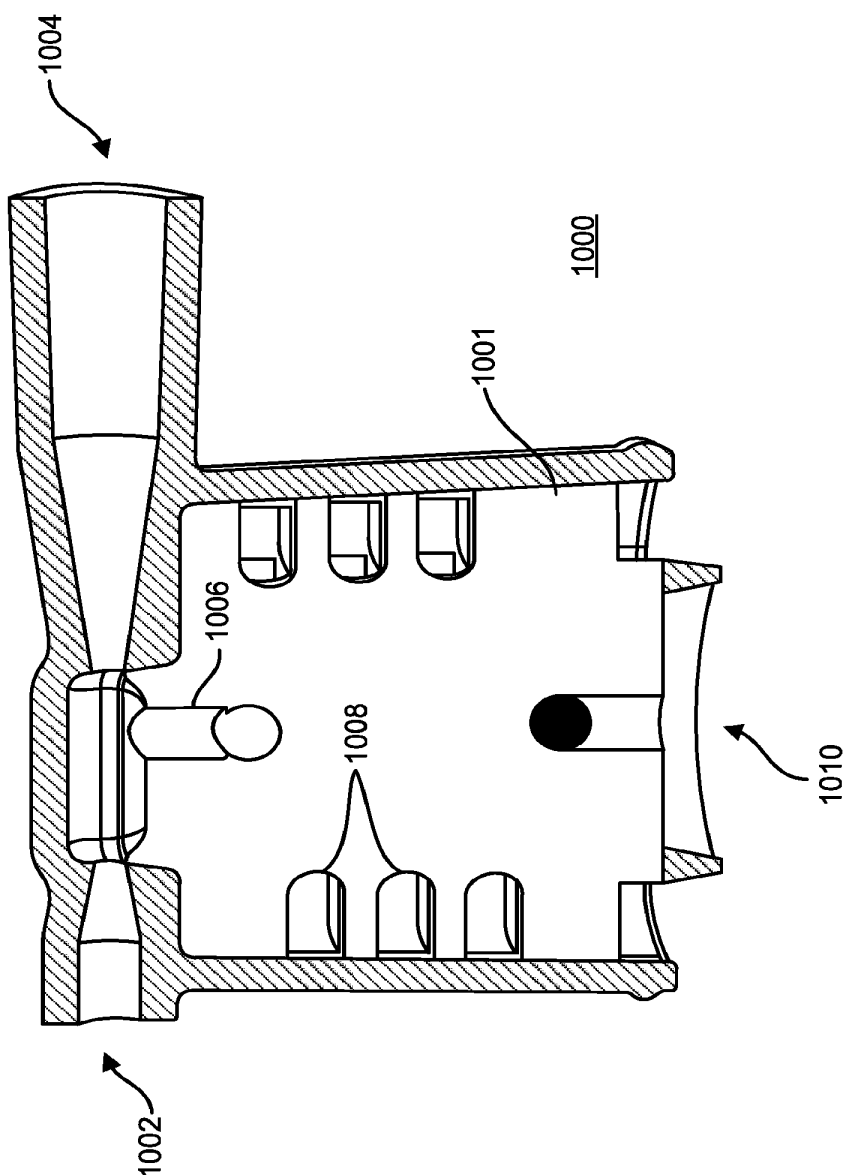


FIG. 10B

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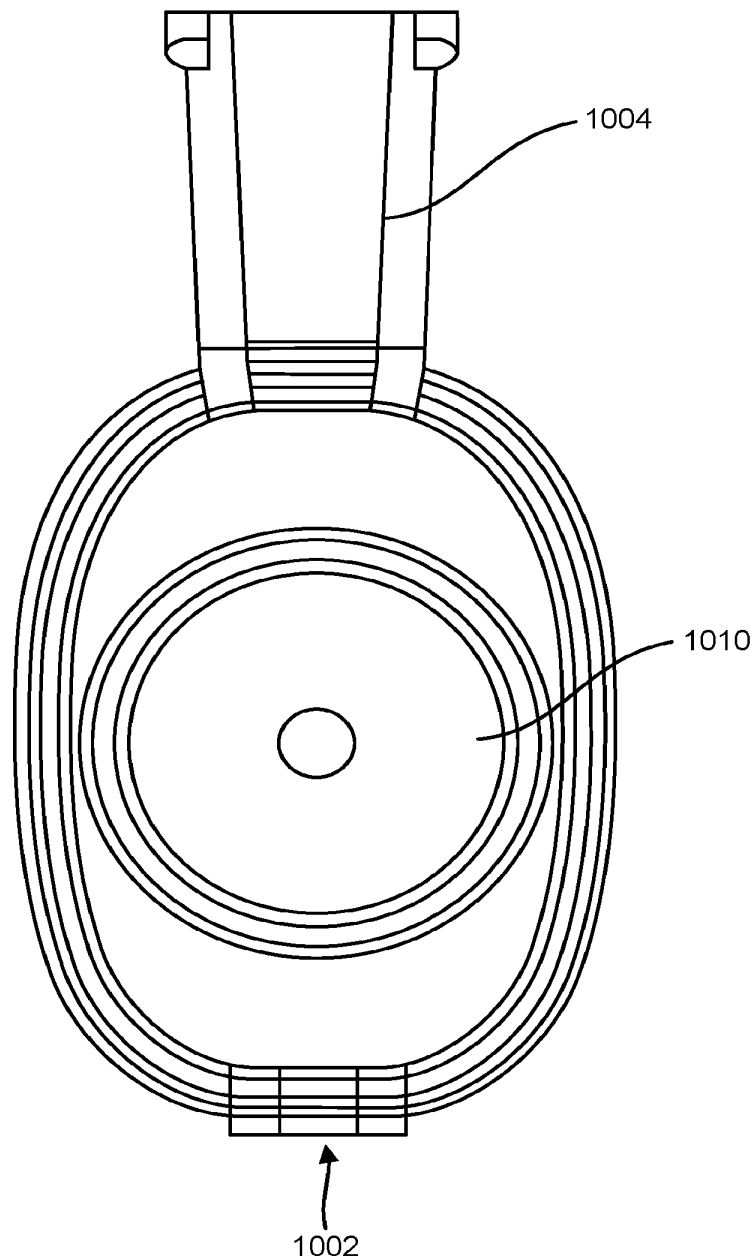


FIG. 10C

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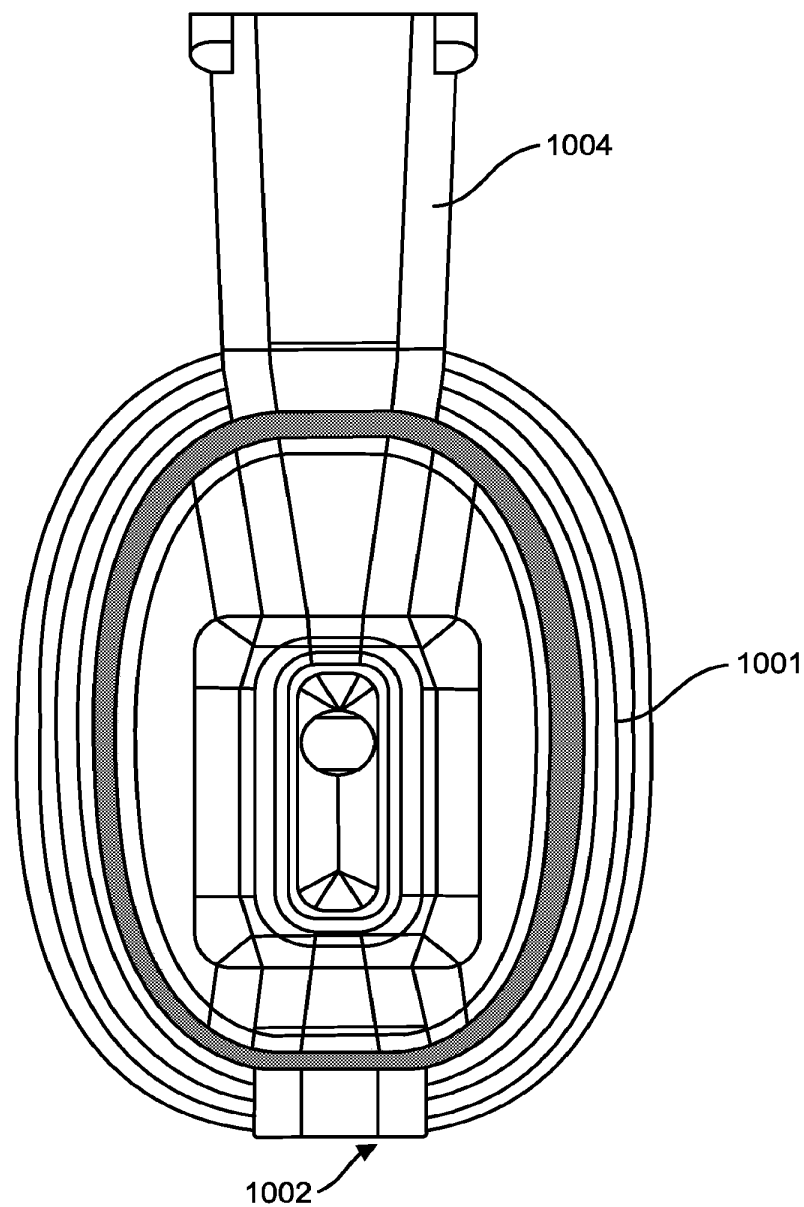
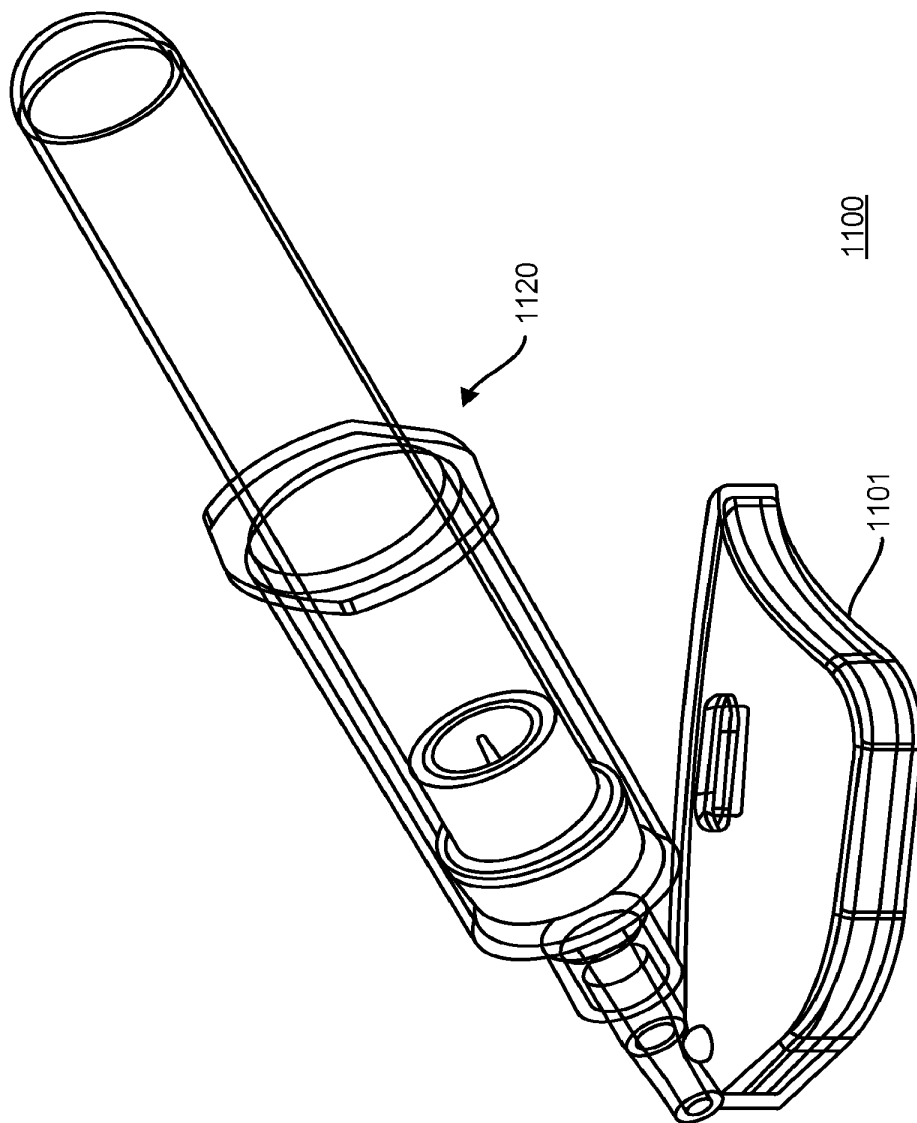


FIG. 10D

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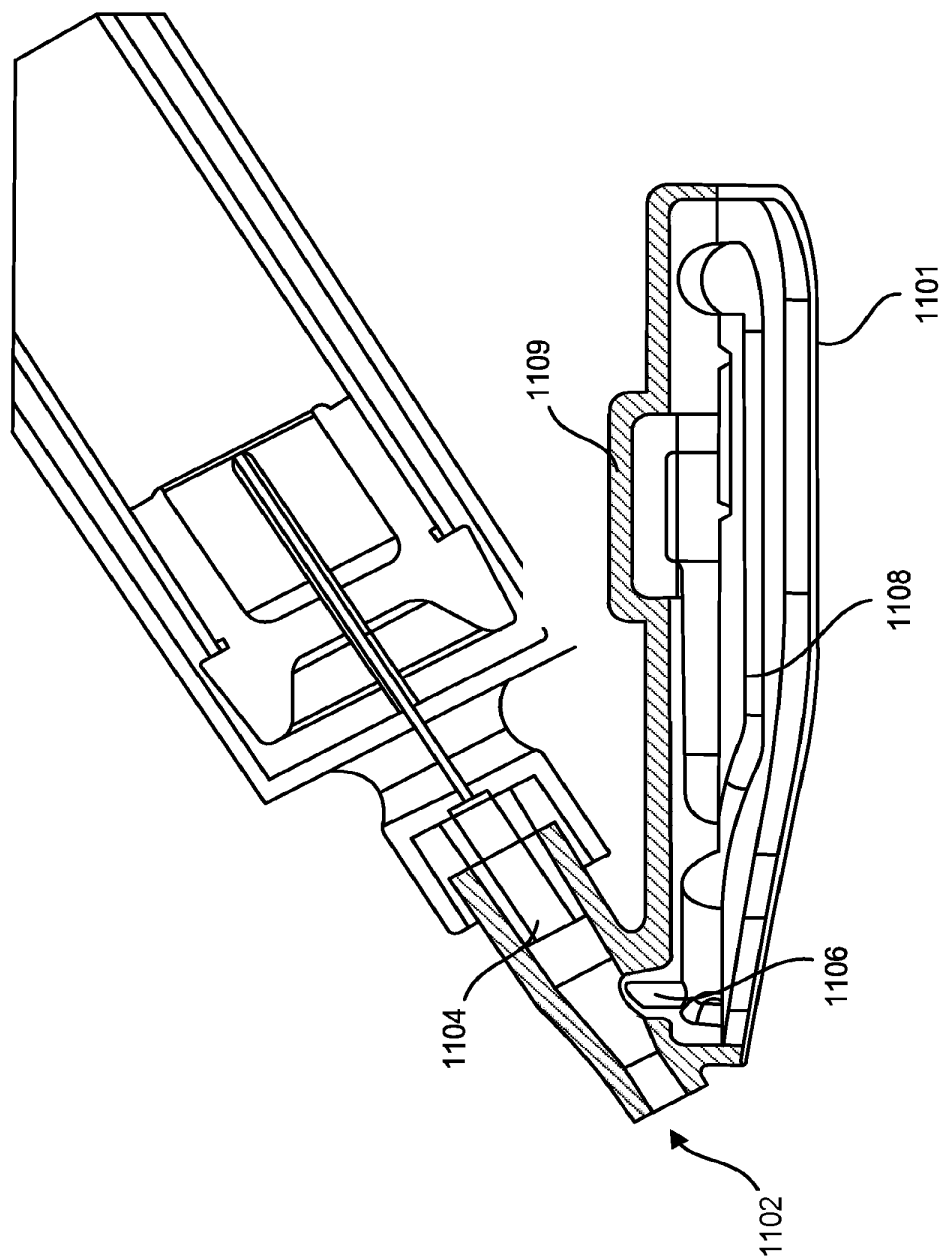


FIG. 11B

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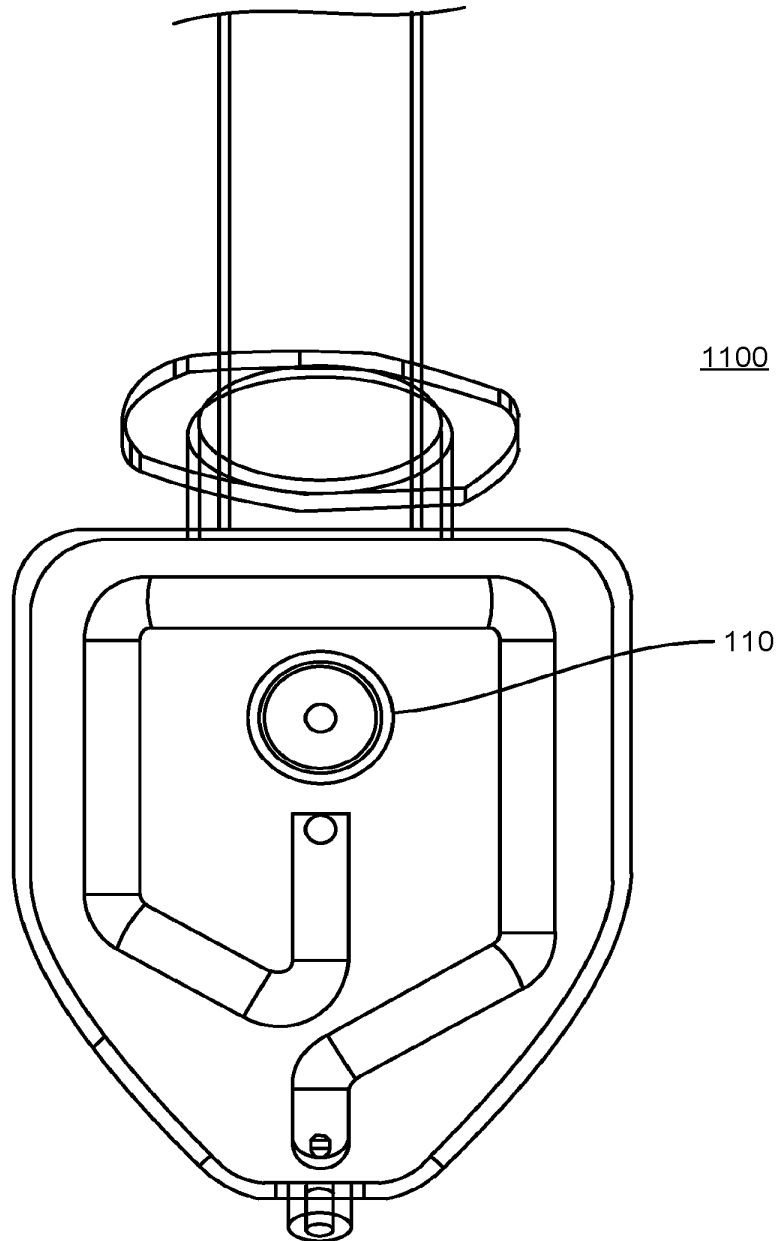


FIG. 11C

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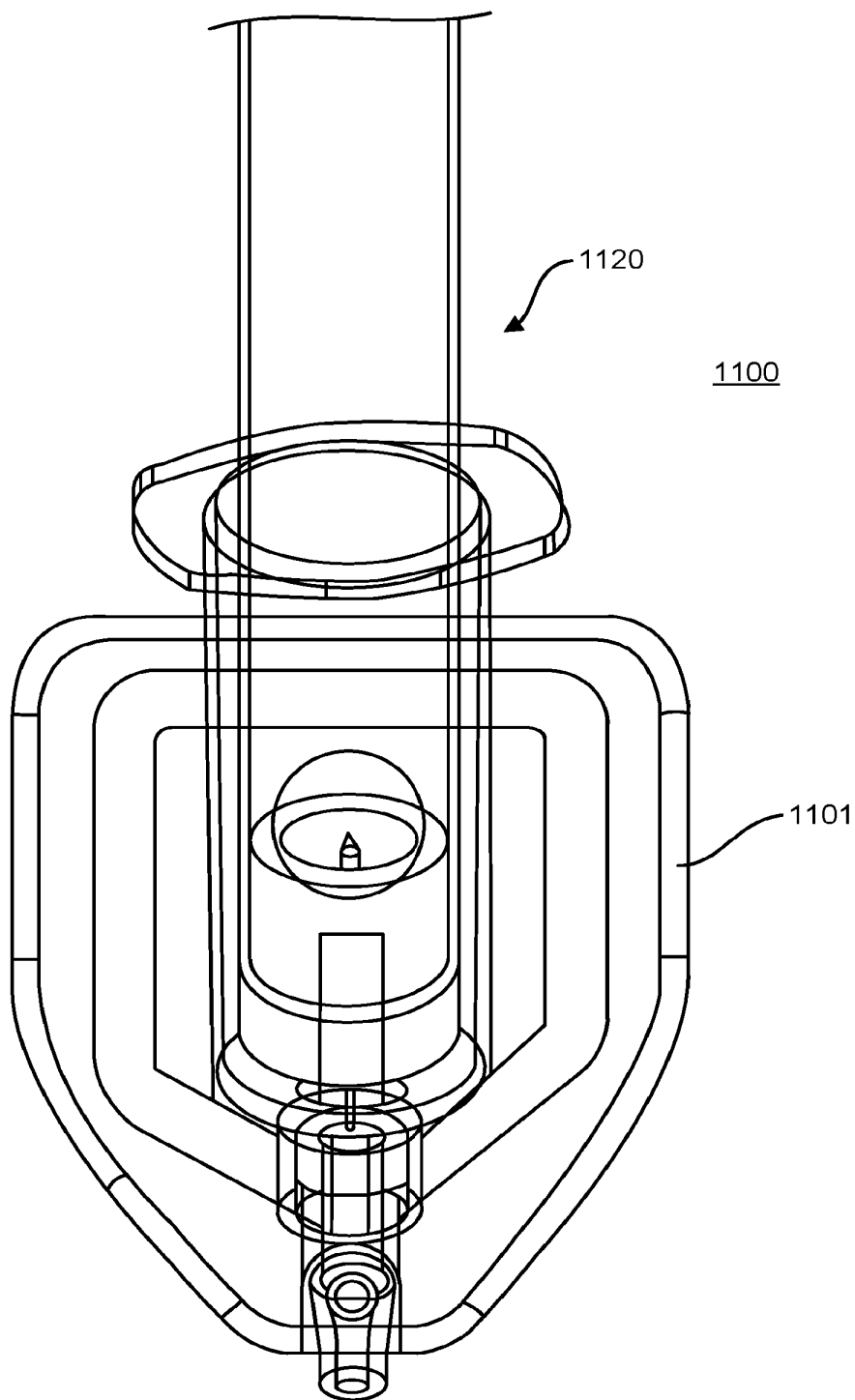


FIG. 11D

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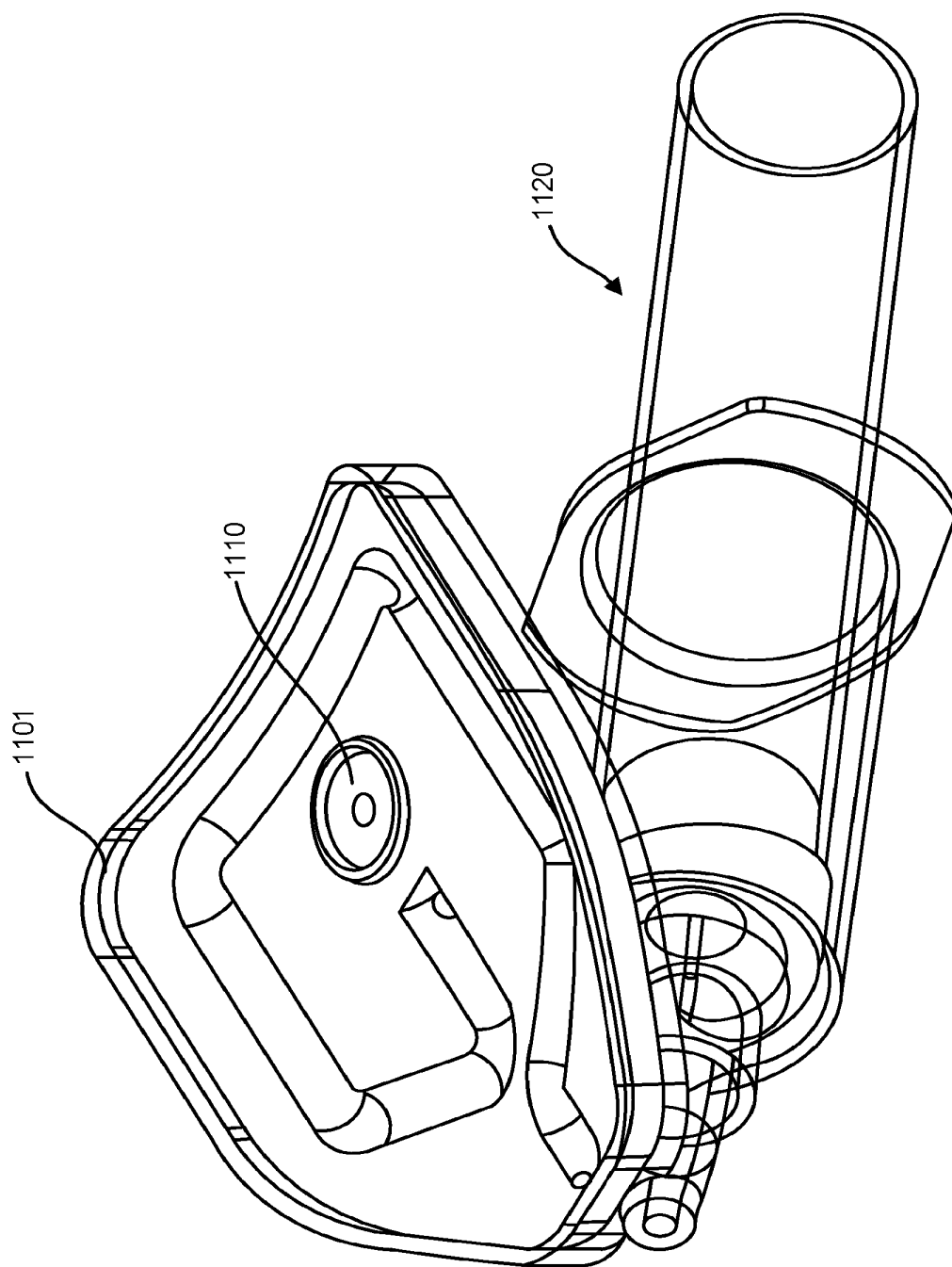
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FIG. 11E

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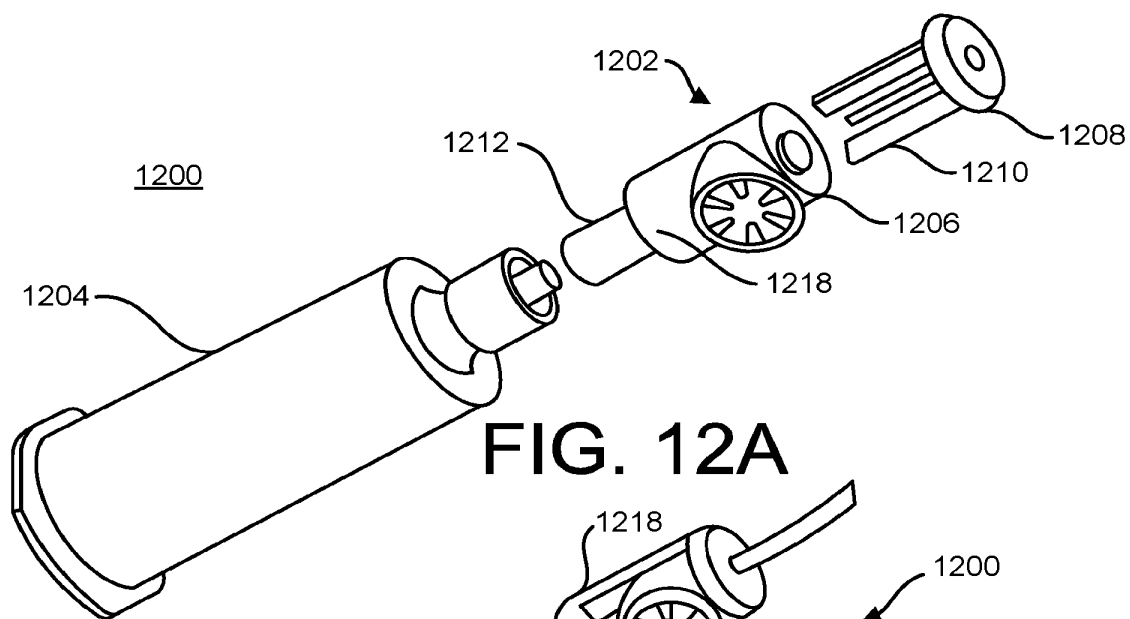
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FIG. 12A

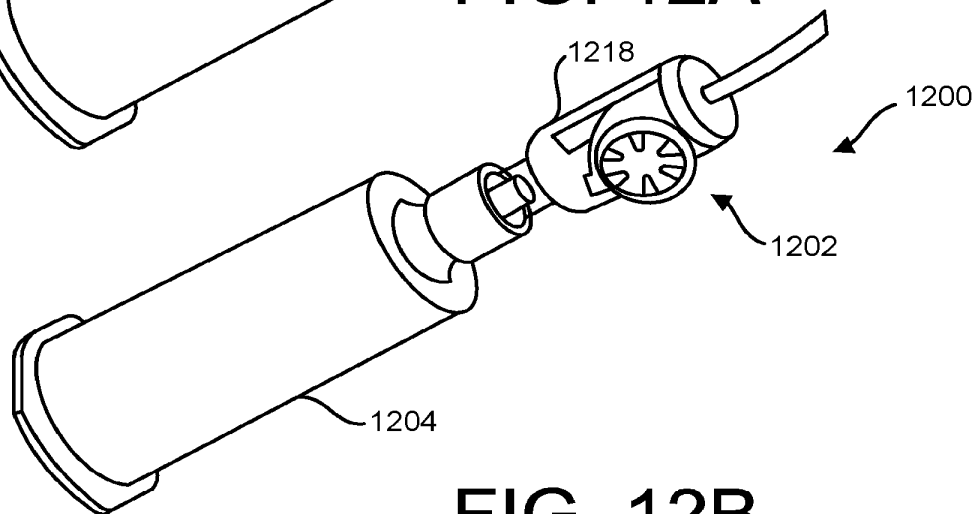


FIG. 12B

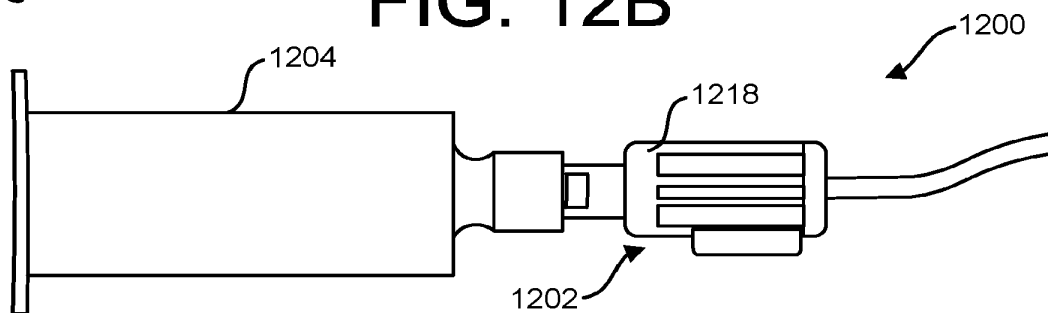


FIG. 12C

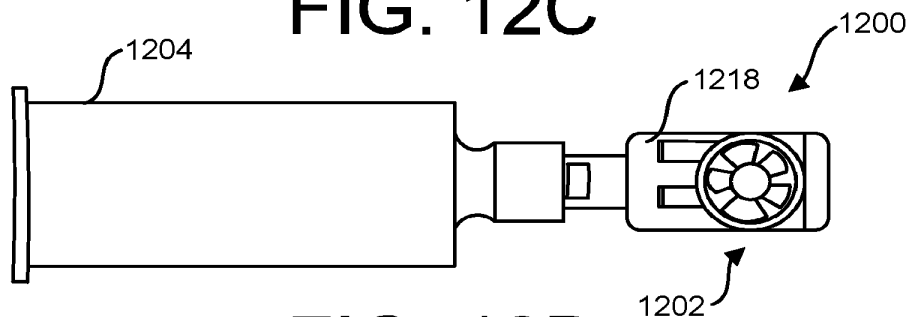


FIG. 12D

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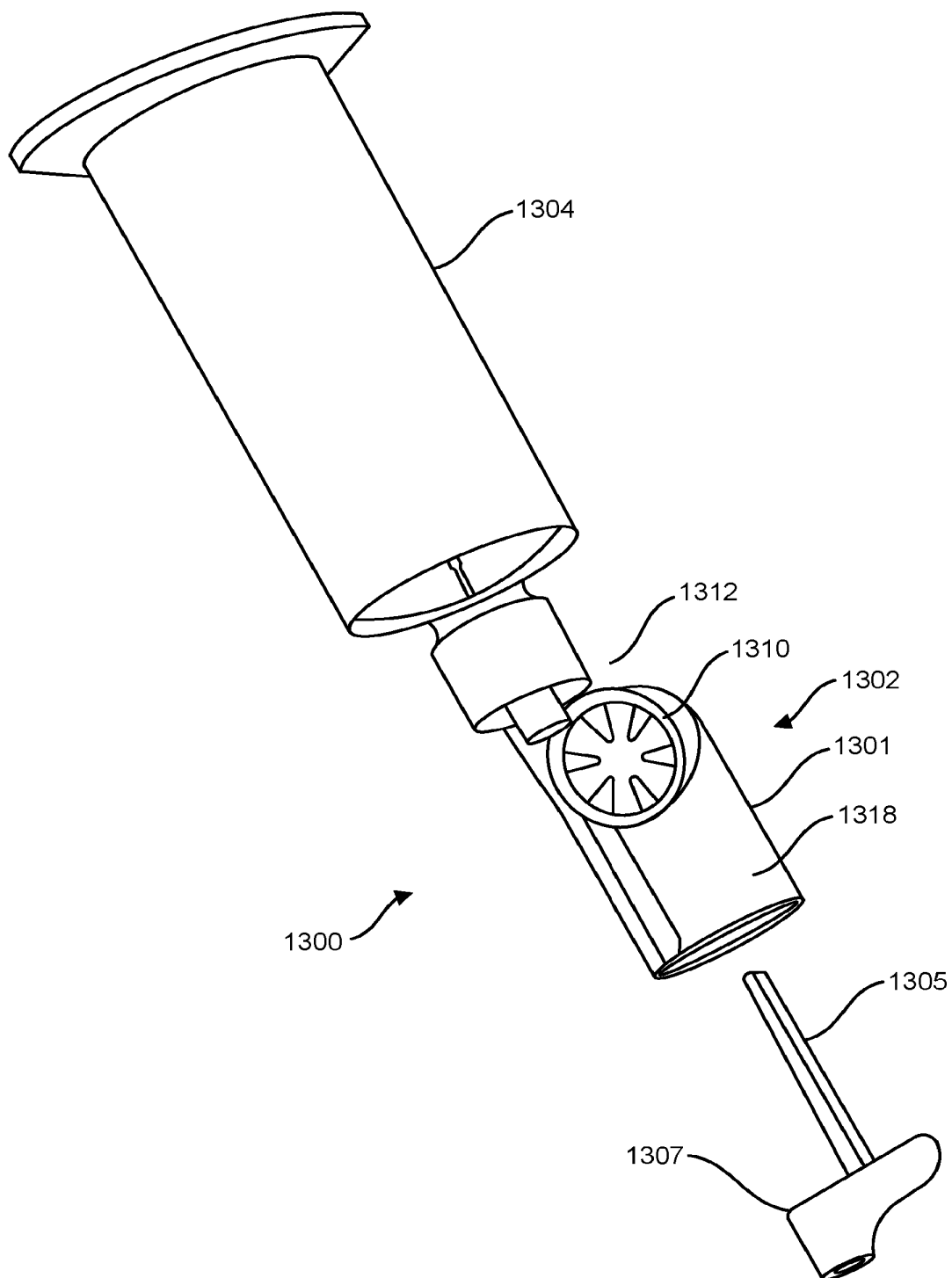
Replacement Sheet
24/69PCT/US2017/068569
PCT/US2017/068569

FIG. 13A

WO 2018/125929

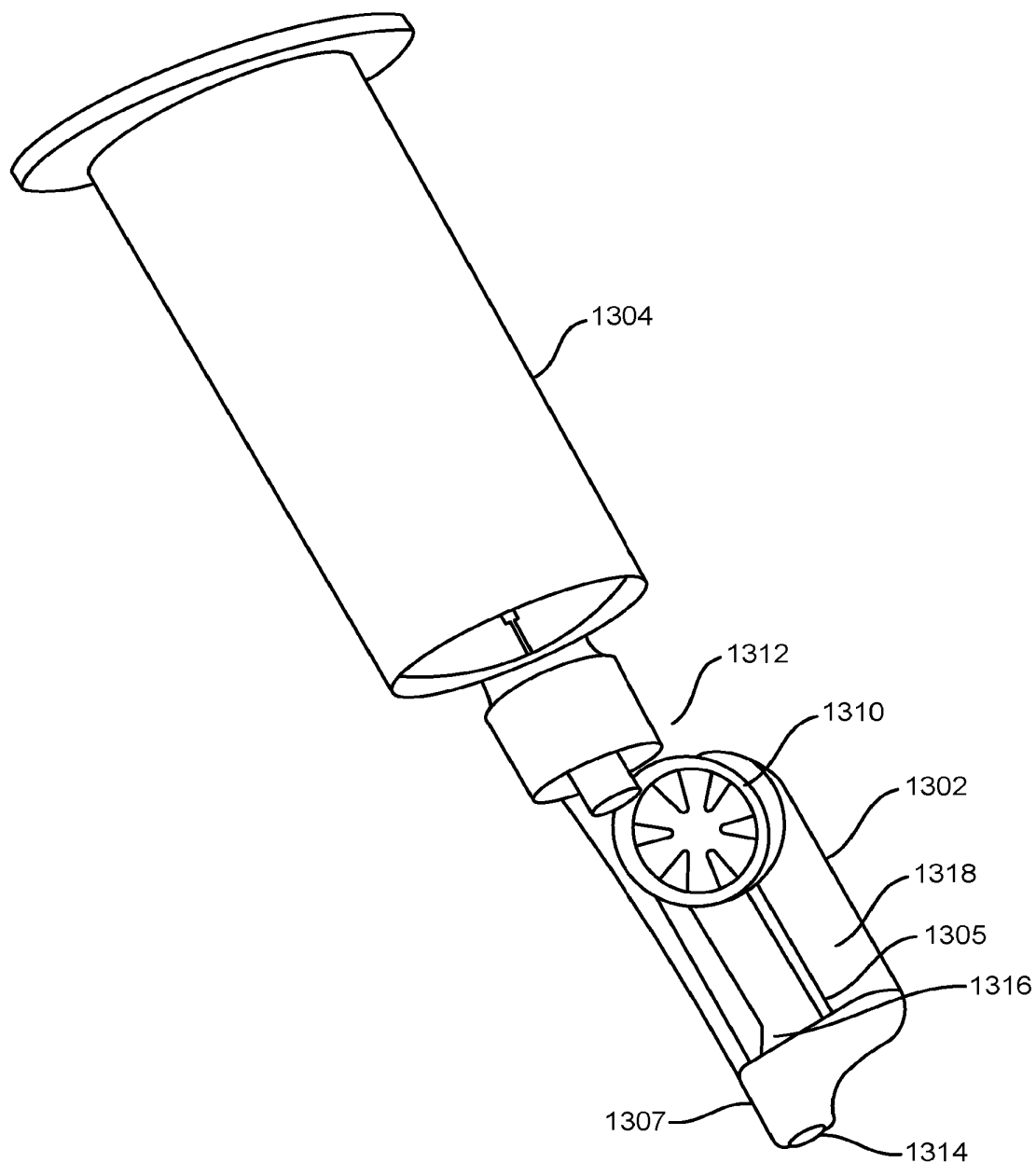
Replacement Sheet
25/69PCT/US2017/068569
PCT/US2017/068569

FIG. 13B

WO 2018/125929

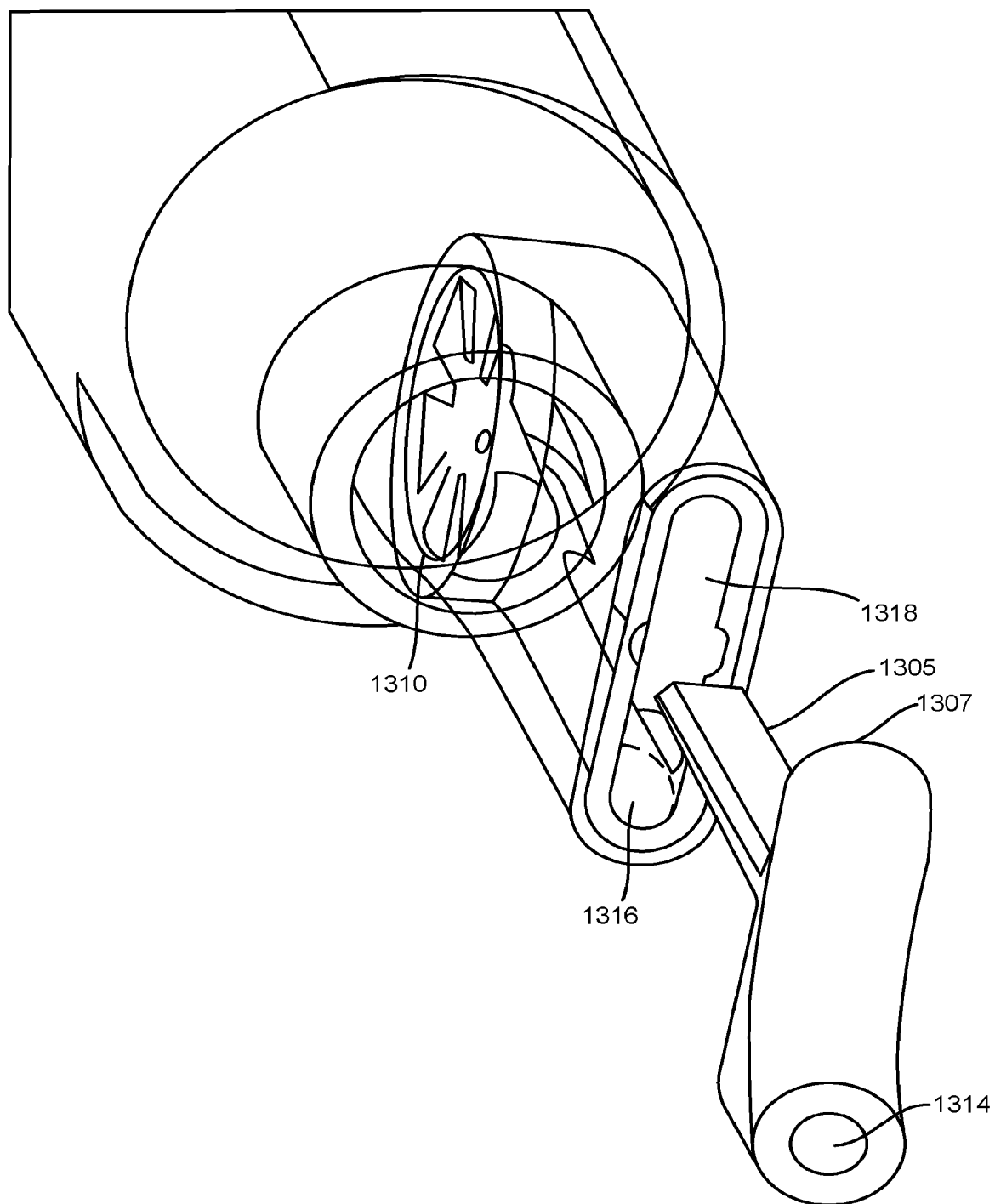
Replacement Sheet
26/69PCT/US2017/068569
PCT/US2017/068569

FIG. 13C

WO 2018/125929

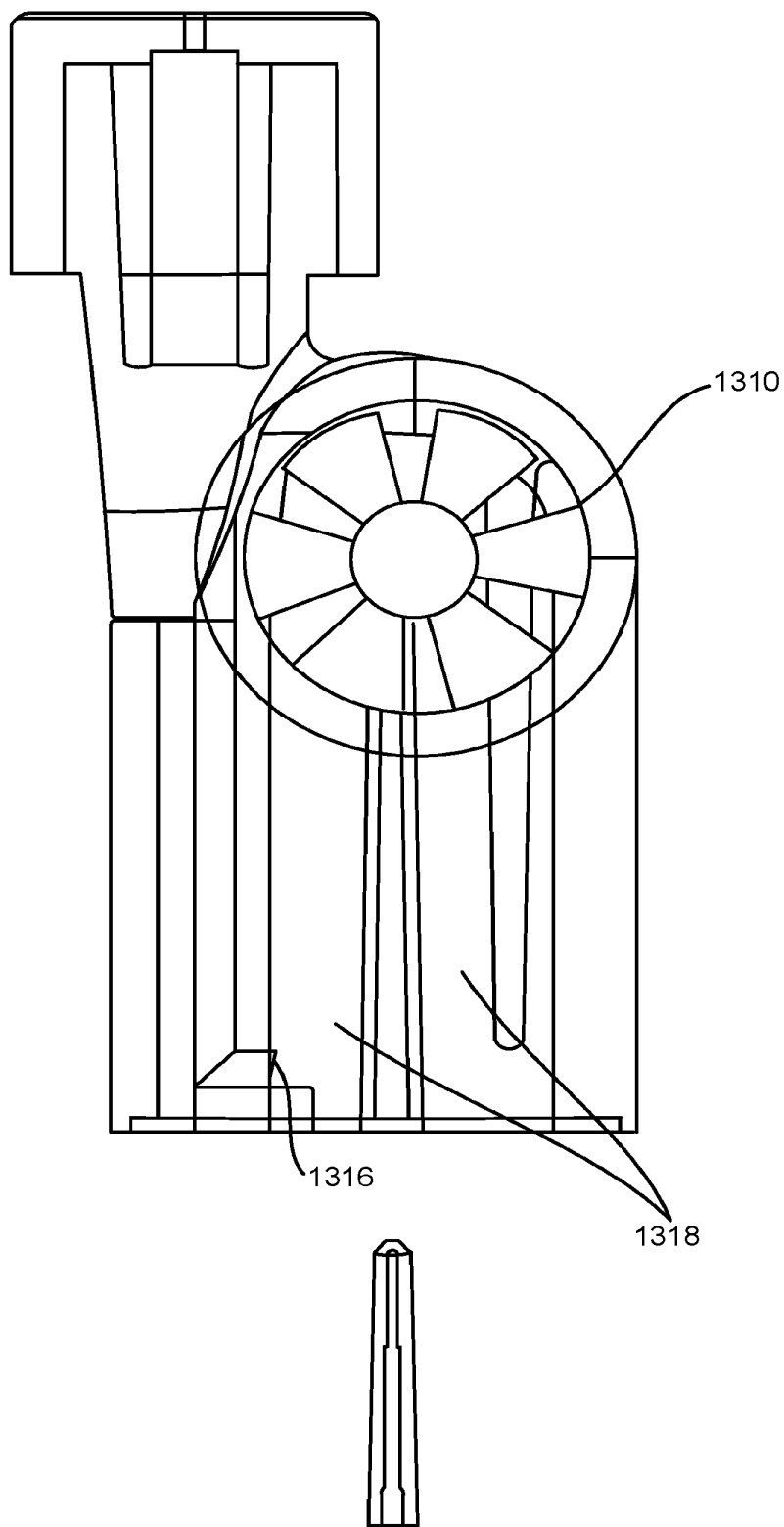
Replacement Sheet
27/69PCT/US2017/068569
PCT/US2017/068569

FIG. 13D

WO 2018/125929

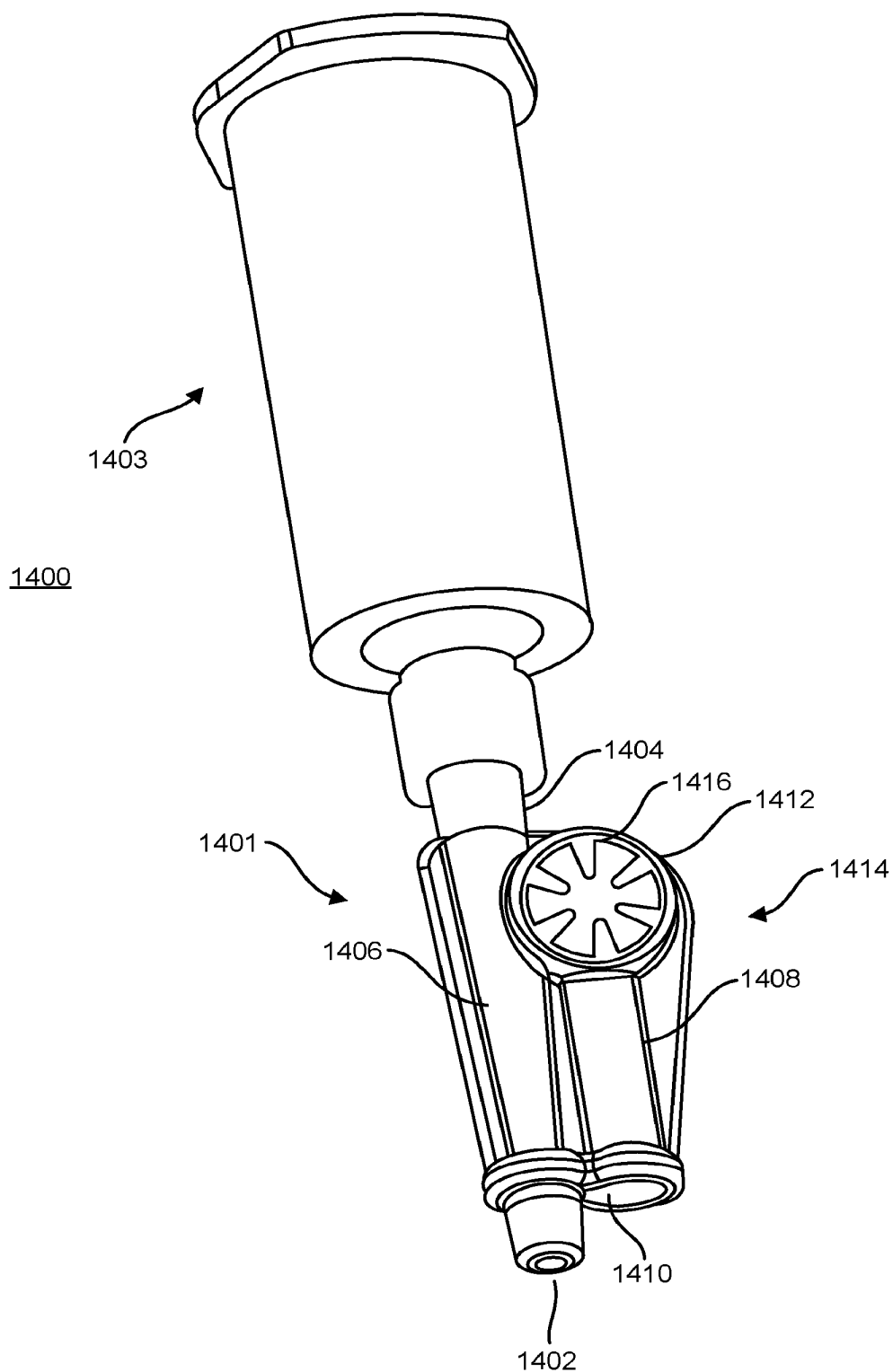
Replacement Sheet
28/69PCT/US2017/068569
PCT/US2017/068569

FIG. 14A

WO 2018/125929

Replacement Sheet
29/69

PCT/US2017/068569
PCT/US2017/068569

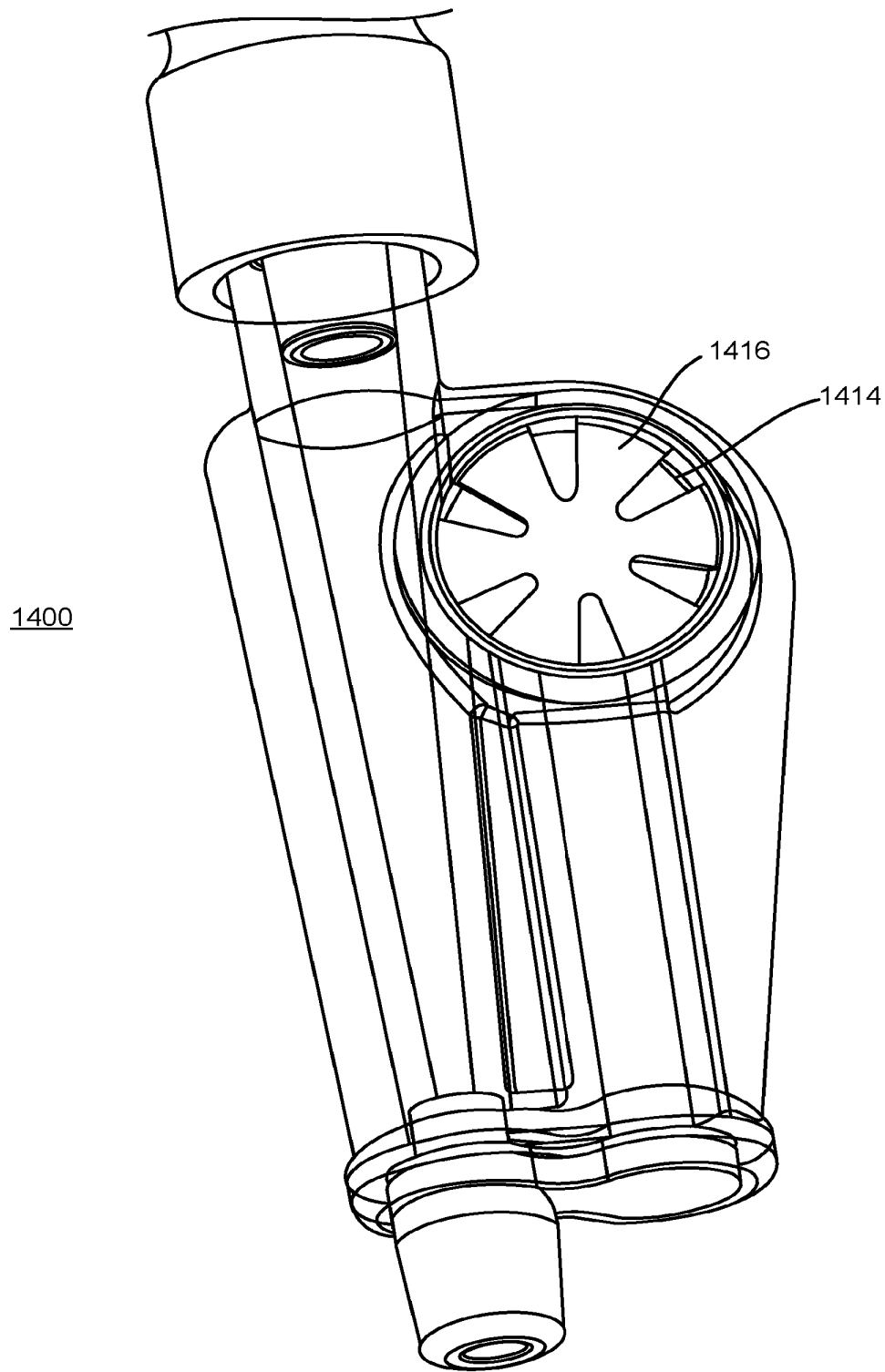


FIG. 14B

WO 2018/125929

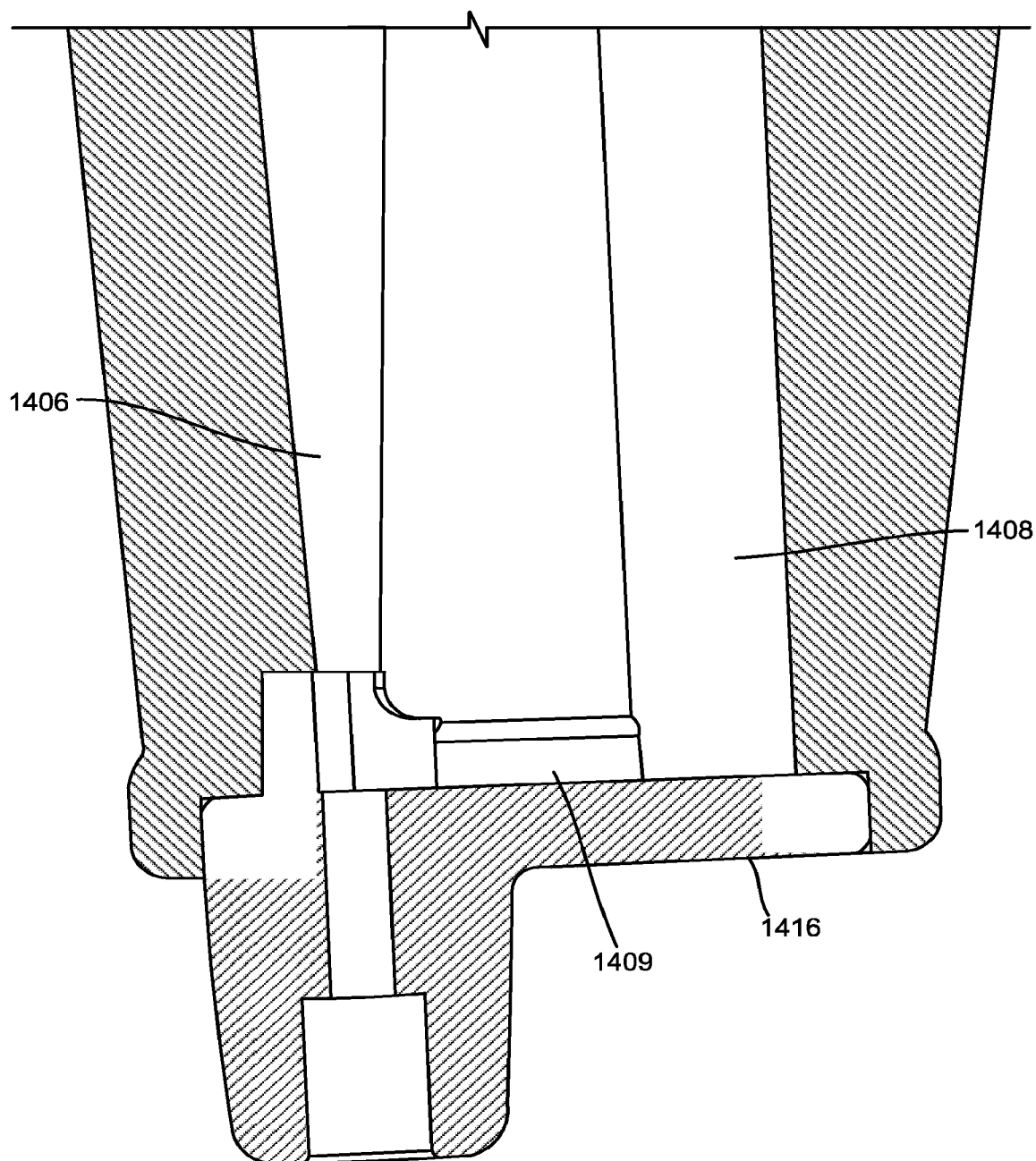
Replacement Sheet
30/69PCT/US2017/068569
PCT/US2017/068569

FIG. 14C

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Replacement Sheet
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PCT/US2017/068569

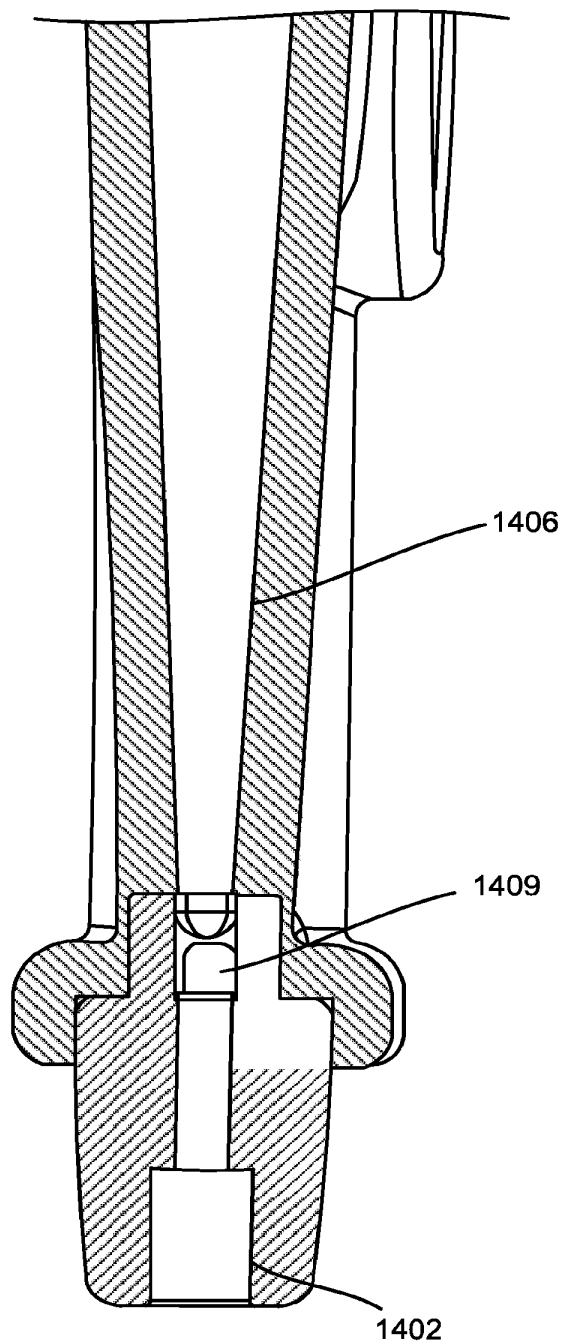


FIG. 14D

WO 2018/125929

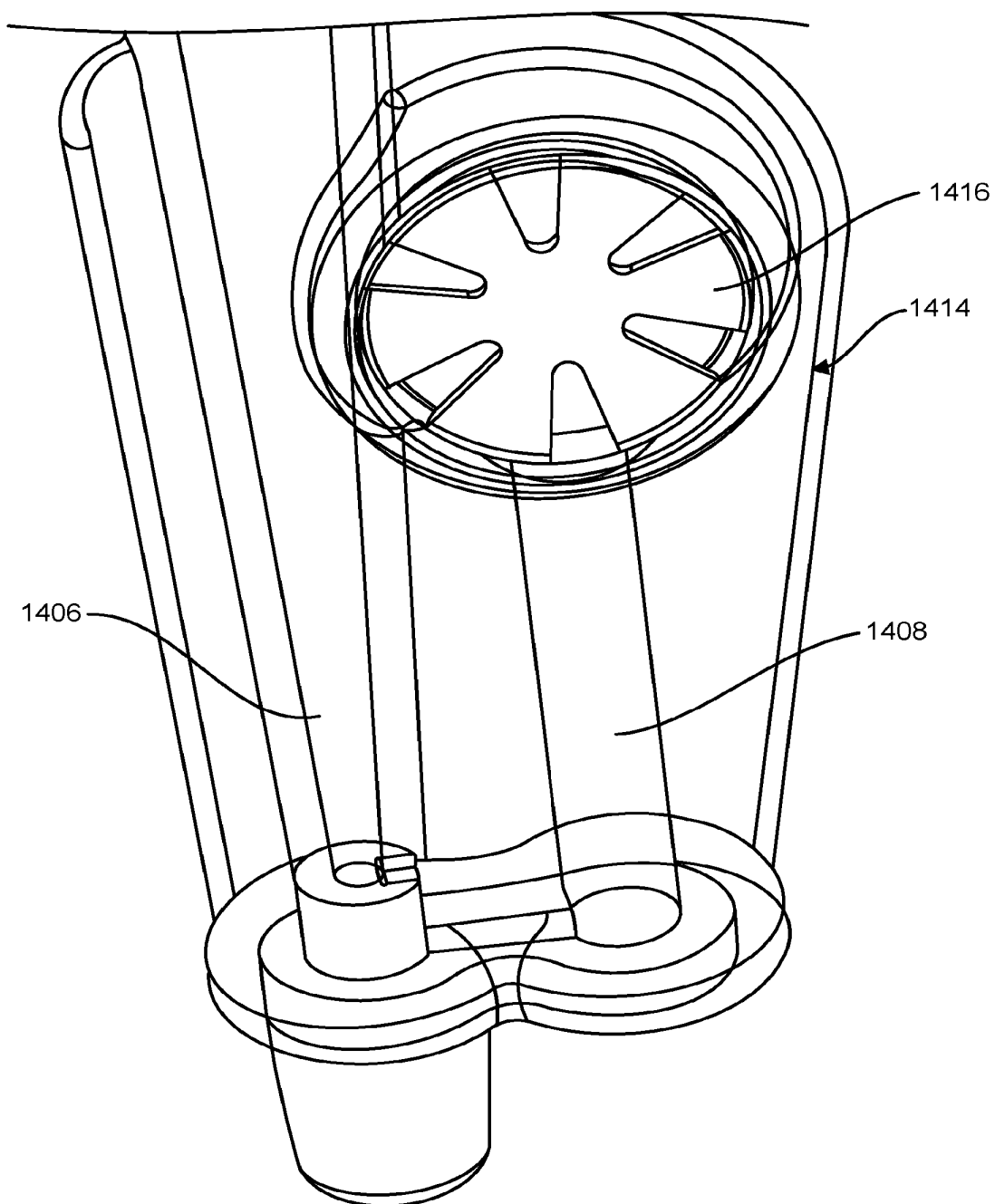
Replacement Sheet
32/69PCT/US2017/068569
PCT/US2017/068569

FIG. 14E

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PCT/US2017/068569

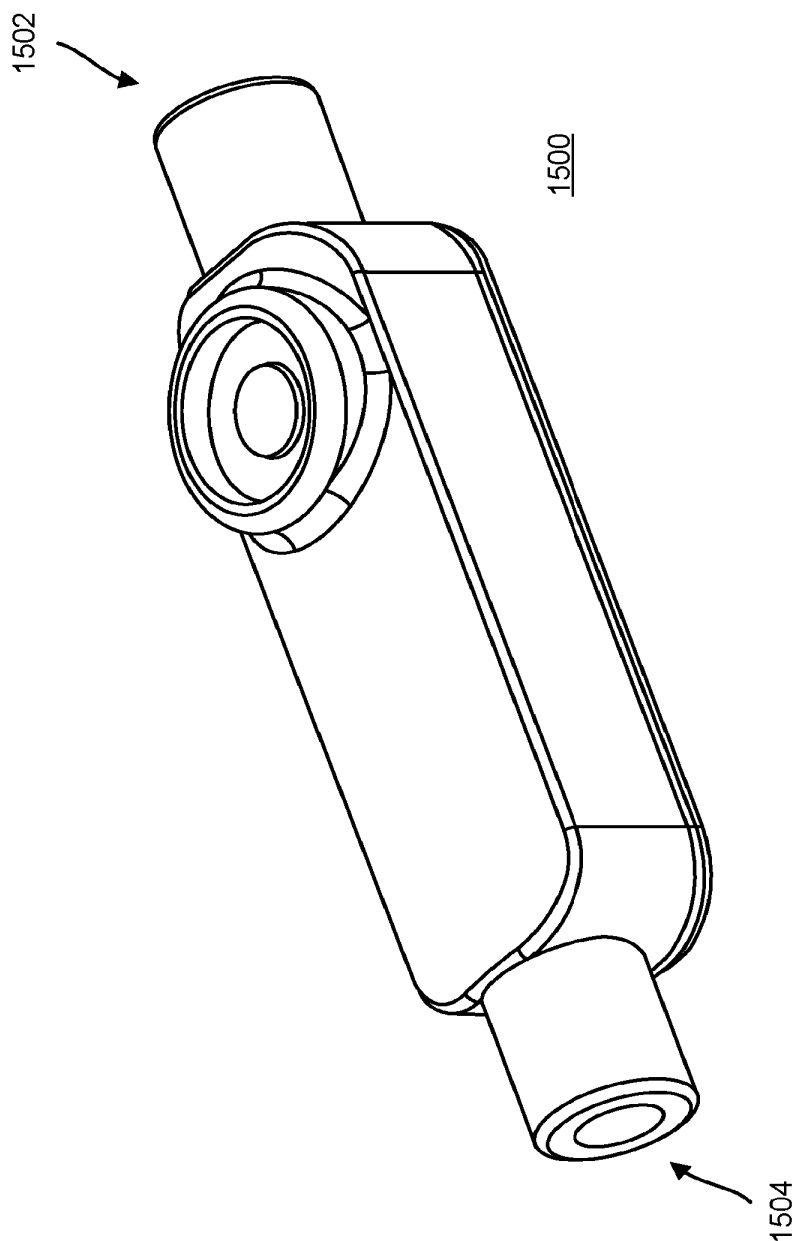


FIG. 15A

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PCT/US2017/068569
PCT/US2017/068569

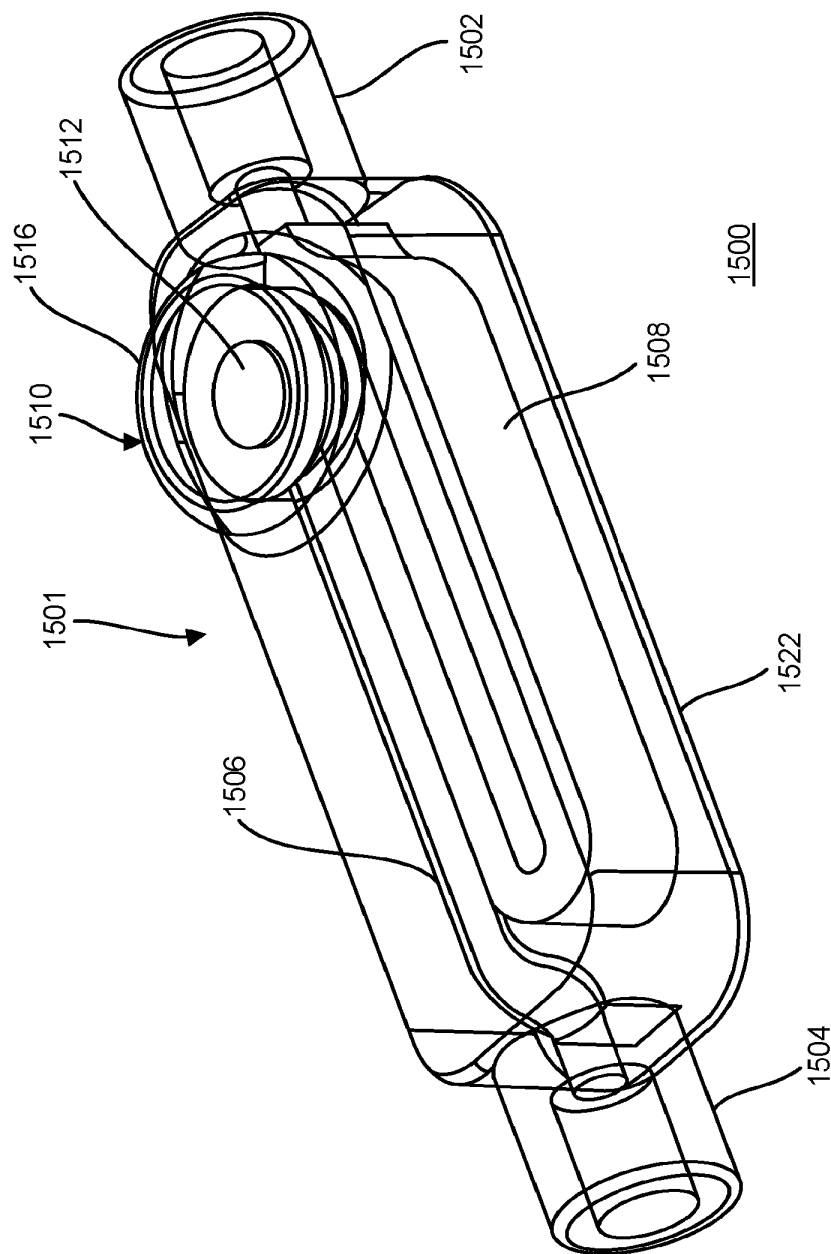


FIG. 15B

WO 2018/125929

Replacement Sheet
35/69

PCT/US2017/068569
PCT/US2017/068569

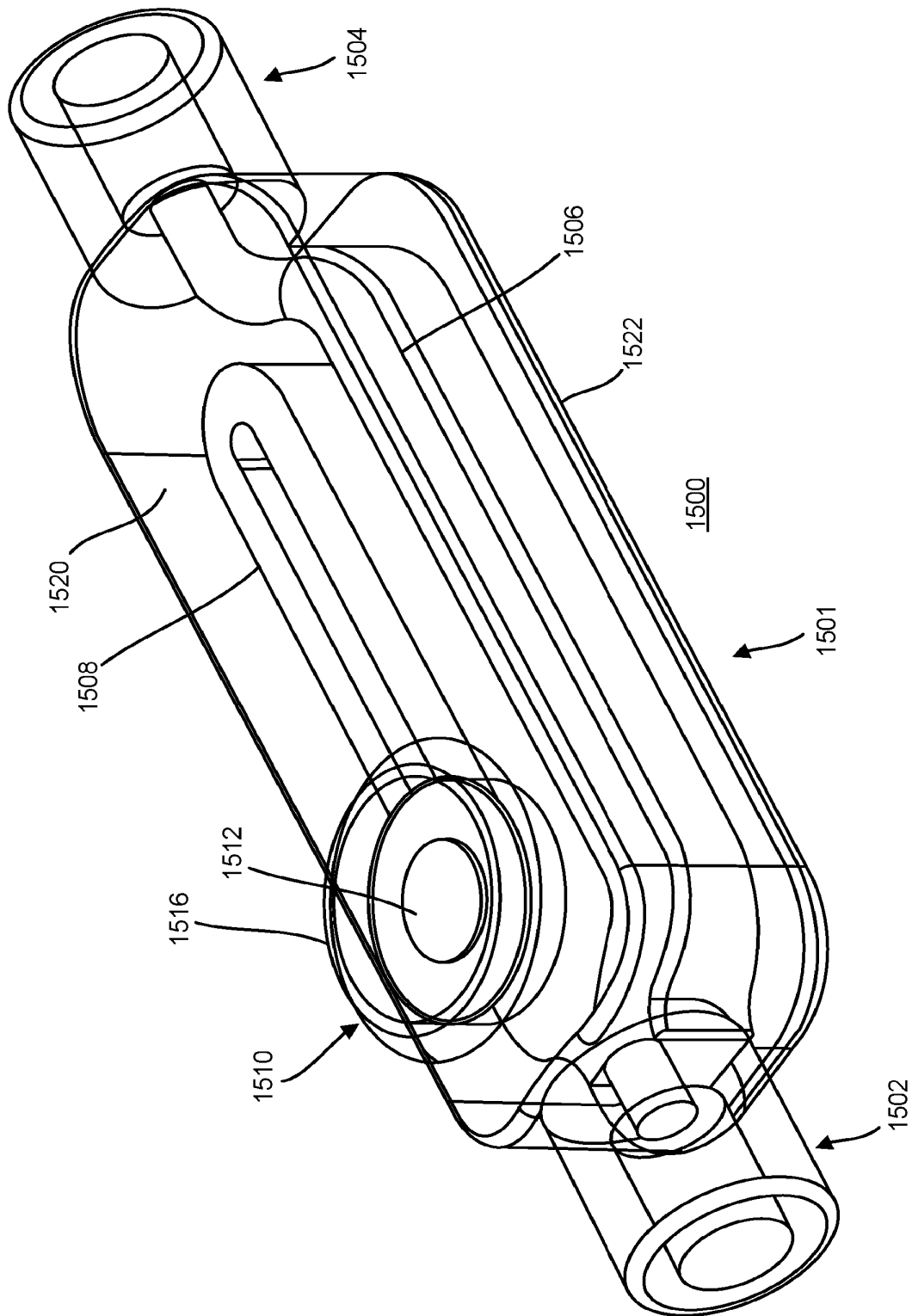


FIG. 15C

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PCT/US2017/068569
PCT/US2017/068569

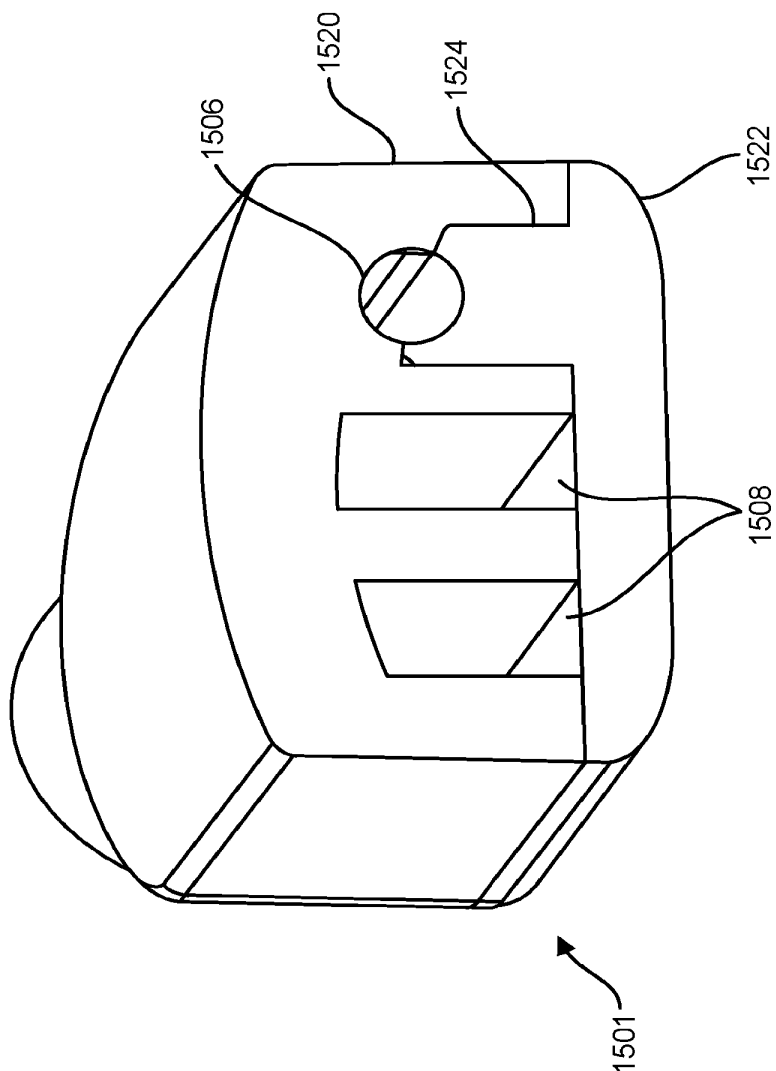


FIG. 15D

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PCT/US2017/068569

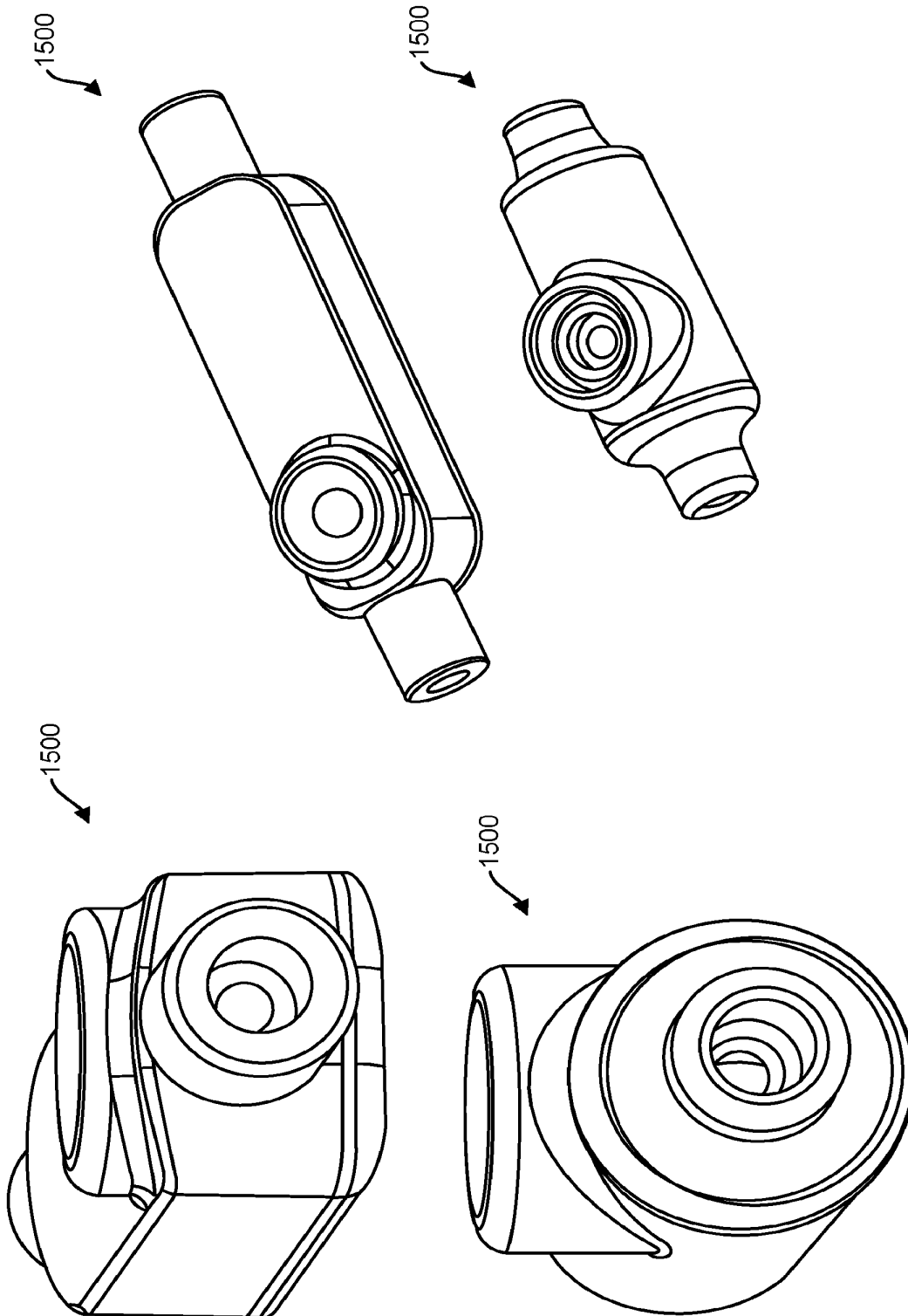


FIG. 15F

FIG. 15E

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PCT/US2017/068569

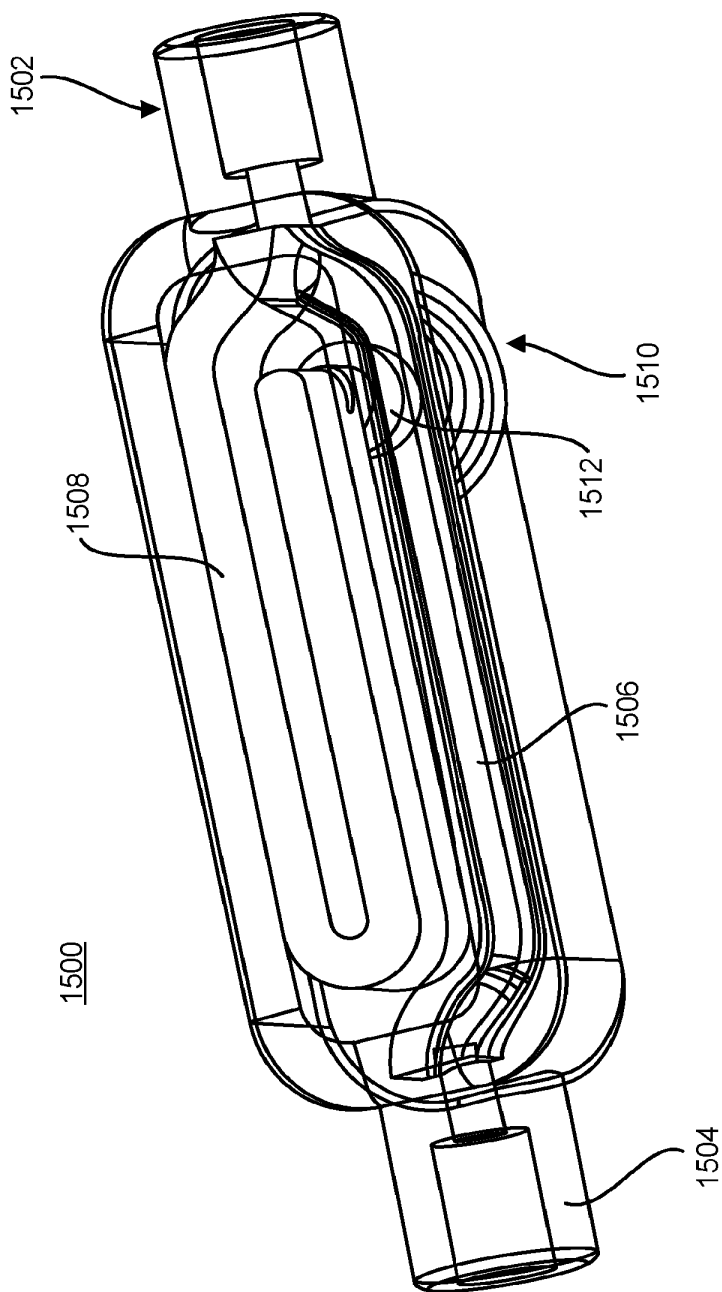


FIG. 15G

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PCT/US2017/068569
PCT/US2017/068569

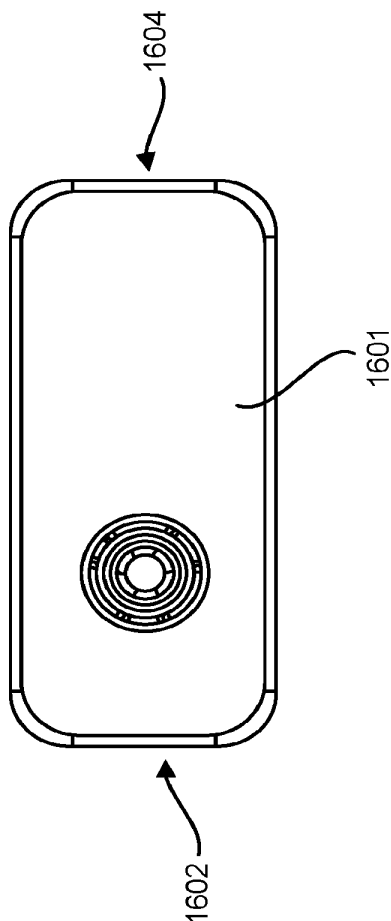


FIG. 16A

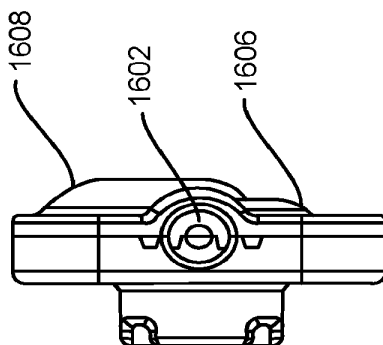


FIG. 16C

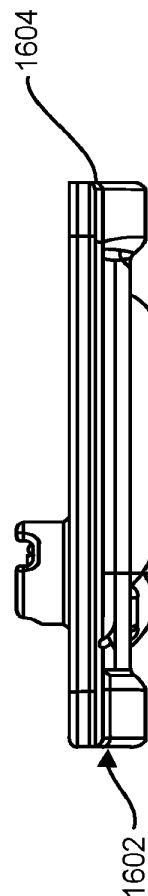


FIG. 16B

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PCT/US2017/068569
PCT/US2017/068569

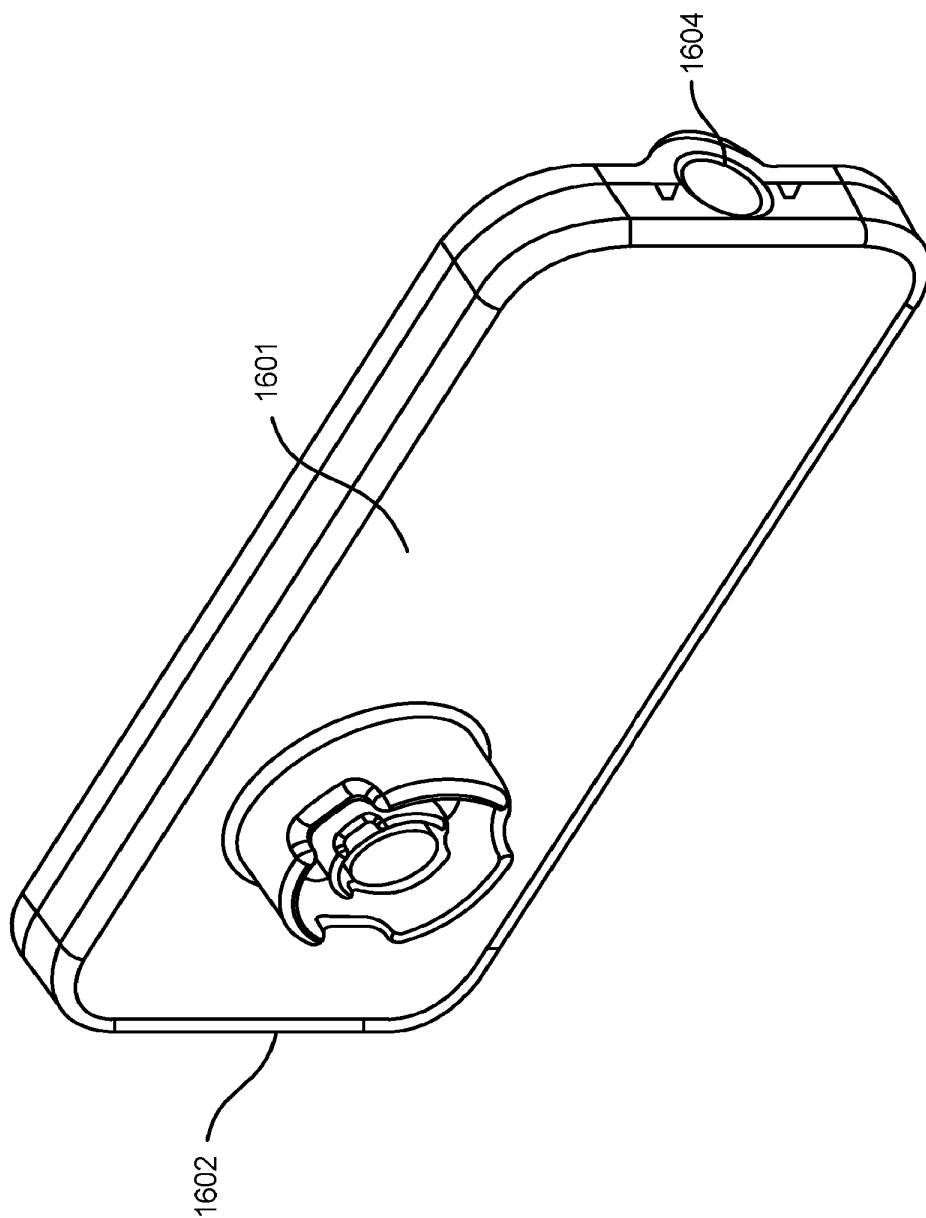


FIG. 16D

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REPLACEMENT SHEET
PCT/US2017/068569
PCT/US2017/068569

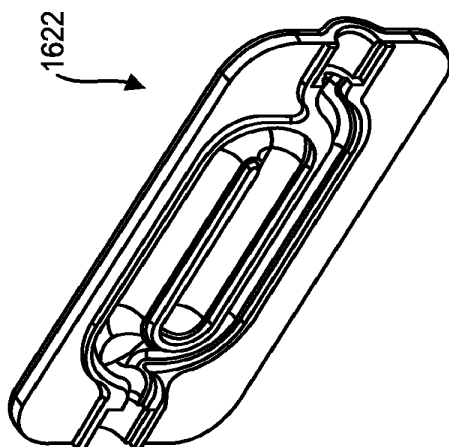


FIG. 17B

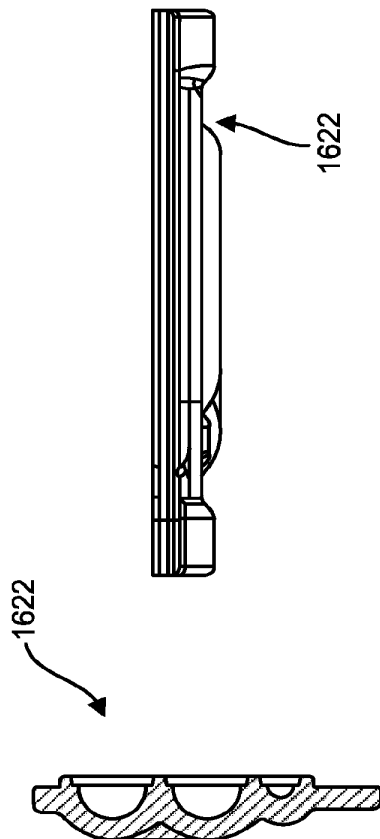


FIG. 17E

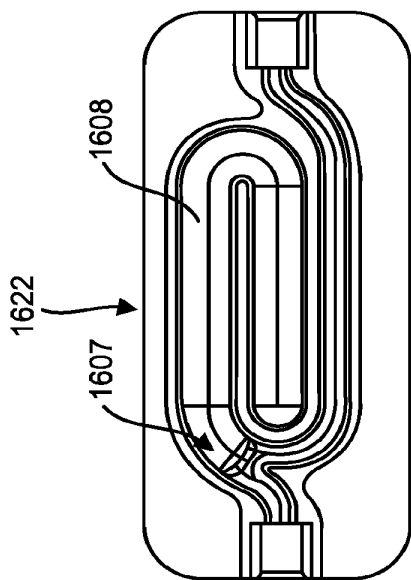


FIG. 17A

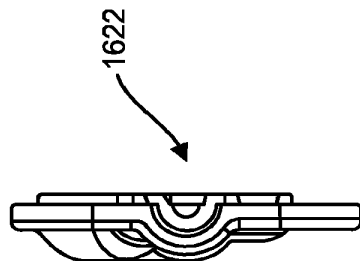


FIG. 17D

FIG. 17C

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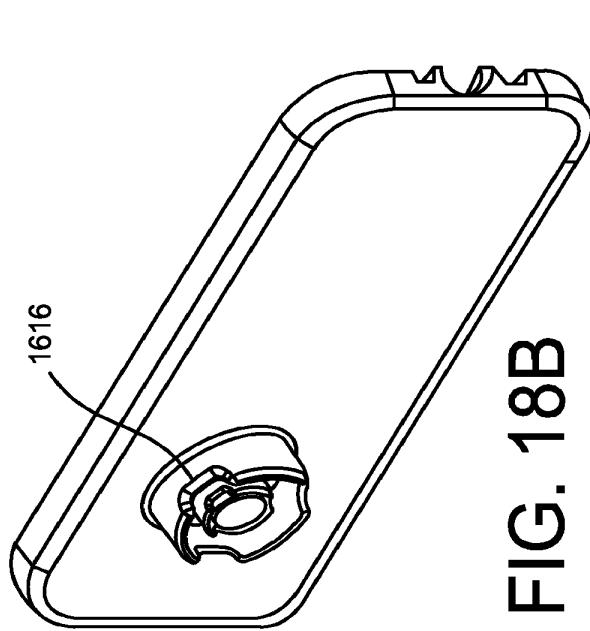
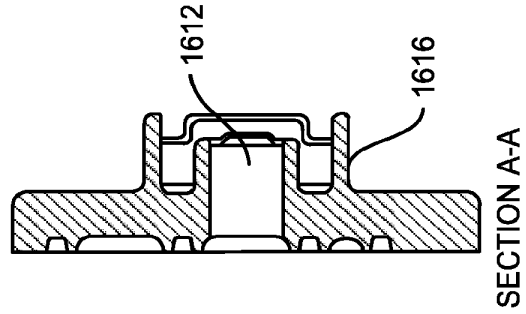


FIG. 18B



SECTION A-A

FIG. 18F

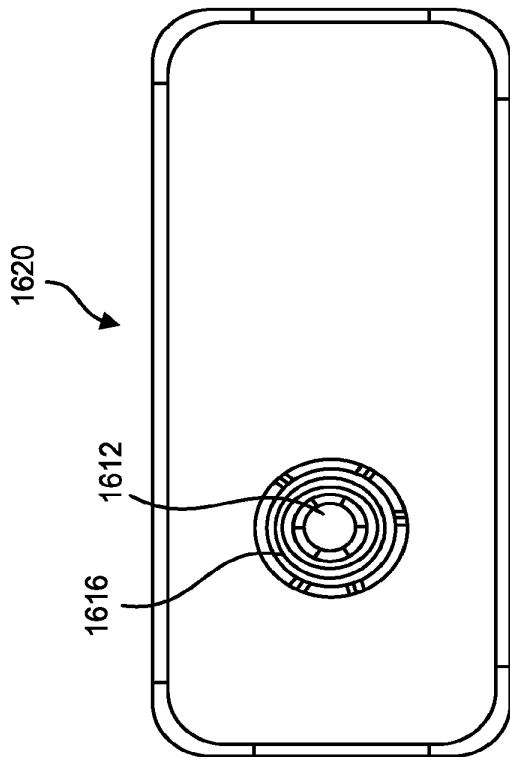
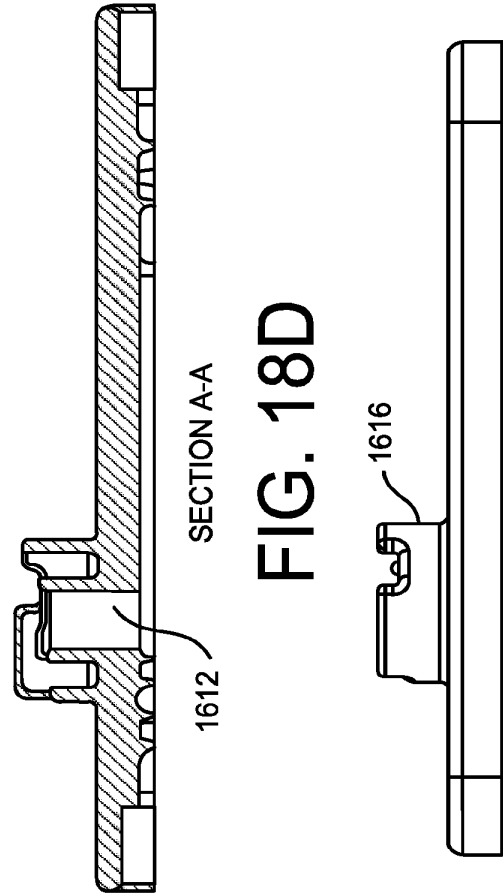


FIG. 18A



SECTION A-A

FIG. 18D

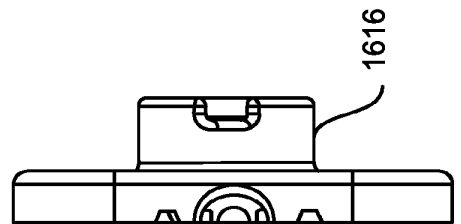


FIG. 18C

FIG. 18E

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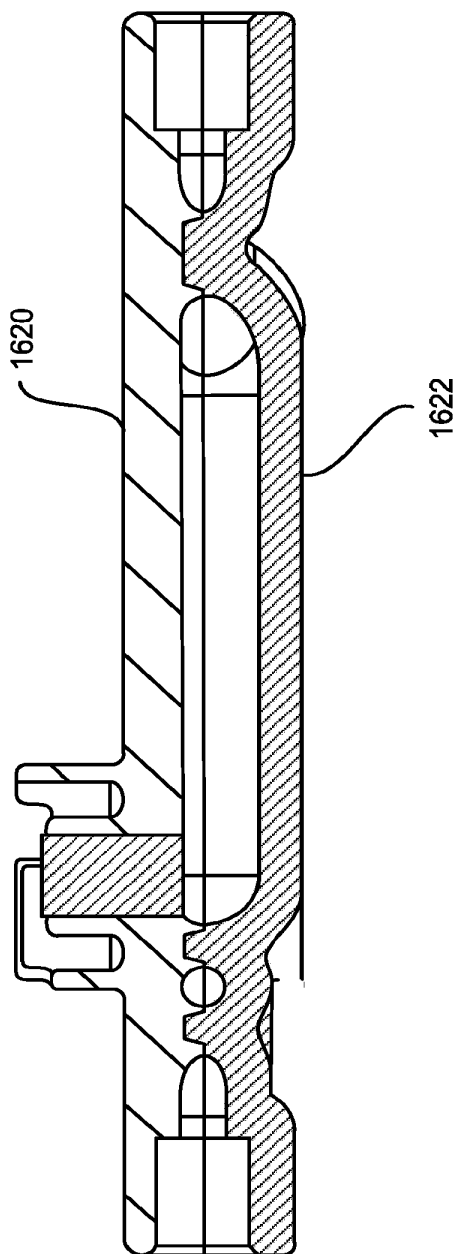


FIG. 19A

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PCT/US2017/068569

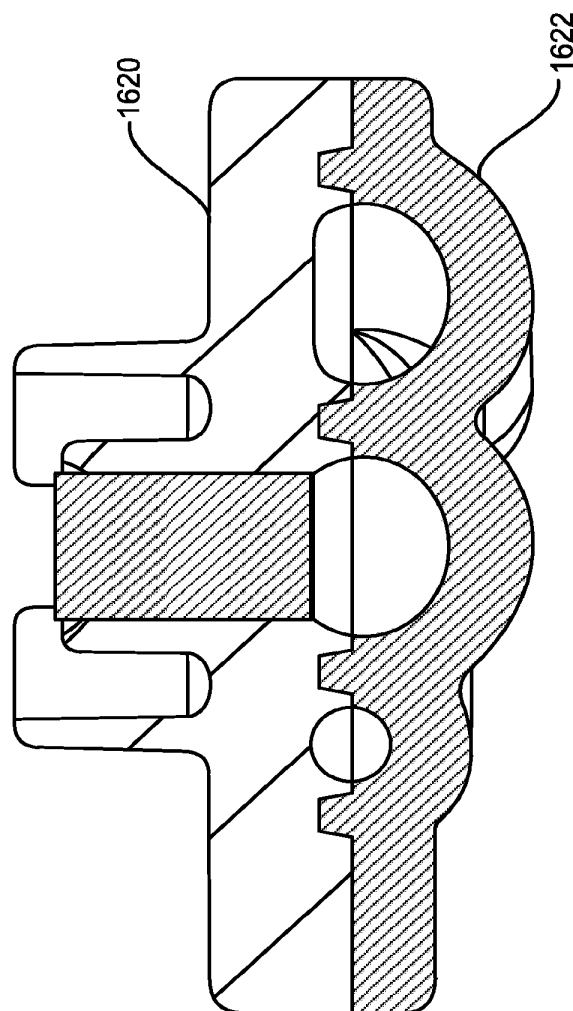


FIG. 19B

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PCT/US2017/068569

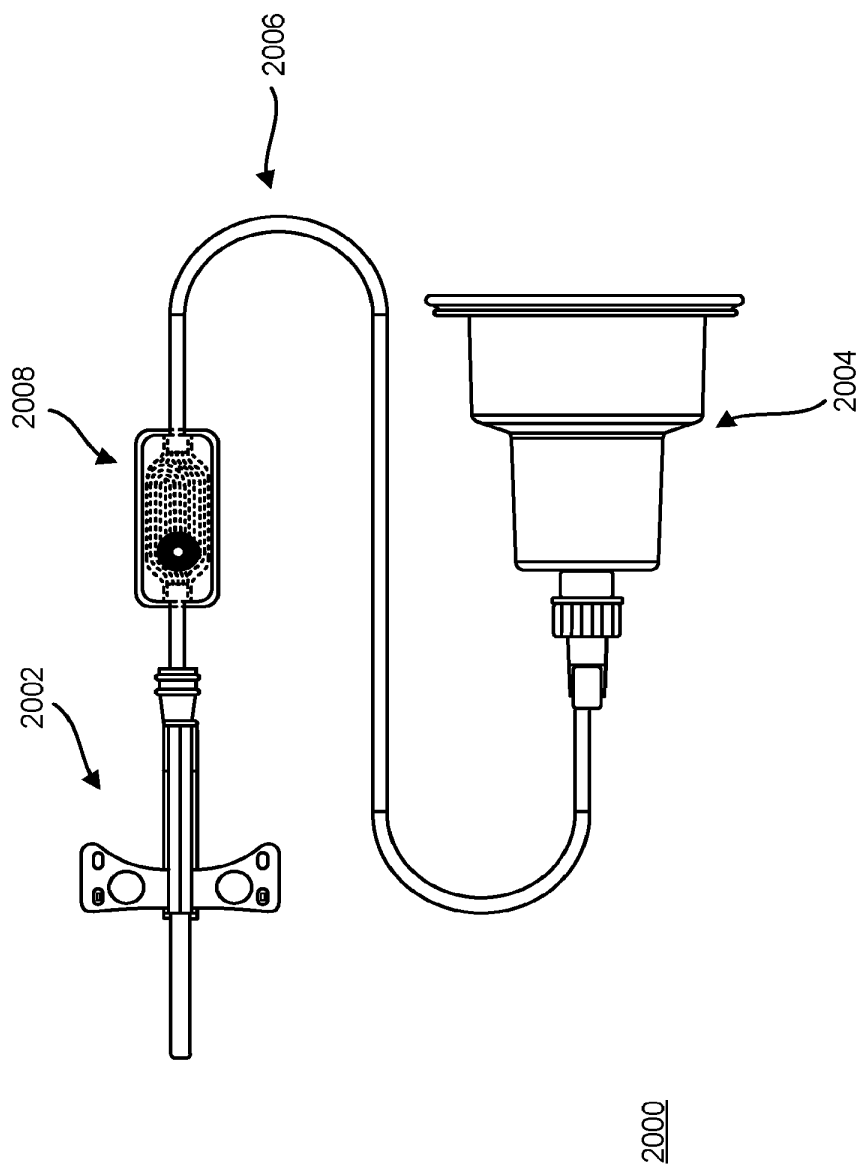


FIG. 20

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PCT/US2017/068569

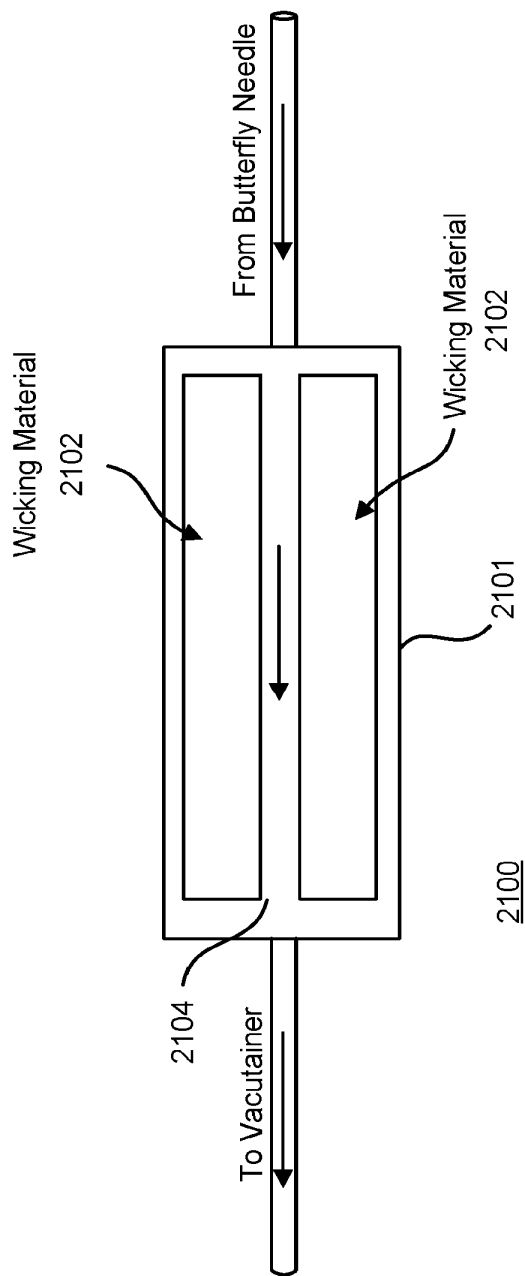


FIG. 21

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PCT/US2017/068569

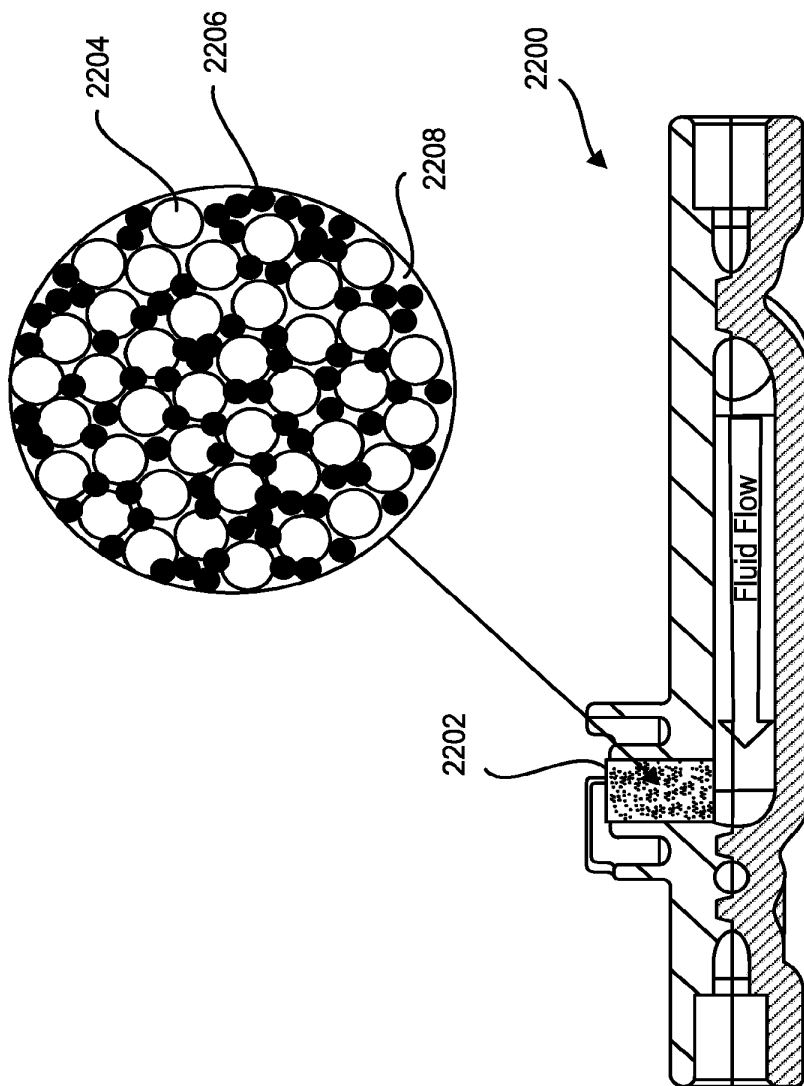


FIG. 22A

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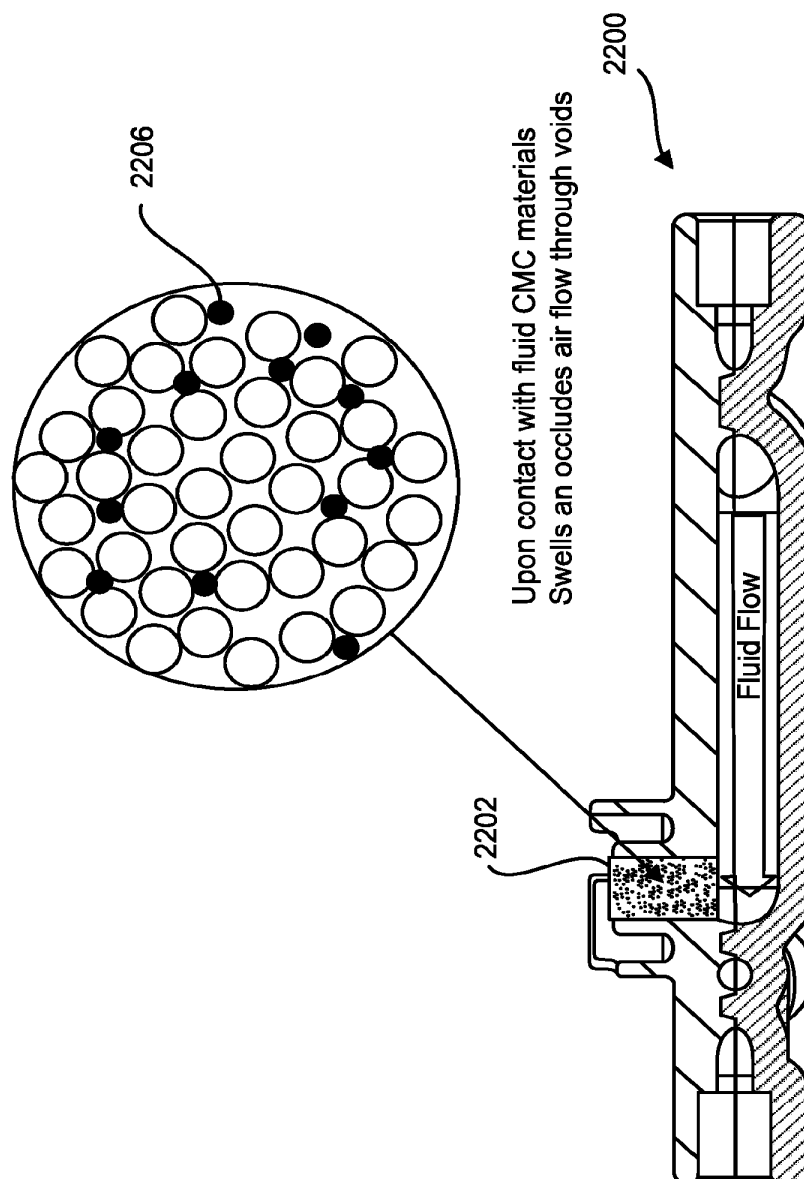
Replacement Sheet
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PCT/US2017/068569

FIG. 22B

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PCT/US2017/068569

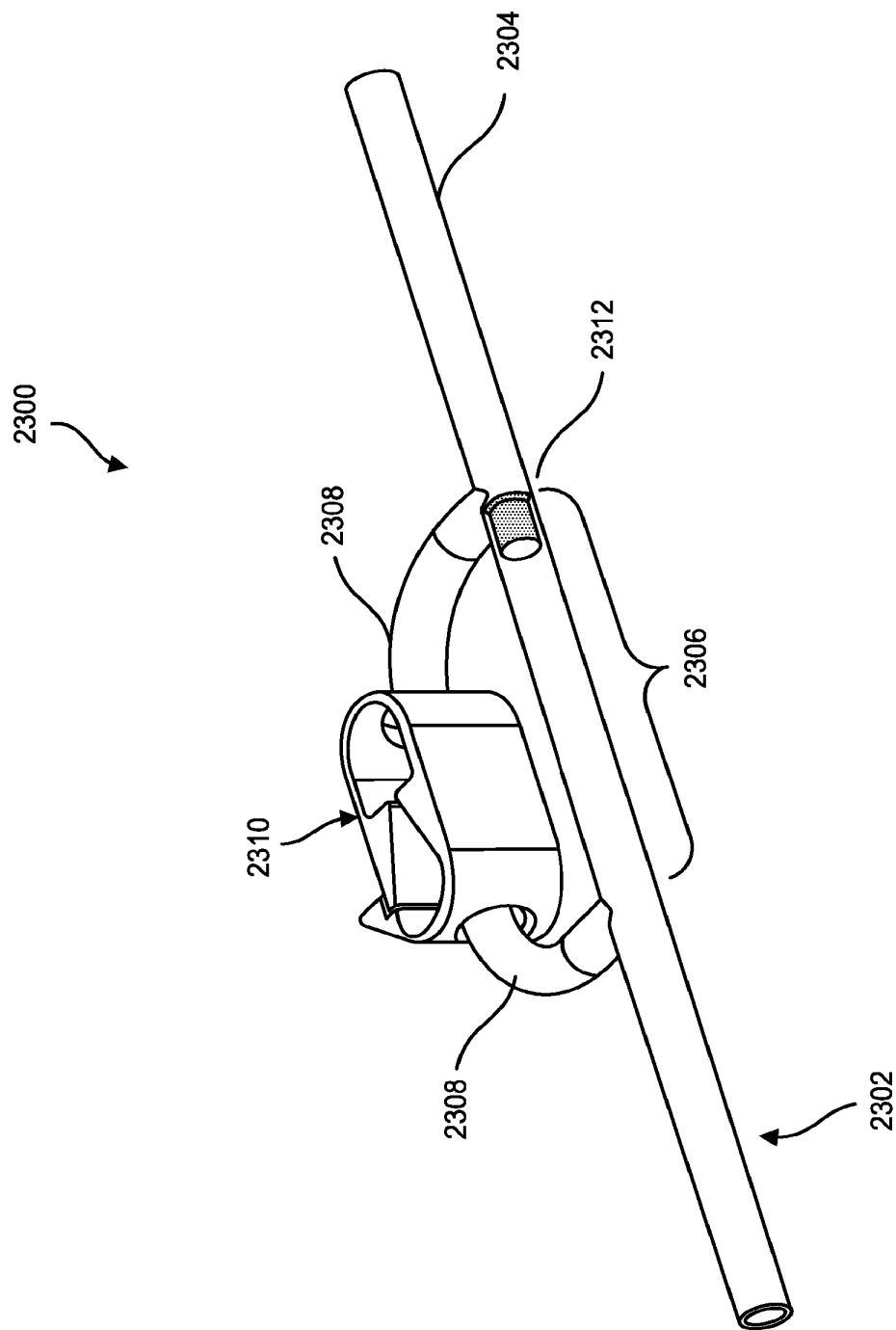


FIG. 23A

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PCT/US2017/068569

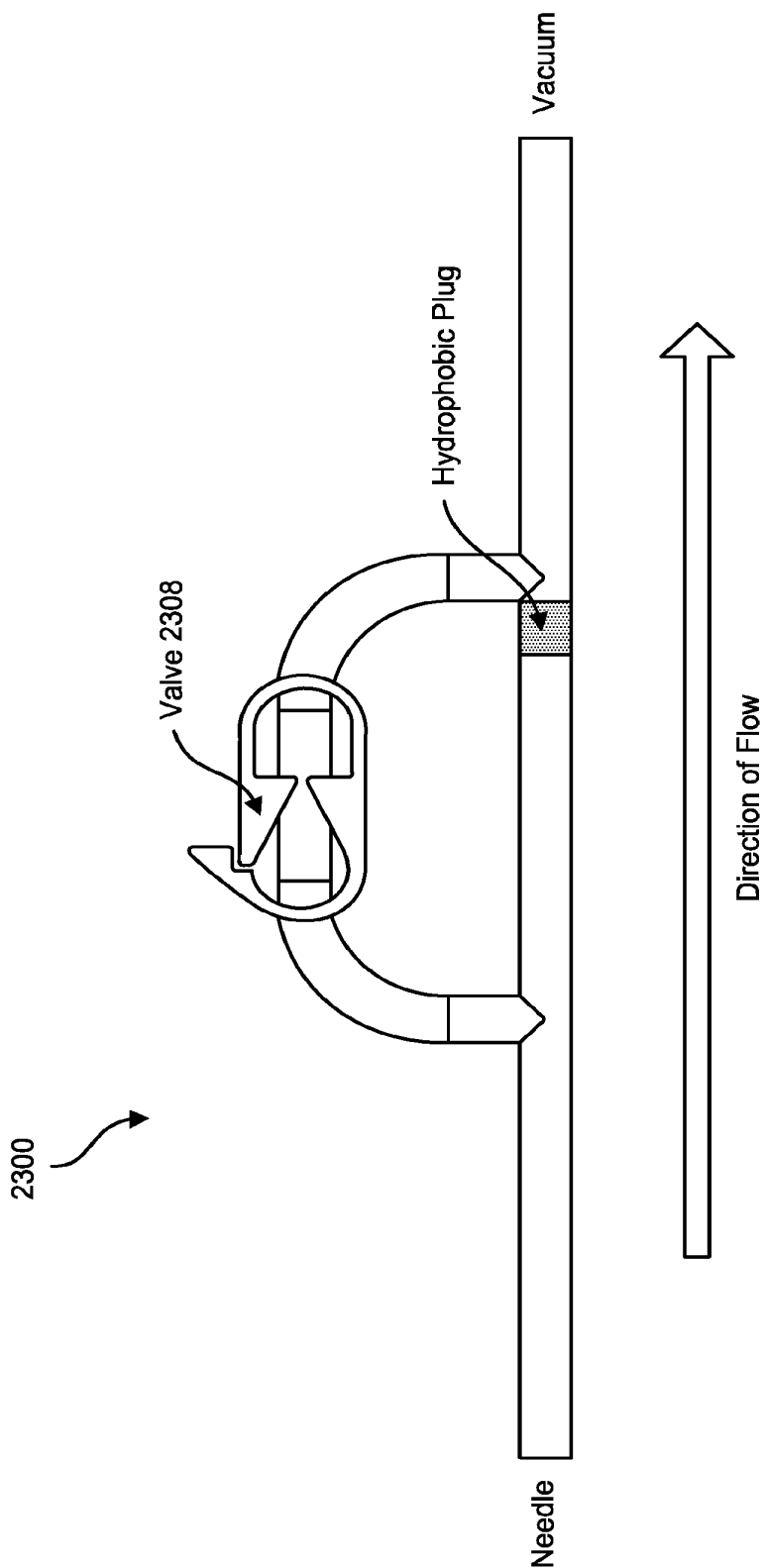


FIG. 23B

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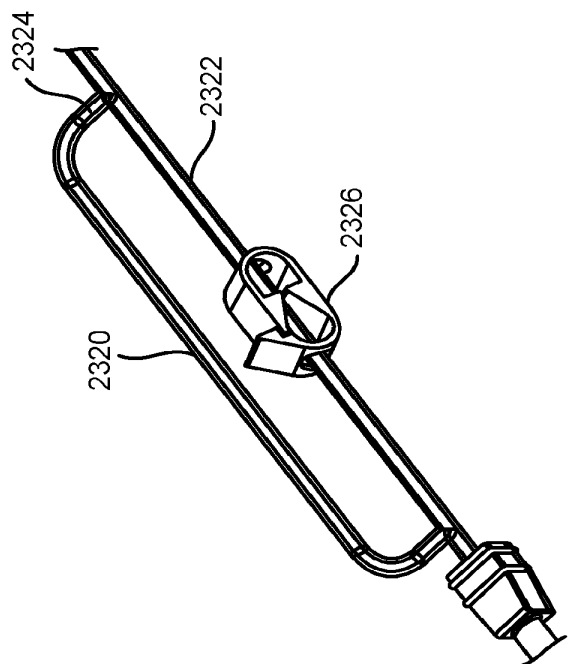


FIG. 23D

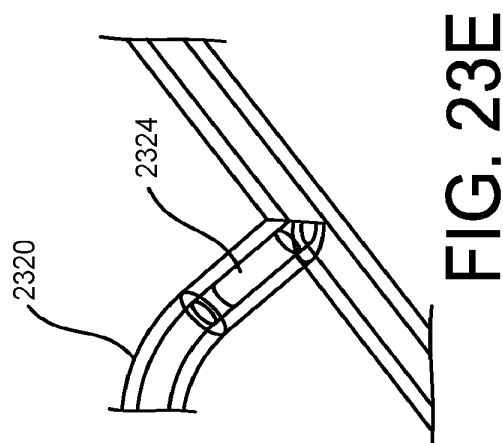


FIG. 23E

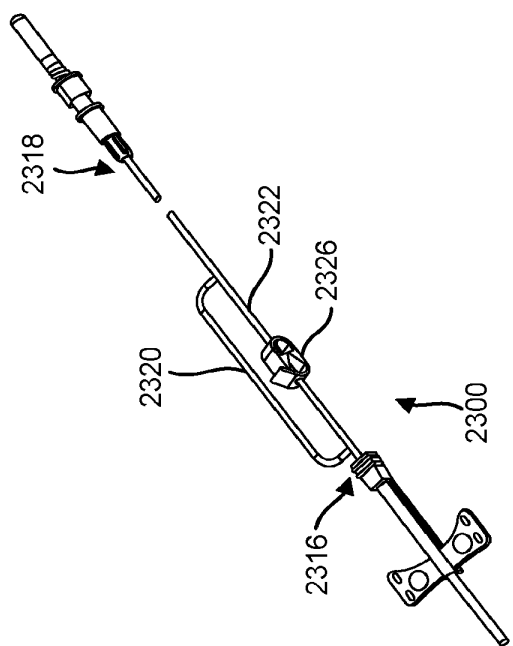


FIG. 23C

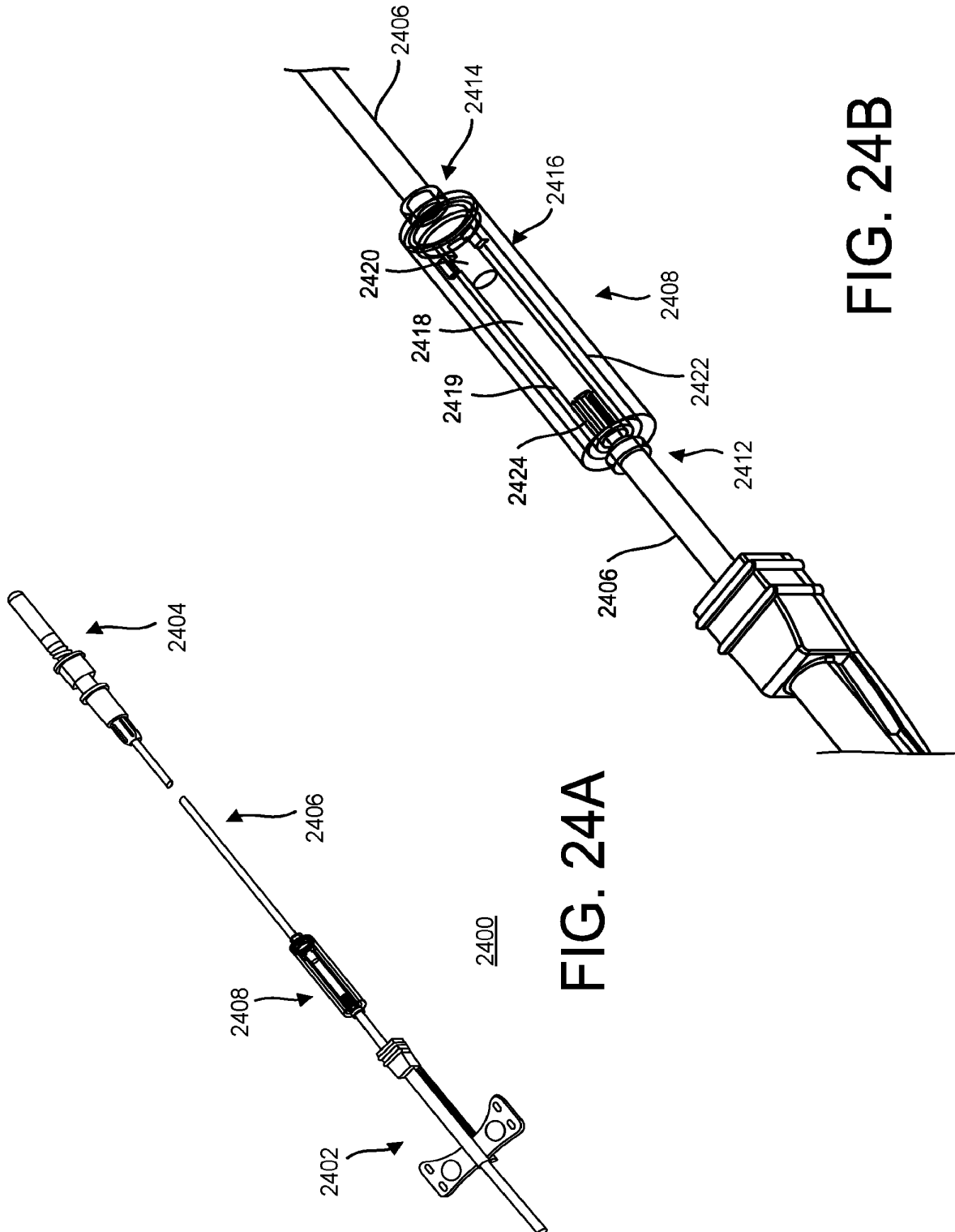
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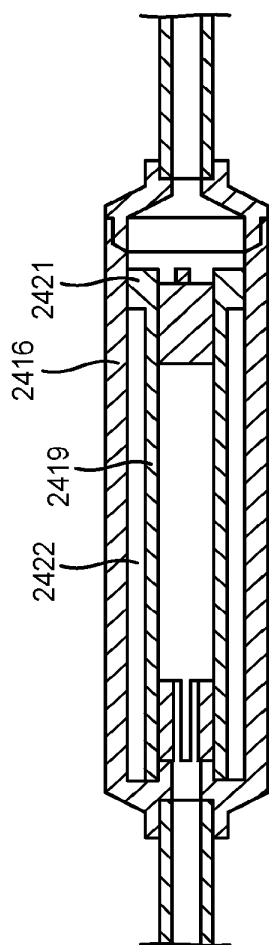


FIG. 24C

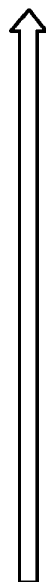
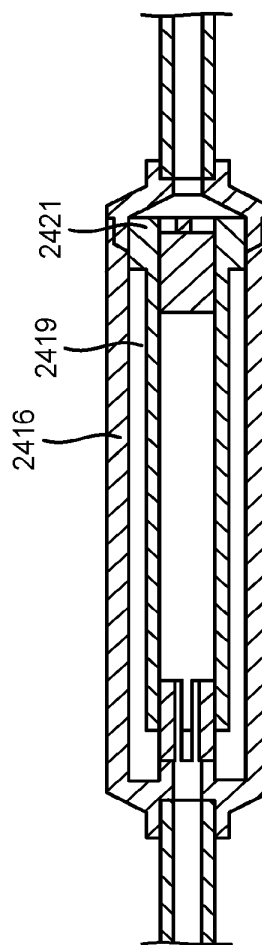
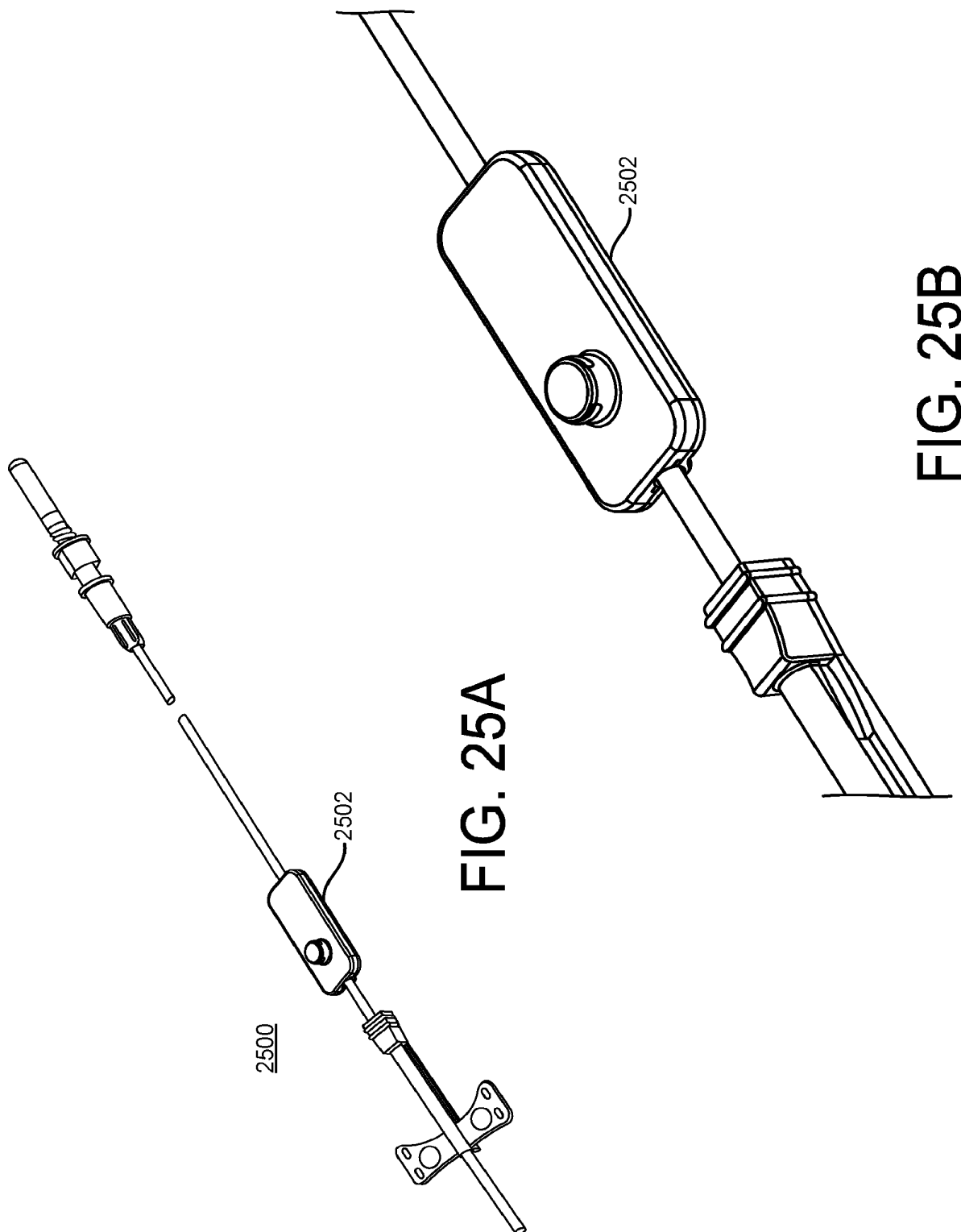


FIG. 24D

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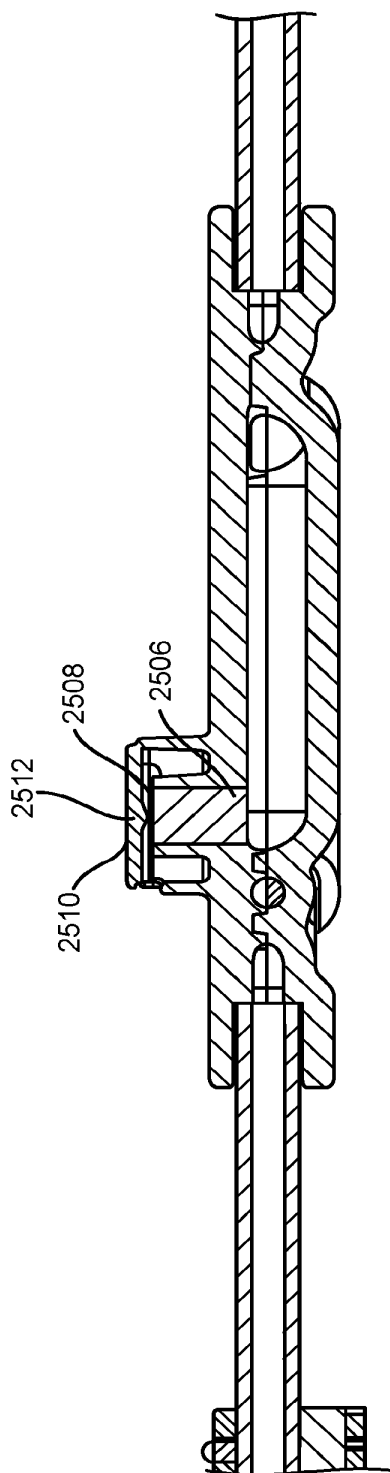
Replacement Sheet
55/69Docket No. KURIN3PCT
PCT/US2017/068569

FIG. 25C

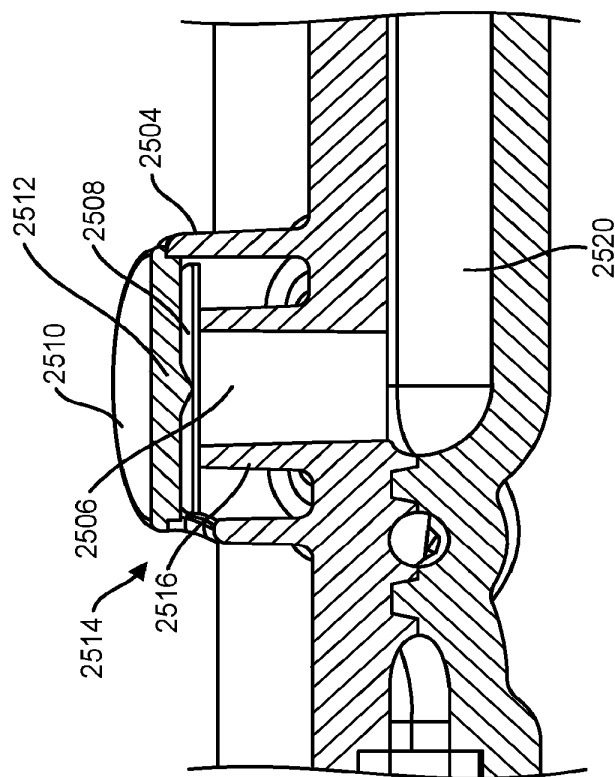


FIG. 25D

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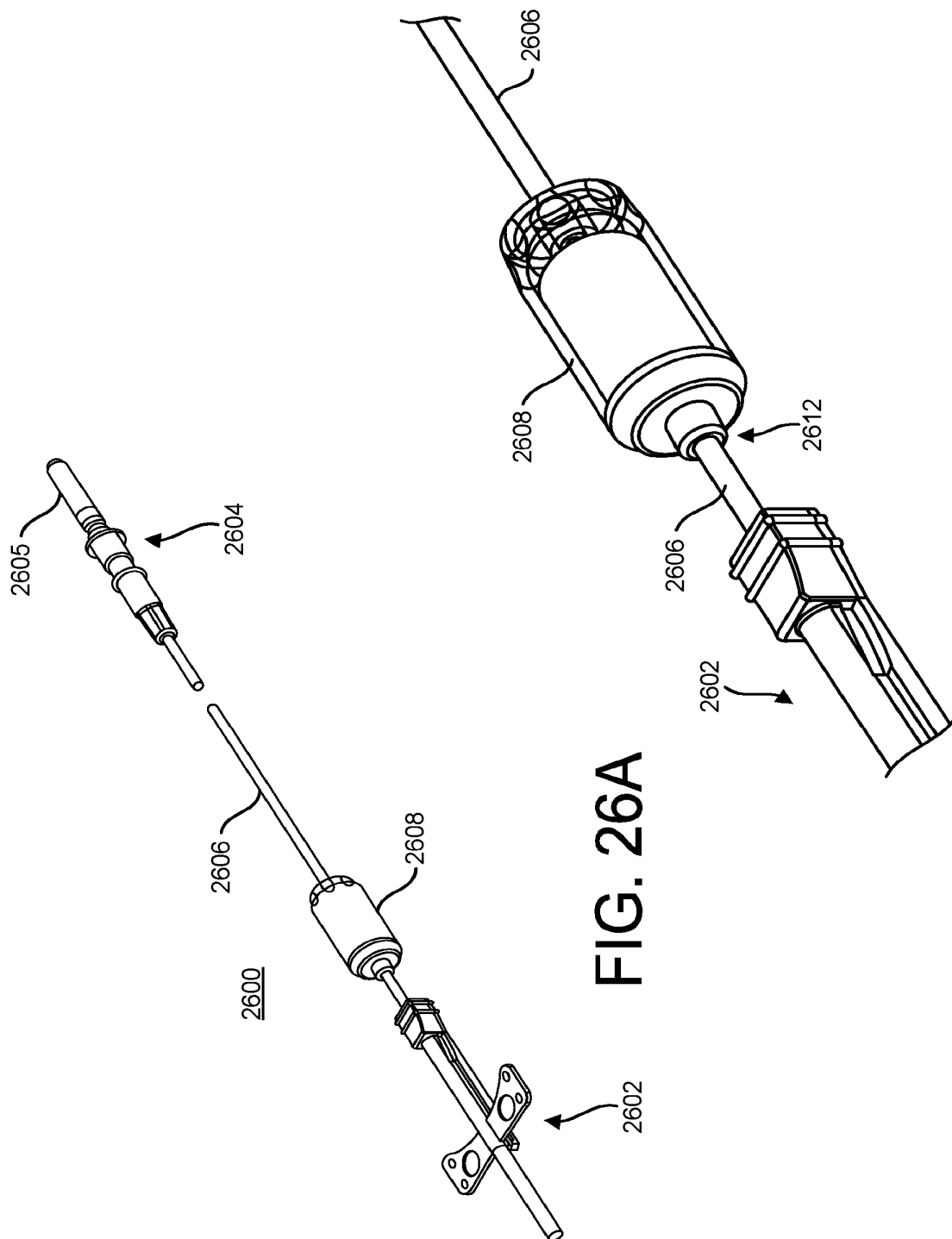
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FIG. 26B

FIG. 26A

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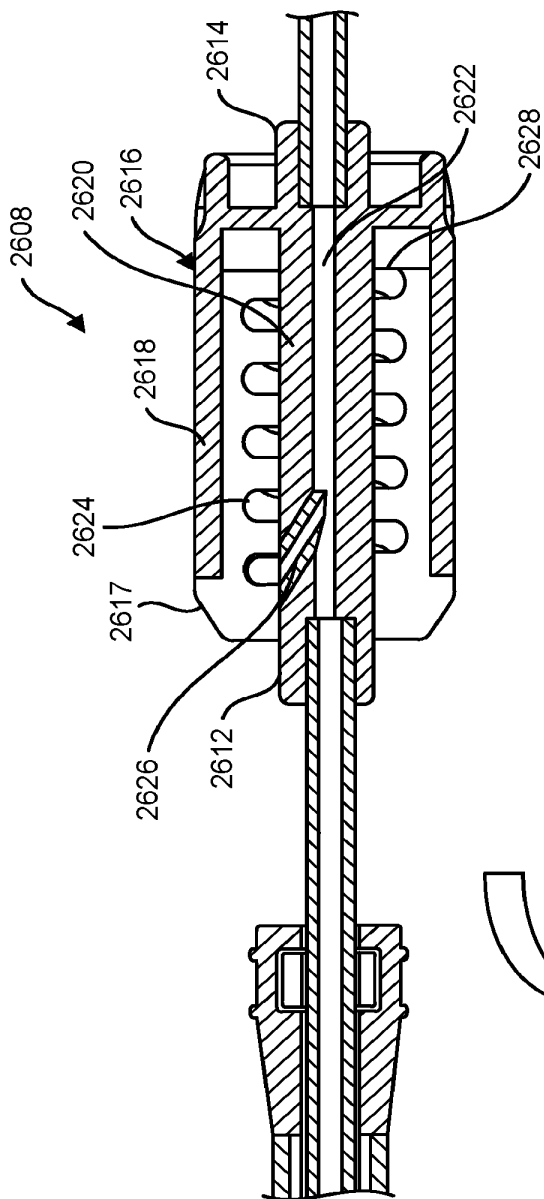


FIG. 26C

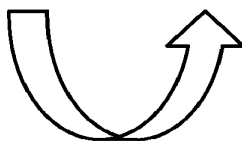
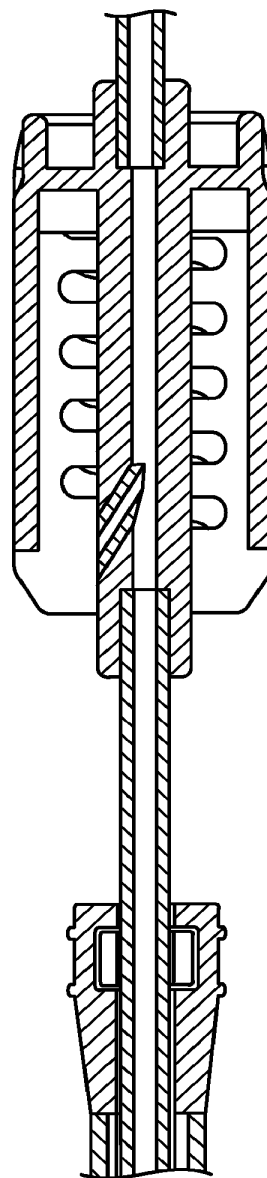


FIG. 26D

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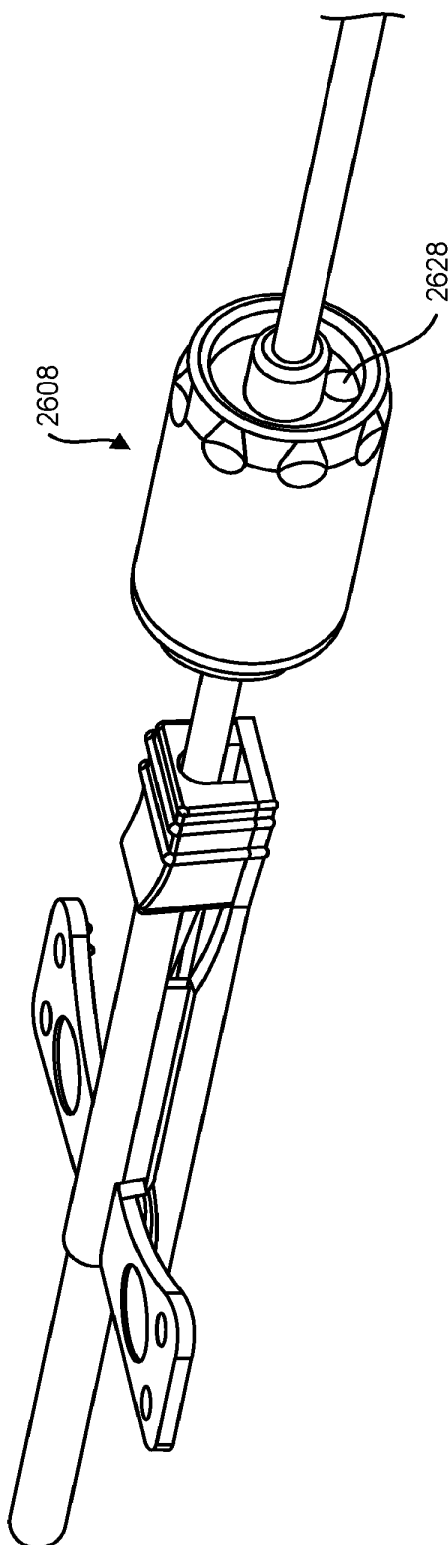
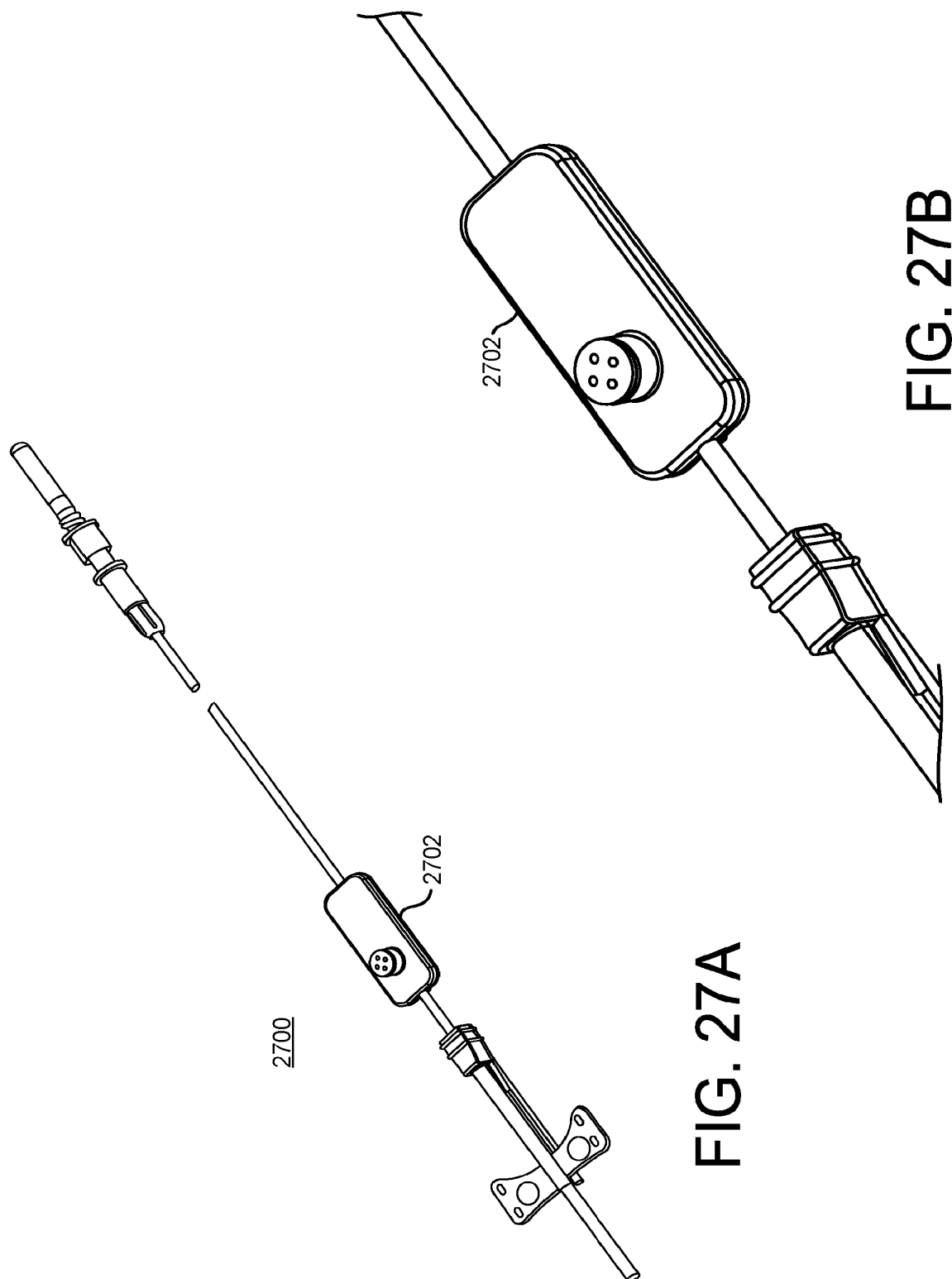
Replacement Sheet
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FIG. 26E

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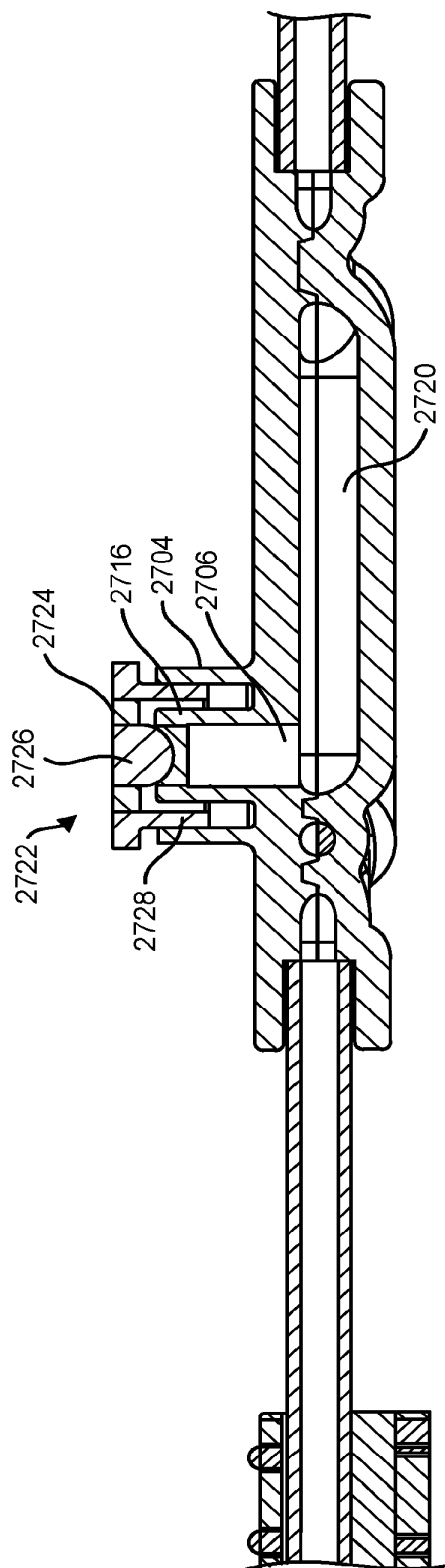


FIG. 27C

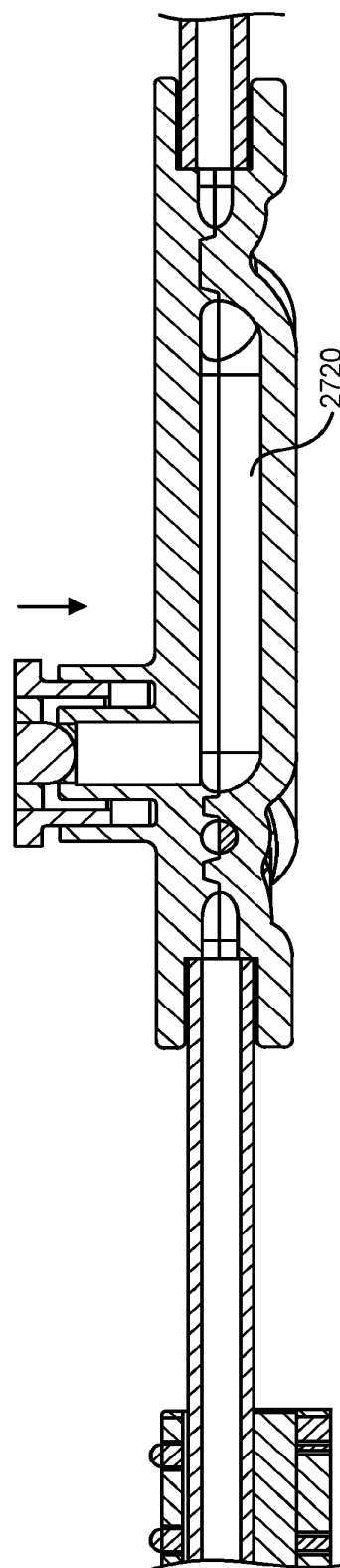


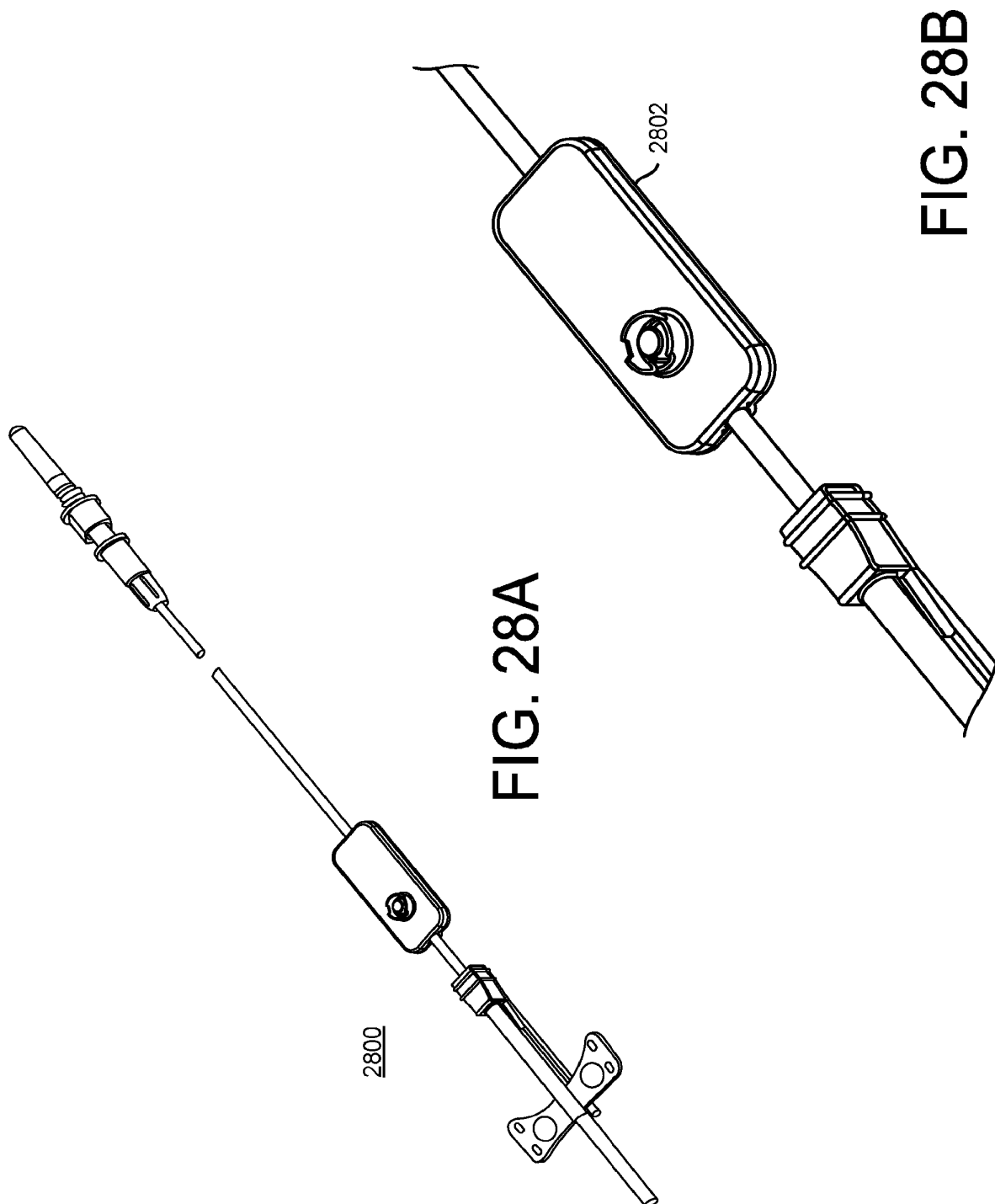
FIG. 27D

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PCT/US2017/068569

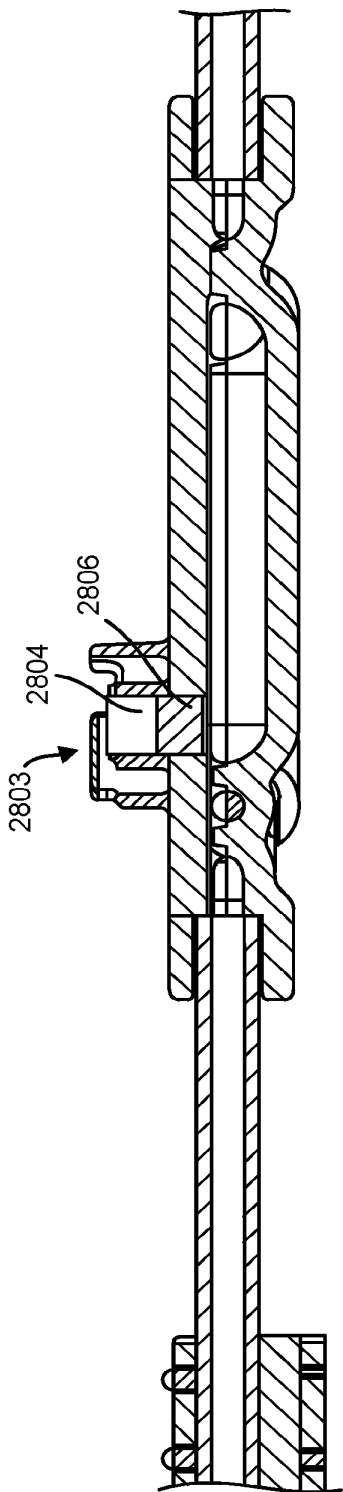


FIG. 28C

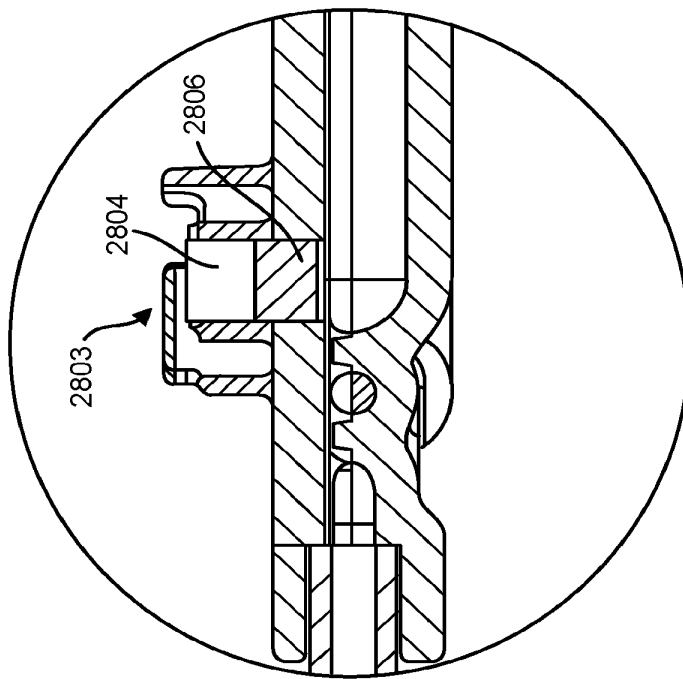


FIG. 28D

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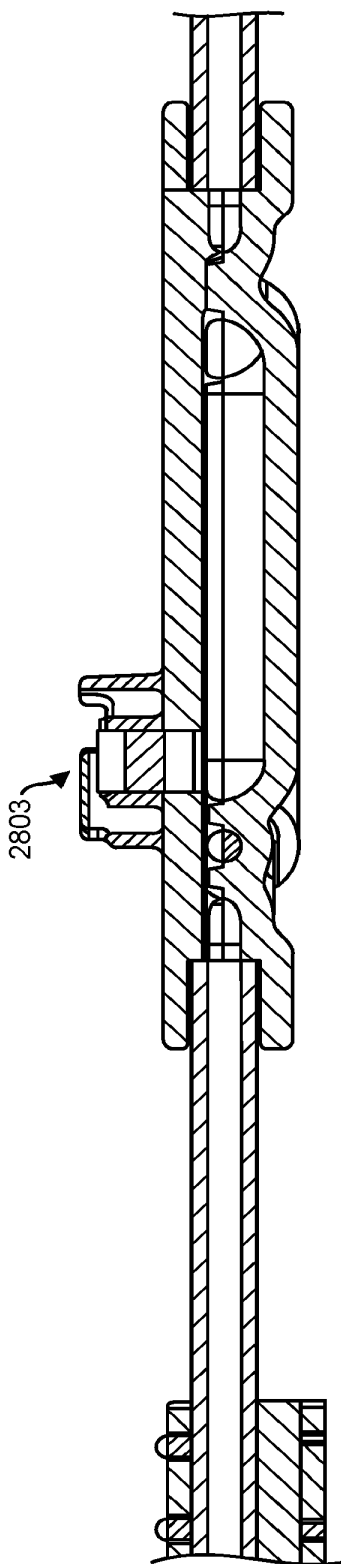


FIG. 28E

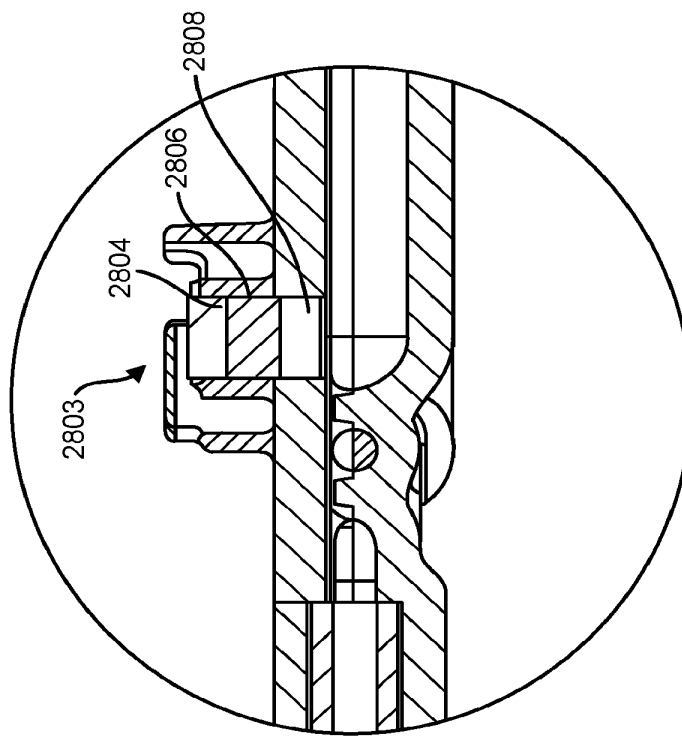


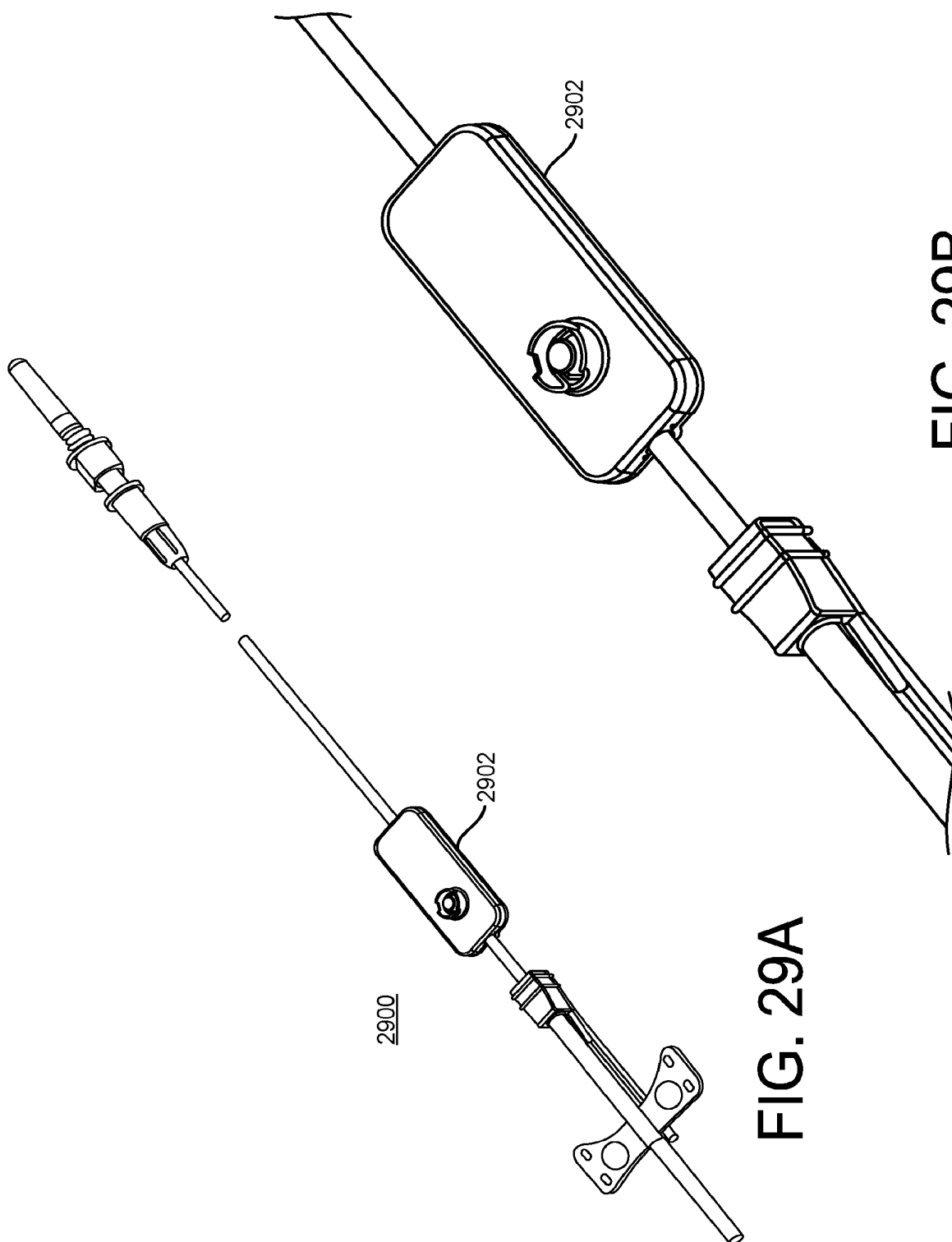
FIG. 28F

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PCT/US2017/068569

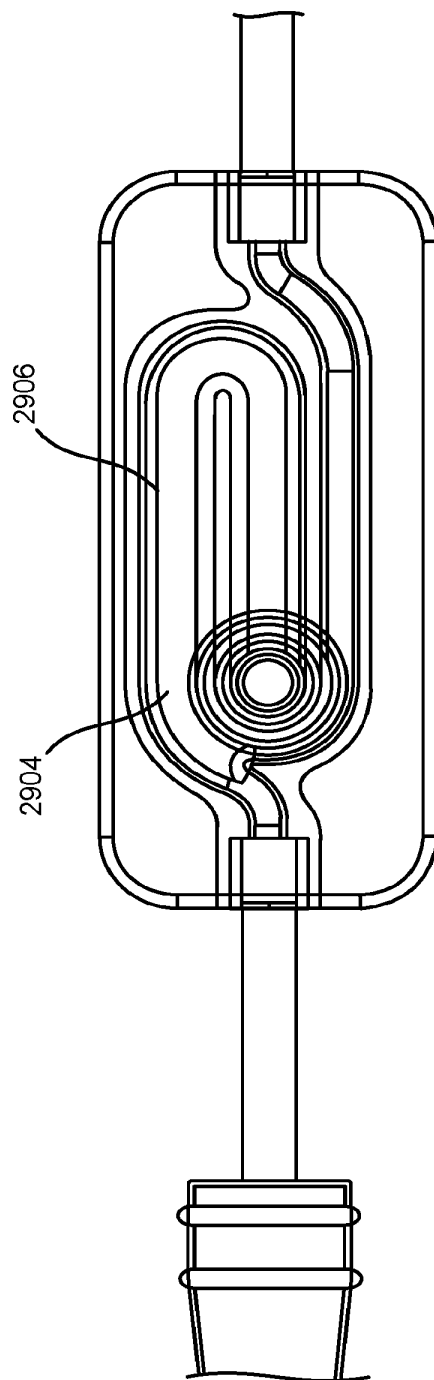


FIG. 29C

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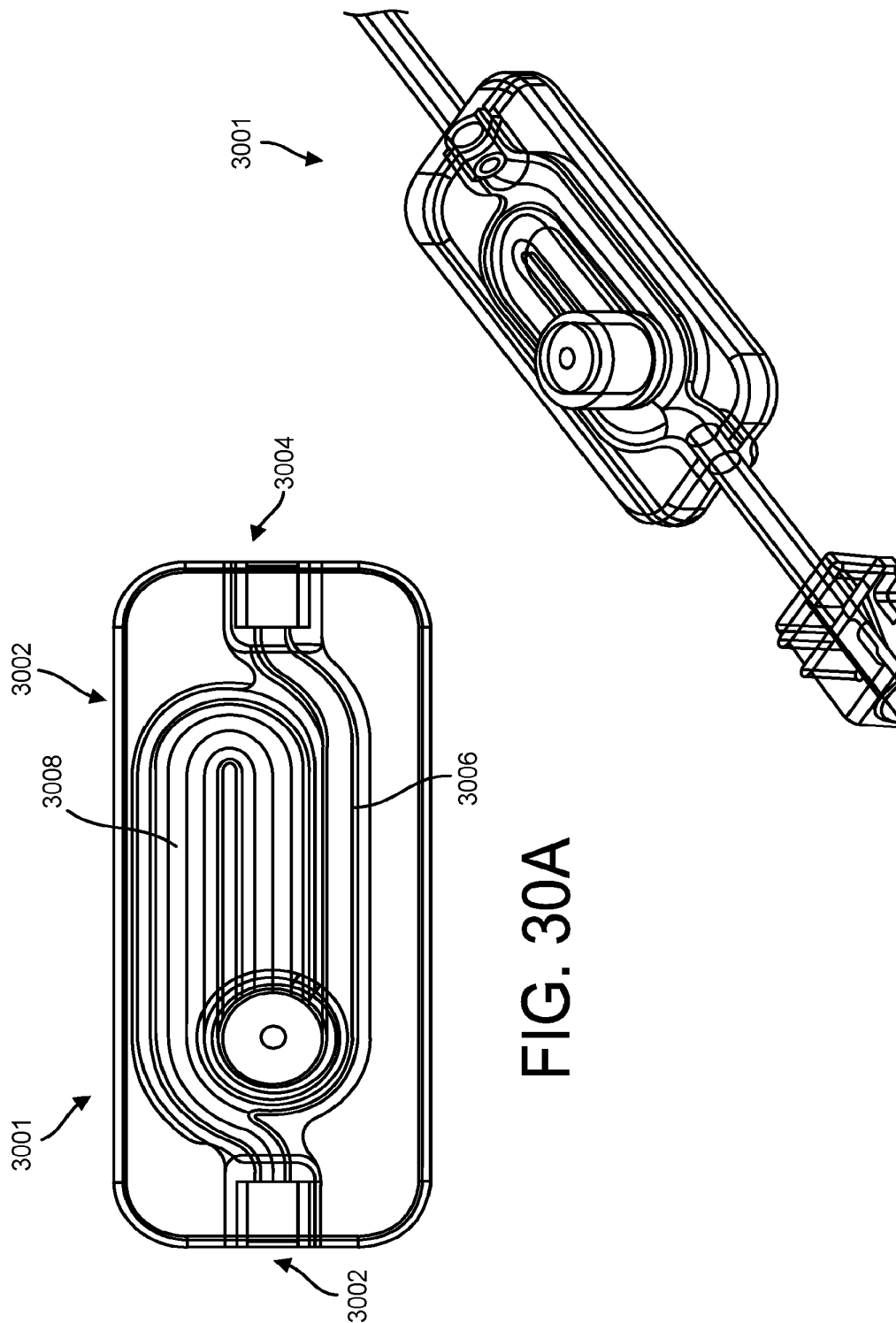


FIG. 30B

FIG. 30A

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PCT/US2017/068569

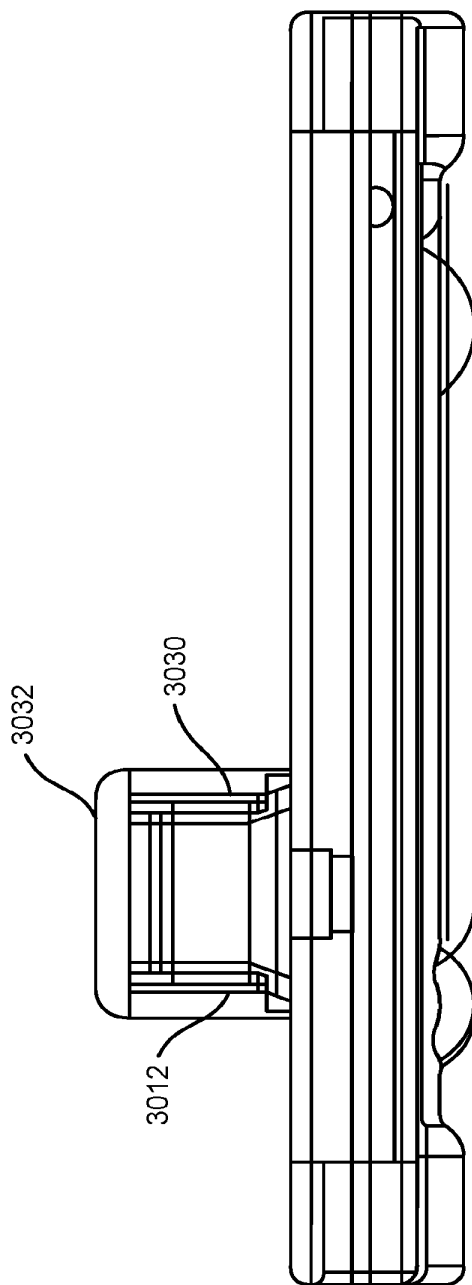


FIG. 30C

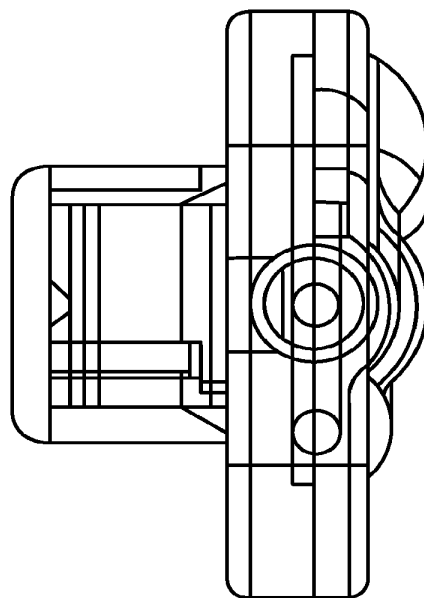


FIG. 30D

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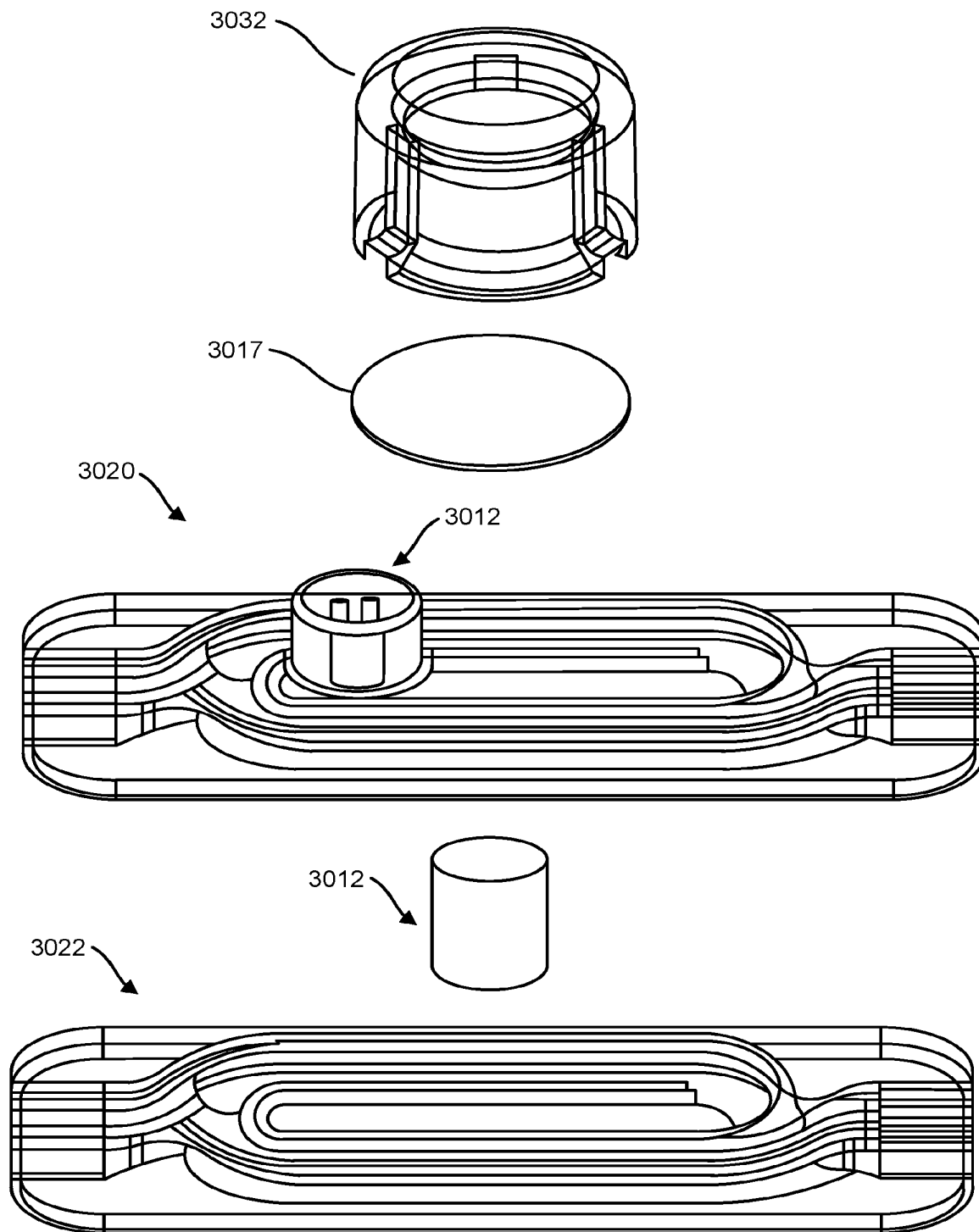


FIG. 30E

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PCT/US2017/068569

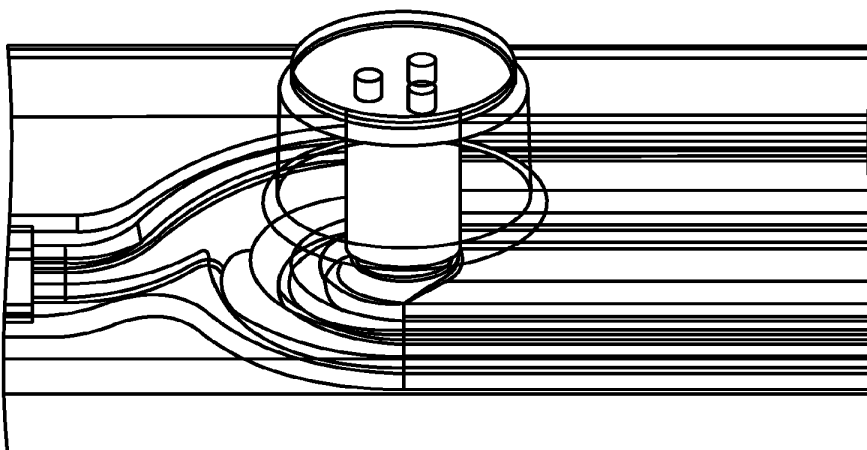
Replacement Sheet
69/69Docket No. KURIN3PCT
PCT/US2017/068569

FIG. 30F

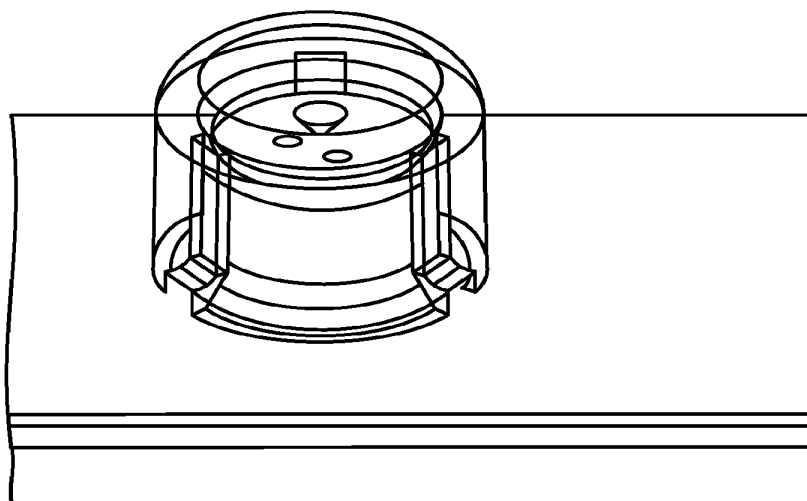


FIG. 30G



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Primary Examiner
Name: Nielsen, Michael
Tel: +49 30 259 01 - 554

Application No. 22 181 212.6 - 1122	Ref. KUR-19212-P-EP	Date 28.09.2023
Applicant Kurin, Inc.		

Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC. One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the Examining Division requesting that you correct this deficiency (R. 137(4) EPC).

In case you withdraw the application within the above-mentioned period, the examination fee will be refunded at a rate of 50% (Art. 11(b) RFees).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).



Nielsen, Michael
Primary Examiner
For the Examining Division

Enclosure(s): 3 page/s reasons (EPO Form 2906)

Datum
Date 28.09.2023
Date

Blatt
Sheet 1
Feuille

Anmelde-Nr:
Application No: 22 181 212.6
Demande n°:

The examination is being carried out on the **following application documents**

Description, Pages

1, 2, 4-46	as originally filed	
3, 3a, 3b	filed in electronic form on	19-05-2023

Claims, Numbers

1-8	filed in electronic form on	19-05-2023
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Drawings, Sheets

1/69-69/69	as originally filed
------------	---------------------

1). The applicants arguments with regard to neither of the documents cited hinting to "a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, **the chamber including a material that is air permeable and blood impermeable**" are agreed upon.

Applicants arguments with regard support for the claims on file, their novelty and inventiveness are likewise agreed upon.

Therefore:

2). The applicant should **bring the description into conformity** with the claims of the present divisional application (Article 84 EPC). In particular should features that are present in the independent claim not be referred to as options in the form of e.g. "in some instances", "in some embodiments", "in a preferred embodiment", "in one implementation" and so forth, but be clearly identified as forming part of the invention. **This applies to the description as a whole**, not only to the introductory part. The "Summary of The Invention" should likewise be amended, i.e. **recitation of superseded claims and subject-matter be removed or adapted** to the wording of the claims on file.

Anything referred to as "**embodiment**" or "**implementation**" and which is not covered by the claims on file should be **excised or clearly referred to as examples not covered by the invention**. This throughout the description and drawings.

- The technical field of the invention (Rule 42(1)(a) EPC; Guidelines F-II.4.2) must correspond to the amended set of claims.

- The summary of the invention (Rule 42(1)(c) EPC; Guidelines F-II.4.5) must correspond to the amended set of claims. Where appropriate, statements such as “The invention is set out in the appended set of claims” or “The invention is as defined in claim X” may be used instead of repeating the claims verbatim.
 - **Embodiments which are no longer covered by the claims must be deleted**, unless they can reasonably be considered to be useful for highlighting specific aspects of the amended subject-matter. If this is the case, they must be clearly marked as not being part of the present invention (T 1808/06 and Guidelines F-IV, 4.3)]:
 - Any combinations of features which do not fall under the scope of the amended independent claims must be clearly marked as not being part of the present invention.
 - Statements such as “The following examples/aspects/embodiments X, Y, Z are not according to the invention and are present for illustration purposes only” may be used **at the start of the description or in the list of figures**.
 - The technical features of the independent claims may not be presented as optional in the description. Where they precede a feature of an independent claim, terms such as “for example”, “may”, “can”, “exemplary”, “optionally”, “preferably” and the like must be removed.
 - The **“claim-like” clauses** in paragraphs [0014] to [0023] and at pages 43 to 46 **must be deleted prior to grant**. Claim-like clauses are clauses present in the description which use claim language such as “according to the preceding clause” or “characterised in that” (Guidelines F-IV, 4.4). Claim-like clauses include examples, embodiments or aspects which are presented as claim-like clauses. The simple conversion of these clauses into separate optional features will not be admitted either.
- 3). The unit inches expressed in paragraphs [0099], [00115] and [00156] does not meet the requirements of Rule 49(10) EPC and should be replaced by the appropriate SI unit (see Guidelines F-II, Annex, 2). The present expression should, however, be retained in parentheses after the replacement expression.
- 4). Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Articles 76(1) and 123(2) EPC).

Datum
Date 28.09.2023
Date

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Sheet 3
Feuille

Anmelde-Nr:
Application No: 22 181 212.6
Demande n°:

5). Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Articles 76(1) and 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).

拒絶理由通知書

特許出願の番号	特願 2 0 1 8 - 5 2 3 3 8 4
起案日	令和 1 年 7 月 1 6 日
特許庁審査官	清水 裕勝 5 2 6 2 2 Q 0 0
特許出願人代理人	三好 秀和 (外 3 名) 様
適用条文	第 2 9 条第 1 項、第 2 9 条第 2 項

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から 3 か月以内に意見書を提出してください。

理由

1. (新規性) この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の記事に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明であるから、特許法第 2 9 条第 1 項第 3 号に該当し、特許を受けることができない。

2. (進歩性) この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の記事に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第 2 9 条第 2 項の規定により特許を受けることができない。

記 (引用文献等については引用文献等一覧参照)

●理由 1 (新規性)、理由 2 (進歩性) について

- ・請求項 1 - 2、5、7 - 9、1 1 - 1 2、1 4
- ・引用文献等 1
- ・備考

引用文献 1 には、静脈に穿刺した針から真空採血管に血液を採取するシステムが記載されている。(特に、特許請求の範囲、第 6 頁左上欄第 2 0 行 - 同頁左下欄第 1 行、第 7 図等参照)

そして、第 7 図を参酌すると、引用文献 1 に記載された発明は、空気透過性血液不透過性の多孔性プラグ 5 2 (本願発明の「空気透過性血液バリア」) に相当。

）と横孔４８との間に空間を有し、かつ、プラグ５２で血液をブロックしてから真空採血管を挿入して横孔４８を通じて、プラグ５２を迂回して血液を採取するものであるから、当該「空間」は、血液サンプルの最初の量を受け入れる「隔離チャンバ」としても機能すると認められる。

そうしてみると、本願請求項１－２、５、７－９、１１－１２、１４に係る発明の構成と、引用文献１に記載された発明の構成との間に差異があるとは認められない。

したがって、本願請求項１－２、５、７－９、１１－１２、１４に係る発明は、引用文献１に記載された発明であるか、引用文献１に記載された発明に基づいて、当業者が容易になし得たものといえる。

●理由２（進歩性）について

- ・請求項６、１６
- ・引用文献等１
- ・備考

採血経路の形状や材質は、発明を具体化する際に当業者が適宜決定する事項と認められる。

したがって、本願請求項６、１６に係る発明は、引用文献１に記載された発明に基づいて、当業者が容易に想到し得たものといえる。

- ・請求項３－４、１３
- ・引用文献等１－２
- ・備考

引用文献２に記載されているように、真空採血管を用いて採血する技術分野において、サンプル針に真空採血管によって穿孔されるシールを設けることは周知技術である。（特に、第２図等参照）

したがって、本願請求項３－４、１３に係る発明は、引用文献１－２に記載された発明に基づいて、当業者が容易になし得たものである。

- ・請求項１０、１５
- ・引用文献等１、３
- ・備考

引用文献３に記載されているように、採血時の最初の血流が通る流路を設けることは周知技術である。（特に、段落〔００１１〕－〔００１２〕等参照）

したがって、本願請求項１０、１５に係る発明は、引用文献１、３に記載された発明に基づいて、当業者が容易になし得たものである。

<引用文献等一覧>

1. 特開昭58-25146号公報
2. 特開昭58-67238号公報 (周知技術を示す文献)
3. 特開2012-16496号公報 (周知技術を示す文献)

<先行技術文献調査結果の記録>

- ・調査した分野 I P C A 6 1 B 5 / 1 5 3 - 5 / 1 5 4

- ・先行技術文献 特開昭57-89869号公報
 特表平9-504726号公報
 特開平2-224742号公報
 米国特許第4207870号明細書

この先行技術文献調査結果の記録は拒絶理由を構成するものではありません。

<補正をする際の注意>

(1) 明細書、特許請求の範囲について補正をする場合は、補正により記載を変更した個所に下線を引いてください(特許法施行規則様式第13備考6、7)。

(2) 補正は、この出願の国際出願日における国際特許出願の明細書若しくは図面(図面の中の説明に限る。)の翻訳文、国際出願日における国際特許出願の請求の範囲の翻訳文(特許協力条約第19条(1)の規定に基づく補正後の請求の範囲の翻訳文が提出された場合にあっては、当該翻訳文)又は国際出願日における国際特許出願の図面(図面の中の説明を除く。)(以下、翻訳文等という。)

(誤訳訂正書を提出して明細書、特許請求の範囲又は図面について補正をした場合にあっては、翻訳文等又は当該補正後の明細書、特許請求の範囲若しくは図面)に記載した事項の範囲内で行わなければなりません。また、意見書で、各補正事項について補正が適法なものである理由を、根拠となる翻訳文等(誤訳訂正書を提出して明細書、特許請求の範囲又は図面について補正をした場合にあっては、翻訳文等又は当該補正後の明細書、特許請求の範囲若しくは図面)の記載箇所を明確に示したうえで主張してください。

(3) 特許請求の範囲について補正をする際には、特許法第17条の2第4項に違反する補正とならないよう、注意してください。

この拒絶理由通知の内容に関するお問合せ又は面接のご希望がありましたら次の連絡先までご連絡ください。

審査第一部 分析診断(医学診断) 清水裕勝
TEL. 03-3581-1101 内線3291
FAX. 03-3585-2055

Japanese Patent Application No. 2018-523384
Your Ref: KURIN2JP
Our Ref: TS/KRN-C0137JP01
August 26, 2019

Translation of “Notice of Reasons for Rejection”

Patent Application Number: JP 2018-523384
Date of Delivery: July 23, 2019
Applied Provision: Patent Law Articles 29(1), and 29(2)

The present application should be rejected for the following reasons. The applicant may present an argument against the reasons within three months from the date of delivery of this notice.

Reasons

1. The inventions of the following claims should not be granted a patent under Patent Law Article 29(1)(iii) as lacking novelty over the documents listed below.
2. The inventions of the following claims should not be granted a patent under Patent Law Article 29(2) as lacking inventive step over the documents listed below.

Remarks (See the Document List below)

- Reasons 1 and 2
- Claims 1-2, 5, 7-9, 11-12 and 14
- Document D1

D1 discloses a system for collecting blood in an evacuated blood collection tube from a needle punctured into a vein. (See especially the claims, page 6, upper left column, line 20 to lower left column, line 1, Figure 7, etc.)

Referring to FIG. 7, the invention disclosed in D1 has a space between an air-permeable blood-impermeable porous plug 52 (corresponding to the “air permeable blood barrier” of the present invention) and a side hole 48, the blood is blocked by the plug 52 before the evacuated blood collection tube is inserted, the blood is collected through the side hole 48 to bypass the plug 52, and thus the “space” functions as a “sequestration chamber” for receiving a first amount of blood sample.

As a result, it is not recognized that there is a difference between the invention of claims 1-2, 5, 7-9, 11-12 and 14 and the invention disclosed in D1.

Therefore, the inventions of claims 1-2, 5, 7-9, 11-12 and 14 are the inventions disclosed in D1 or could have been easily made by those skilled in the art based on the invention disclosed in D1.

- Reason 2

Japanese Patent Application No. 2018-523384
Your Ref: KURIN2JP
Our Ref: TS/KRN-C0137JP01
August 26, 2019

- Claims 6 and 16
- Document D1

The shape and material of the blood sampling pathway are matters that could have been appropriately determined by those skilled in the art when the invention is embodied.

Therefore, the inventions of claims 6 and 16 could have been easily conceived by those skilled in the art based on the invention disclosed in D1.

- Claims 3-4 and 13
- Documents D1 and D2

As disclosed in D2, in the technical field of collecting blood using an evacuated blood collection tube, it is a well-known art to provide a sample needle with a seal to be pierced by an evacuated blood collection tube. (See especially Figure 2 etc.)

Therefore, the invention of claims 3-4 and 13 could have been easily made by those skilled in the art based on the invention disclosed in D1 and D2.

- Claims 10 and 15
- Documents D1 and D3

As disclosed in D3, it is a well-known art to provide a channel through which an initial blood flow passes during blood collection. (See especially paragraphs [0011]-[0012] etc.)

Therefore, the invention of claims 10 and 15 could have been easily made by those skilled in the art based on the invention disclosed in D1 and D3.

Document List

D1: JP S58-25146A
D2: JP S58-67238A (Document disclosing well-known art)
D3: JP 2012-16496A (Document disclosing well-known art)

Record of the Result of Prior Art Search

Technical field(s) searched	IPC A61B 5/153-5/154
Prior art document(s)	JP S57-89869A
	JP H9-504726A
	JP H2-224742A
	US 4,207,870B

This record is not a component of the reasons for rejection.



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240
27500 7590 02/21/2023 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER NGUYEN, HUONG Q	
			ART UNIT 3791	PAPER NUMBER
			NOTIFICATION DATE 02/21/2023	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

DETAILED ACTION

It noted that there are two claims numbered 15. The second of which has been renumbered as Claim 16, and all others following have been renumbered accordingly. Thus, there are 31 claims in total and the claims are referred to by the new numbering.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

It is noted that no IDS has been submitted. Applicant is reminded of the duty to disclose all known prior art resulting from all prior art searches.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the structural components to enable the fluid controller to move from a first to a second position as described in the specification and in **Claims 6, 9, 24, and 27**. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended

drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. —An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element

(also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

- (A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;
- (B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g., “means for”) or another linking word or phrase, such as “configured to” or “so that”; and
- (C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step”) in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under

35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word “means,” but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

First flow controller (Claim 9, 12, 26, 27 – defined in specification by air permeable blood barrier 0060)

Second flow controller that is movable between first and second position (Claim 6, 9, 13, 23, 26, 28 – Figure 24, element 2419).

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL. — The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 8, 9, 13, 24, and 26-31 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or

for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regard to Claims 6, 9, 24, 27, per the drawing objections and 112(b) rejection below, it is unclear that applicant has proper support for the entire structural mechanism of the flow controller that is movable from a first position to a second position through a pressure differential.

While Figure 24B shows inner chamber housing 2419 that is movable from a first position to second position (0141), it is unclear both from the drawings and the limited disclosure how this occurs structurally. For example, there are no details provided or explanation of the structural connection between the inner chamber housing 2419, the apertures 2424, and the housing 2416 that enable movement of said inner chamber housing 2419 *from the first position*. Further, though paragraph 0142 states that as the blood contacts blood barrier 2420, this forces the inner chamber housing 2419 to the second position, it is again unclear how the inner chamber housing 2419 structurally moves to the second position from the first. Again, while paragraph 0143 describes tangs 2421 to stop the inner chamber housing 2419 in the second position, this does not provide any information about how the chamber moved from the first position.

Claims 8, 13, 26, and 29 recite that a pressure differential moves the inner chamber housing. However, as elaborated above, the details of this have not been provided to sufficiently describe the mechanics of said movement from the first position to the second position. As this mechanism is the crux of the embodiment in Figure 24 which are recited in the claims, the claims are therefore not properly supported by the disclosure.

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

In regard to Claims 1 and 18, the recitation of “an air permeable bodily fluid resistor” is indefinite. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

The term “resistor” in claims 1 and 18 is used by the claim to mean “an air permeable blood barrier” (see paragraph 0060 of publication – listed as known in the art to include membranes, coatings, mesh, filter, valve, etc.) while the accepted meaning is “a specific electrical circuit component” The term is indefinite because the specification does not clearly redefine the term. In fact, the specification does not use the term “resistor” at all. Therefore, the use of the term above is unclear because a skilled artisan would not reasonably be able to ascertain its desired meaning from the limitation.

In the rejection that follows, it is assumed that the term “an air permeable bodily fluid resistor” refers to the air permeable blood barrier as disclosed in the specification. However, clarification and correction are required.

In regard to Claims 6, 9, 23, 26, per the drawing objections and 112(a) rejection above, it is unclear how the flow controller that is movable from a first position to a second position through a pressure differential is structured to enable such functioning.

While Figure 24B shows inner chamber housing 2419 that movable from a first position to second position (0141), it is unclear both from the drawings and the limited disclosure how this occurs structurally. For example, there are no details provided or explanation of the structural connection between the inner chamber housing 2419, the apertures 2424, and the housing 2416 that enable movement of said inner chamber housing 2419 *from the first position*. Further, though paragraph 0142 states that as the blood contacts blood barrier 2420, this forces the inner chamber housing 2419 to the second position, it is again unclear how the inner chamber 2419 structurally moves to the second position from the first. Again, while paragraph 0143 describes tangs 2421 to stop the inner chamber housing 2419 in the second position, this does not provide any information about how the chamber moved from the first position.

Claims 8, 13, 25, and 28 recite that a pressure differential moves the inner chamber housing. However, as elaborated above, the details of this have not been provided to sufficiently describe the mechanics of said movement from the first position to the second position. As this mechanism is the crux of the embodiment in Figure 24 which are recited in the

claims, the claims are therefore indefinite because a skilled artisan cannot ascertain how the invention operates as claimed.

In regard to Claims 4, 6, 21, and 23, the recitation of “the connection” between the sample path and the inlet lacks proper antecedent basis. Correction is requested.

In regard to Claims 18 and 26, the recitation of “a bodily fluid source comprising a venipuncture device” is indefinite because it is unclear how a venipuncture device may provide a body fluid source as claimed. As known to a skilled artisan in the art, venipuncture devices are used to collect blood from human veins but the devices themselves are not sources of fluid. The specification also does not appear to provide support for a structure within the venipuncture device that provides a source of body fluid other than from the human body itself. Furthermore, applicant is reminded that human body parts are not eligible subject matter. Clarification is requested.

It is also noted that there are two claims numbered 15. The second of which has been renumbered as Claim 16, and all others following have been renumbered accordingly. Thus, there are 31 claims in total. Correction of the misnumbering including claim dependencies is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-5 and 19-23 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Haynes et al (US Pat No. 4980297).

In regard to Claim 1, Haynes et al disclose a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device 63 from a bodily fluid source (vein Figure 16-17), a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization device comprising:

an inlet 61 configured to connect with the bodily fluid source, best seen in Figure 9 (Col.7: 15-Col.8: 68);

an outlet 62 configured to connect with the bodily fluid collection device 63, best seen in Figure 9 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sample path 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46); and

a contaminant containment reservoir 55/55a between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor 112 (Figure 24) proximate the outlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (vacuum force – Col.9: 3-46), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the

contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17),

such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet 62 and to the bodily fluid collection device 63, best seen in Figure 15-18 (Col.9: 3-46).

2, 20. The bodily fluid sample optimization device in accordance with claim 1, further including a housing 48, 49 that defines the inlet 61 and the outlet 62, and contains the sample path 54 and the contaminant containment reservoir 55, and wherein the housing does not vent to atmosphere when the outlet is connected with the bodily fluid collection device, best seen in Figure 9 and 15-18 (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17).

3, 21. The bodily fluid sample optimization device in accordance with claim 1, wherein the pressure differential applied between the inlet 61 and the outlet 62 is applied by a vacuum of the bodily fluid collection device relative to a pressure of the bodily fluid source (Col.9: 3-46).

4, 22. The bodily fluid sample optimization device in accordance with claim 1, wherein the connection between the sample path 54 and the inlet 61 is made when the contaminant containment reservoir 55 receives the first portion of the bodily fluid sample (Col.9: 3-46).

5, 23. The bodily fluid sample optimization device in accordance with claim 1, wherein once the first portion is received in the contaminant containment reservoir 55, a resistance to a flow of the subsequent portions of the bodily fluid sample in the contaminant containment reservoir is higher than a resistance in the sample path due to the pressure (Col.9: 3-46).

In regard to Claim 19, Haynes et al disclose a patient bodily fluid sample optimization system comprising:

a bodily fluid source comprising a venipuncture device 58 configured for venipuncture of the patient, best seen in Figure 15-18;

a bodily fluid collection device 63 comprising a sealed collection needle 69 (Figures 21-22 show sleeve 105 – Col.11: 18-50) on which an evacuated tube 63, 80 can be placed to draw the patient bodily fluid with a pressure differential between the evacuated tube and the patient (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17); and

a bodily fluid sample optimization device comprising:

an inlet 61 configured to connect with the bodily fluid source, best seen in Figure 9 (Col.7: 15-Col.8: 68);

an outlet 62 configured to connect with the bodily fluid collection device, best seen in Figure 9 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sample path 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46); and

a contaminant containment reservoir 55/55a between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor 112 (Figure 24) proximate the outlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

the contaminant containment reservoir being arranged to receive, when the pressure differential is formed between the inlet and the outlet (vacuum force – Col.9: 3-46), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the

contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17),

such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet 62 and to the bodily fluid collection device 63, best seen in Figure 15-18 (Col.9: 3-46).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 6-8 and 24-26 is/are rejected under 35 U.S.C. 103 as being unpatentable over Haynes et al as applied to claims 1 and 18 above, further in view of Eldridge (US Pat No. 4207870).

Haynes et al disclose the invention above but do not expressly disclose a flow controller that is movable from a first position to a second position.

Eldridge teach an analogous fluid sampling device comprising a flow controller 22 that is movable from a first position to a second position to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

6, 24. The bodily fluid sample optimization device in accordance with claim 4, wherein the contaminant containment reservoir includes a flow controller 22 that is movable from a first position to enable the contaminant containment reservoir to receive, when the pressure differential is applied between the inlet and the outlet, the first portion of the bodily fluid

sample from the bodily fluid source via the inlet, to a second position to open the connection between the sample path and the inlet to allow the subsequent portions of the bodily fluid sample to be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

7, 25. The bodily fluid sample optimization device in accordance with claim 6, wherein movement of the flow controller exposes at least one aperture between the inlet and the sample path (after valve skirt 22 opens), best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

8, 26. The bodily fluid sample optimization device in accordance with claim 6, wherein the flow controller is movable by the pressure differential, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al such that there is included a flow controller that is movable from a first position to a second position as taught by Eldridge above to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded.

Claim(s) 9-12, 14-18, 27-28, and 30-31 is/are rejected under 35 U.S.C. 103 as being unpatentable over Haynes et al in view of Bullington et al (US Pub No. 20140155781).

In regard to Claim 9, Haynes et al disclose a bodily fluid control device comprising:

an inlet 61 fluidically coupleable to a bodily fluid source (vein, Figure 16-17), best seen in Figure 9 (Col.7: 15-Col.8: 68);

an outlet 62 fluidically coupleable to a bodily fluid sample collection device 63, and to allow a negative pressure differential between the outlet and the inlet when the outlet is fluidically coupled to the bodily fluid sample collection device, best seen in Figure 9 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sampling channel 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a containment chamber 55/55a between the inlet and the outlet, the containment chamber having a first flow controller 112 (Figure 24) that allows air to flow from the containment chamber to the outlet by the negative pressure differential between the outlet and the inlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

such that a first volume of bodily fluid is drawn from the inlet into the containment chamber, and to prevent the first volume of bodily fluid from flowing to the outlet (plasma in receiving portion 55/55a is collected by tube 80, not 63), best seen in Figure 15-18 (Col.9: 3-46).

However, Haynes et al do not expressly disclose a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device.

Bullington et al teach that it is well-known in the art to provide an analogous body sampling device comprising a flow controller 120, 130, 140 that is movable from a first position

as the first volume of bodily fluid is drawn from the inlet into a containment chamber 170, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device 180 (0006, 0054). Bullington et al teach that in the second position, fluid is directed into a second reservoir 180 and bypassing a first reservoir 170, which must be used first. This enables controlled sampling to reduce contamination of the sample by requiring isolation of the first volume of the collected body fluid in the first reservoir initially. (0002-0004).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al such that there is included a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device, as taught by Bullington et al to effectively reduce contamination of the sample by requiring isolation of the first volume of the collected body fluid in the first reservoir initially.

10. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the bodily fluid source includes a patient needle 58, best seen in Figure 15-19.

11. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the bodily fluid sample collection device includes a sealed collection needle 69 (Figures

21-22 show sleeve 105 – Col.11: 18-50) on which an evacuated tube 63, 80 can be placed (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17).

12. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the first flow controller 112 includes an air permeable blood barrier that seals upon contact with bodily fluid, best seen in Figure 24 (Col.12: 38-Col.13: 17).

14. Haynes et al disclose the bodily fluid control device in accordance with claim 9, further including a housing 48, 49 that defines the inlet 61 and the outlet 62, and wherein the housing contains the containment chamber 55 and the sampling channel 54, best seen in Figure 9 and 17 (Col.7: 15-Col.8: 68; Col.9: 3-46).

15. Haynes et al disclose the bodily fluid control device in accordance with claim 14, wherein the housing 48, 49 does not vent to atmosphere when the inlet 61 is fluidically coupleable to the bodily fluid source and the outlet 62 is fluidically coupled to the bodily fluid sample collection device 63 (Col.7: 15-Col.8: 68; Col.9: 3-46).

16. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the negative pressure differential applied between the inlet 61 and the outlet 62 is applied by a vacuum of the bodily fluid sample collection device relative to a pressure of the bodily fluid source (Col.9: 3-46).

17. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein a fluidic coupling between the sample path 54 and the inlet 61 is made only after the containment chamber 55 receives the first volume of the bodily fluid (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17).

18. Haynes et al disclose the bodily fluid control device in accordance with claim 1, wherein once the first portion is received in the containment chamber 55, a resistance to a flow of the subsequent volumes of the bodily fluid in the containment chamber is higher than a resistance in the sampling channel due to the pressure (Col.9: 3-46).

In regard to Claim 27, Haynes et al disclose a patient bodily fluid control system comprising:

- a bodily fluid source comprising venipuncture device 58 for venipuncture to the patient, best seen in Figure 9;

- a bodily fluid sample collection device 63, 80 comprising a sealed collection needle 69 (Figures 21-22 show sleeve 105 – Col.11: 18-50) on which an evacuated tube 63, 80 can be placed to draw the patient bodily fluid with a pressure differential between the evacuated tube and the patient (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17); and

- a bodily fluid control device comprising:

- an inlet 61 fluidically coupleable to the bodily fluid source, best seen in Figure 9 (Col.7: 15-Col.8: 68);

- an outlet 62 fluidically coupleable to a bodily fluid sample collection device, and to allow a negative pressure differential between the outlet and the inlet when the outlet is fluidically coupled to the bodily fluid sample collection device, best seen in Figure 9 and 15-18 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sampling channel 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a containment chamber 55/55a between the inlet and the outlet, the containment chamber having a first flow controller 112 (Figure 24) that allows air to flow from the containment chamber to the outlet by the negative pressure differential between the outlet and the inlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

such that a first volume of bodily fluid is drawn from the inlet into the containment chamber, and to prevent the first volume of bodily fluid from flowing to the outlet (plasma in receiving portion 55/55a is collected by tube 80, not 63), best seen in Figure 15-18 (Col.9: 3-46).

However, Haynes et al do not expressly disclose a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device.

Bullington et al teach that it is well-known in the art to provide an analogous body sampling device comprising a flow controller 120, 130, 140 that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber 170, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device 180 (0006, 0054). Bullington et al teach that in the second position, fluid is directed into a second reservoir 180 and bypassing a first reservoir 170, which must be used first. This enables controlled sampling to reduce contamination of the sample by requiring

isolation of the first volume of the collected body fluid in the first reservoir initially. (0002-0004).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al such that there is included a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device, as taught by Bullington et al to effectively reduce contamination of the sample by requiring isolation of the first volume of the collected body fluid in the first reservoir initially.

28. Haynes et al disclose the bodily fluid control system in accordance with claim 26, wherein the first flow controller includes an air permeable blood barrier 112 that seals upon contact with bodily fluid, best seen in Figure 24.

30. Haynes et al disclose the bodily fluid control system in accordance with claim 26, further including a housing 48, 49 that defines the inlet 61 and the outlet 62, and wherein the housing contains the containment chamber 55 and the sampling channel 54, best seen in Figure 9 and 15-18 (Col.7: 15-Col.8: 68).

31. Haynes et al disclose the bodily fluid control system in accordance with claim 29, wherein the housing 48, 49 does not vent to atmosphere when the inlet 61 is fluidically coupleable to the bodily fluid source and the outlet 62 is fluidically coupled to the bodily fluid sample collection device 63 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17).

Claim(s) 13 and 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Haynes et al in view of Bullington et al as applied to Claim 9 above, further in view of Eldridge.

Haynes et al in combination with Bullington et al disclose the invention above but do not expressly disclose the second flow controller that is movable from a first position to a second position by the pressure differential.

Eldridge teach an analogous fluid sampling device comprising a flow controller 22 that is movable from a first position to a second position by a pressure differential to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al as modified by Bullington et al such that the second flow controller is movable from a first position to a second position by the pressure differential as taught by Eldridge above to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely

online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Claims 1 and 18 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a patient bodily fluid sample optimization system comprising: a bodily fluid source comprising a venipuncture device configured for venipuncture of the patient; a bodily fluid collection device comprising a sealed collection needle on which an evacuated tube can be placed to draw the patient bodily fluid with a pressure differential between the evacuated tube and the patient; and a bodily fluid sample optimization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when the pressure differential is formed between the inlet and the outlet, a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet, such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device, wherein air is necessarily displaced in such configuration.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet, such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 20 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid

sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device (functional use); a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device when the bodily fluid collection device is connected.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 8 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization

device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.Q. NGUYEN
Examiner
Art Unit 3791

/TSE W CHEN/
Supervisory Patent Examiner, Art Unit 3791



European Patent Office
80298 MUNICH
GERMANY

Questions about this communication?
Contact Customer Services at www.epo.org/contact



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Date	15.11.2022
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Reference KUR-18996-P-EP	Application No./Patent No. 20781928.5 - 1122 / 3948211 PCT/US2020026276
Applicant/Proprietor Kurin, Inc.	

Communication pursuant to Rules 70(2) and 70a(2) EPC

A supplementary European search report has been drawn up concerning the above-identified European patent application (publication number: 3948211).

Since the request for examination has been filed (R. 70(1), 159(1)(f), Art. 94(1) EPC) prior to the transmission of the supplementary European search report, you are hereby invited to indicate within

six months

of notification of this communication whether you wish to proceed further with the European patent application.

If you do not indicate in due time that you wish to proceed further with the European patent application, it **will be deemed to be withdrawn** (R. 70(3) EPC).

You are invited, within the above-mentioned six-month period, to comment on the objections raised in the opinion accompanying the European search report and/or to file any amendments to the description, claims and drawings correcting any deficiencies noted in the opinion (R. 70a(2), R. 137(2) EPC; Guidelines for Examination in the EPO, B-XI, 8).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the Examining Division requesting that you correct this deficiency (R. 137(4) EPC).

Should the reply to the invitation pursuant to Rule 70a(2) EPC be filed in an admissible non-EPO language, a translation is to be submitted within one month of its filing (R. 6(2) EPC).

Should you not comply with this invitation within the time limit, the application **will be deemed to be withdrawn** in accordance with Rule 70a(3) EPC.

Receiving Section



Registered Letter

EPO Form 1224 11.12 (RTB/ESOP01=N) DMEX

page 1 of 1



רשות המכס



מדינת ישראל
משרד הביטחון

פ.ק. 26

תאריך: י"ח שבט תשפ"ב

20/01/2022

מספר: 1000-018-01

לכבוד
כץ, פרזנט ושות'
דרך אבא הלל 14, ת.ד.
רמת גן, מיקוד 52506

א. ג. נ.

הנדון: הודעה על ליקויים בבקשת פטנט מספר 267684

סימוכין: מכתבכם מיום

לתשומת לבכם: מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ"ז – 1967. מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ"ח – 1968. עליכם להשיב על הודעה זו תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה, עם בקשת הארכה שתוגש יש לשלם אגרה בסך 208.00 ש"ח בעד כל חודש או חלק ממנו. לא יינתנו יותר מארבעה חודשי ארכה בגין כל הודעה על ליקויים וסך כל תקופות הארכה במהלך הבחינה לא יעלה על 12 חודשים בהתאם לכללים שנקבעו בחוזר הרשם 035/2017-פטנטים.

הודעה זו מבוססת על המסמכים הבאים:

שרטוטים מתאריך: 26/06/2019

פרטי הבקשה מתאריך: 26/06/2019

תביעות מתאריך: 26/06/2019

בהתאם למפורט בהמשך הודעה זו להלן סיכום עמדותי לעניין כשירות התביעות לפטנט:

בתביעה/ות מס' 1-20 נמצאו ליקויים.

ראה הנימוקים בהמשך הודעה זו.

בהתאם להוראות תקנה 41 הנני להודיעכם כי נמצאו בבקשה הנ"ל הליקויים המפורטים להלן:

1. חידוש והתקדמות המצאתית

1.1 תביעה/ות 1-20 עונה/ות על דרישות סעיפים 4 ו-5 לחוק, מאחר והאמצאה המוגדרת בתביעה/ות זו/אלה

לא נתפרסמה בפומבי לפני תאריך הבקשה ויש בה התקדמות המצאתית.

2. התביעות

2.1 תביעות מס' 1-20 אינן עומדות בהוראות סעיף 13(א) לחוק היות שהן אינן כוללות את כל יסודות

האמצאה הדרושים לביצועה כפי שנלמד מהתיאור.

לגבי התביעות הבלתי 1, 8, 15, בלשון תביעות אלו מופיע הביטוי:

"the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents"

שיוצר אי בהירות האם ה- vents הנוספים הם חלק מה- vent השייך ל- sequestration chamber או



שהם חלק מה- outer wall.

כמו כן, בלשון תביעות 1,8,15 מופיע הביטוי :

"the vent further including a cap that at least partially covers the wall **and a one-way seal**"

שיוצר אי בהירות האם ה- cap מכסה גם את ה- one-way seal או שאותו one-way seal הוא חלק מה- vent עצמו.

התביעות התלויות 2-7,9-14,16-20 אינן עומדות בהוראות **סעיף 13(א)** לחוק עקב תלותן בתביעות 1,8,15 בהתאמה.

2.2 בניגוד **לתקנה 20(א)(3)**, תביעות 4,11,18 אינן ברורות מאחר שהביטוי/המונח "the inner wall" המופיע בתביעות אלו זו מחוסר התייחסות קודמת (antecedence) בתביעה/ות קודמת/ות מתאימה/ות.

חובת המבקש לעדכן את הרשות

תשומת לבכם **לסעיף 18 לחוק** לעניין חובת המבקשת לעדכן את הרשות על כל שינוי שחל ברשימת האסמכתאות או הפרסומים כאמור **בסעיף 18(א) לחוק ולסעיף 18 לחוק** בדבר אמצעי האכיפה.

הגשת תיקונים לפירוט במהלך בחינת הבקשה

באם יבוצעו תיקונים בבקשת הפטנט, תשומת לבכם מופנית **לתקנה 22(א)**. יש לשלוח לרשות עותק מלא של חלק הבקשה שבו הוכנסו התיקונים תוך סימונם באופן ברור. יש לסמן תוספות בקו תחתי (כך : דוגמה) והשמטות בקו חוצה (כך : דוגמה). אין להגיש מחדש קבצים שלא תוקנו.

לתשומת לבכם :

א) בהתאם לתקנות 22(ב) ו-42 במידה שהנכם מתקנים את הפירוט כדי להתגבר על הליקויים בהודעה זו, עליכם לפרט את הליקויים שהתיקונים באים לסלקם, לנמק כיצד תיקון הפירוט מתקן את הליקוי ולגבי תיקון בתביעות, כיצד עומד התיקון בתנאי סעיף 13 לחוק.

ב) בהתאם להוראות חוזר רשם 034/2017-פטנטים, במידה שבחינת הבקשה החלה לאחר 27.03.2017, תיקון פירוט בדרך של החלפת האמצאה שנבחנה ואשר לגביה הועלה ליקוי, באמצאה אחרת, בין אם היא הופיעה בתביעות מלכתחילה ובין אם תוארה בלבד, גם אם היא נובעת מהתיאור, אינו מהווה תיקון הליקוי ויביא לשליחת ההודעה לפני סירוב.

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור :

<https://israelpatents.justice.gov.il/#/en/patent-file/details/267684>

ראיון עם בוחר

בהתאם לה.ע. 23.3, המפורסמת באתר הרשות, ניתן לקיים ראיון עם הבוחר באמצעות פגישה במשרדי הרשות או בשיחה טלפונית.

רשות הפטנטים מעודדת קיום של קשר ישיר בין הבוחר למבקש או בא-כוחו באמצעות שירות זה.



רשות המכסות



מדינת ישראל
משרד המשפטים

קיום ראיון עם בוחן מאפשר לרוב את ייעול וקיצור זמן הבחינה ואף לחיסכון בעלויות בתהליך הבחינה והאישור של בקשה לפטנט.

במסגרת הראיון ניתן לדון עם הבוחן בנושאים הקשורים לתיאור האמצאה והגדרתה, בליקויים שהועלו במהלך הבחינה ואף בתיקונים אפשריים לליקויים אלה.

תיאום הראיון יתבצע ישירות מול הבוחן (פרטי הקשר מופיעים מטה) וילווה בהודעה כתובה של יוזם הראיון שתפרט את הנושאים לדיון ואת הטיעונים העיקריים לגביהם.

לתשומת לבכם, בקשה לקיום ראיון אינה מהווה תשובה להודעת הליקויים כמשמעה בתקנה 42.

השגה בפני הרשם

על פי סעיף 161 לחוק, הנכם רשאים להשיג על החלטתי בפני רשם הפטנטים תוך ארבעה חודשים ממועד משלוח ההודעה.

בכבוד רב

אלברט אקרמן

בוחן פטנטים בכיר

טלפון : 073-3927233

דואר אלקטרוני : albertak@justice.gov.il

ראש צוות : מוריה שלמה לוי



Notice of Reasons for Refusal

Application number: Japanese Patent Application No. 2020-118498
Date of Drafting: Reiwa 3(2021) August 2
Patent examiner: OKAZAKI, Jun 3330 2Q00
Representative/Applicant: MIYOSHI, Hidekazu (other trinominal)
Applied Provisions: Article 29 (2) (Inventive Step) Article 36 (6) (ii) (Clarity Requirement)

This application should be refused for the reason mentioned below. If the applicant has any opinion(s) against the reason, a written opinion should be submitted within 3 months from the date on which this notification was dispatched.

Reason

1. (Inventive step) The claimed invention(s) listed below of this patent application shall not be granted a patent under the provision of Patent Act Article 29 (2) for the reason that the claimed invention(s) could have easily been made by persons who have common knowledge in the technical field to which the claimed invention(s) pertains, on the basis of the invention(s) described in the distributed publication listed below or made available to the public through electric telecommunication lines in Japan or other foreign countries prior to the filing of the patent application.

2. (Clarity) This patent application does not fulfill the requirement of the provision of Patent Act Article 36(6)(ii) in terms of the item(s) listed below regarding the statement of the scope of claims.

Note (For the cited documents, please refer to the list of cited documents below.)

- Reason 1 (Inventive step)

- Claim 1-10

- Cited Document, etc. 1-2

- Remarks

[About Claim 1]

Are the blood isolation device which was connected to the patient needles (first needle 508;[0038] etc.) which it was a blood sample optimization system for optimizing the blood samples ([0020] etc.) brought together in Cited document 1 ([0019]-[0055], Fig.5-8) with blood collecting machines (sample vessels 506;[0038] etc.) (sample-procurement system;[0038] etc.), and were constituted for a patient's venipuncture in order to be able to take out the first portions of a patient's blood sample and the aforementioned blood samples ([0021] etc.) which contain a pollutant

at least, and the aforementioned patient needle, and was connected to the aforementioned blood collecting course between the sample needle (refer to suggestion of Fig.5 etc.) constituted so that the aforementioned blood collecting machine might be accepted in order to collect the second portion of the aforementioned blood sample as the blood collecting course constituted so that the aforementioned blood sample might be carried, and the aforementioned patient needle and the aforementioned sample needle, and are connected to the inlet ports (sterile input tubing 514;[0039] etc.) constituted so that the aforementioned blood sample might be accepted, and the aforementioned inlet port, and are an isolation chamber and it accepts the first portion of the aforementioned blood sample (Refer to / etc / Fig.5]), The isolation chamber (pre-sample reservoirs 504;[0038] etc.) constituted so that a pollutant might be included in the first portion of the aforementioned blood sample, Including a sampling channel, and (second sterile output tubing 518;[0038], Fig.5), etc. which were constituted so that it might have a proximal edge connected to the aforementioned inlet port and the second portion of the aforementioned blood sample might be accepted, the aforementioned isolation chamber, [the aforementioned sampling channel and the aforementioned inlet port] Enable the second portion of the aforementioned blood sample to bypass the aforementioned isolation chamber, are constituted so that the second portion of the aforementioned blood sample may be made to go to the aforementioned exit port, and, [the aforementioned exit port] Blood sample optimization system , containing ([0038] etc.) blood isolation devices constituted so that the second portion of the aforementioned blood sample may be discharged in the aforementioned blood collecting machine is described.

Cited document 2 ([0012]-[0013] etc.) has disclosed the technology , which constitutes the housing (needle tube base material 2) which stores and demarcates the technology, the port, isolation chamber, and flow path which constitute the isolation chamber which is an isolation chamber which has a vent containing the air permeability blood barrier (air permeability blood impermeable component 23) in a blood sample optimization system (blood collecting needle), and drives out the air in an isolation chamber through a vent.

An invention described in Cited documents 1-2 belongs to the same technical field of the blood collecting field.

In an invention described in Cited document 1, it is easy for a person skilled in the art to constitute by referring to the technology of the description to Cited document 2, so that the same air permeability blood barrier and housing as an invention related to the Claim 1 of this application may be provided.

[About Claims 2 and 4]

Refer to [0012]-[0013] of Cited document 2.

[About Claim 3]

It can be called design matter to arrange sealant to a sample needle.

[About Claim 5]

Refer to [0011] of Cited document 2.

[About Claim 6]

Refer to the Fig.5 of Cited document 1.

[About Claims 7-10]

Refer to the explanation as stated above including the description of Cited document 1-2.

- Reason 2 (Clarity)

- The description of Claims 1-10 Claims 1-10 is indefinite in respect of the following. Therefore, The claimed invention in Claims 1-10 is not clear.

(1) About the description of Claim 1

As for a description with "the first portions of a patient's blood sample and the aforementioned blood sample which contains a pollutant at least" of Claim 1, what "a pollutant is included for at least" is indefinite considering whether the "blood sample" is started and whether "the first portion of the aforementioned blood sample" is started as Japanese. In dependent claim -- the same .

(2) About the description of Claims 4 and 7

The description with "the portion of succession of the aforementioned blood sample" of Claims 4 and 7 is indefinite in whether what "follows" what kind of portion is specified. In dependent claim -- the same .

<The list of cited documents etc.>

- 1.The description of US Publication of Unexamined Patent Application No. 2008/0145933
- 2.JP 2001-000424A

Record of the result of prior art search

- Technical fields searched:

IPC

A61B 5/00 - 5/398

DB name

- Prior art documents: JP S 58 - 025146A

JP H 09-504726A

JP H 02-224742A

The description of US Publication of Unexamined Patent Application No. 2011/0306899

This record of the result of prior art search does not constitute the reasons for refusal.

<Suggestions in amending>

(1) When making amendment to the description or the scope of claims, the amended

parts should be underlined so as to be clearly identified (please refer to Note 6 and 7 of Form 13, Regulations under the Patent Act).

(2) Correction must be performed within the scope of the matter described in the The translation of a document written in foreign language (or the after Amendment Description by Correction of Erroneous Translation, a scope of the claim, or Drawings) of this application. In addition, for the evidence of the legality of each amendment, allege the legality in a written opinion with clear indication of the corresponding parts in the translation (or the description, scope of the claims or drawings after amendment by Written Correction of Mistranslation).

(3) One should make sure not to perform any corrections that invoke a violation against Patent Act Article 17-2(4) when amending the scope of claims.

Please contact the following contact, if there is any inquiries about the contents of this Notification of Reasons for Refusal or a request for an interview with the examiner. When sending of a draft amendment etc. is wished by E-mail etc., please inform me of that by telephone.

The First Examination Department analysis diagnosis (medicine diagnosis) Okazaki *
TEL.03-3581-1101 Extension 3291

A Director(p.p.), an examiner, and assistant examiner OKUMA, Yasuo -- * ▲ tearing --
▼ and 9710 3330

拒絶理由通知書

特許出願の番号	特願 2 0 2 0 - 1 1 8 4 9 8
起案日	令和 3 年 8 月 2 日
特許庁審査官	岡▲さき▼ 潤 3 3 3 0 2 Q 0 0
特許出願人代理人	三好 秀和（ほか 3 名） 様
適用条文	第 2 9 条第 2 項（進歩性） 第 3 6 条第 6 項第 2 号（明確性）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から 3 か月以内に意見書を提出してください。

理由

1.（進歩性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第 2 9 条第 2 項の規定により特許を受けることができない。

2.（明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第 3 6 条第 6 項第 2 号に規定する要件を満たしていない。

記 （引用文献等については引用文献等一覧参照）

●理由 1（進歩性）について

- ・請求項 1-1 0
- ・引用文献等 1-2
- ・備考

[請求項 1 について]

引用文献 1（[0019]-[0055], 図 5-8）には、
採血器（sample vessels 506; [0038]等）によって集められる血液サンプル（[0020]等）を最適化するための血液サンプル最適化システム（sample-procurement system; [0038]等）であって、

患者の血液サンプル、少なくとも汚染物質を含む（[0021]等）前記血液サンプルの第 1 の部分を取り出せるようにするために患者の静脈穿刺用に構成された患者針（first needle 508; [0038]等）と、

前記患者針に接続され、前記血液サンプルを運ぶように構成された採血経路と（図5等参照）、

前記血液サンプルの第2の部分を集めるために前記採血器を受け入れるように構成されたサンプル針（図5等の示唆参照）と、

前記患者針と前記サンプル針との間の前記採血経路に接続された血液隔離装置であって、

前記血液サンプルを受け入れるように構成された入口ポート（sterile input tubing 514; [0039]等）と、

前記入口ポートに接続され、隔離チャンバであって、前記血液サンプルの第1の部分を受け入れ、前記血液サンプルの第1の部分に汚染物質を含むように構成された隔離チャンバ（pre-sample reservoirs 504; [0038]等）と、

前記入口ポートに接続される近位端を有し、前記血液サンプルの第2の部分を受け入れるように構成されたサンプリング流路と（second sterile output tubing 518; [0038], 図5等）を含み、

前記隔離チャンバ、前記サンプリング流路及び前記入口ポートは、前記血液サンプルの第2の部分が前記隔離チャンバを迂回することを可能にし、前記血液サンプルの第2の部分を前記出口ポートに向かわせるように構成され、前記出口ポートは、前記血液サンプルの第2の部分を前記採血器に排出するように構成される（[0038]等）、血液隔離装置とを含む、血液サンプル最適化システム、が記載されている。

引用文献2（[0012]-[0013]等）には、血液サンプル最適化システム（採血針）において、空気透過性血液バリア（空気透過性血液不透過性部材23）を含む通気口を有する隔離チャンバであって、通気口を通して隔離チャンバ内の空気を追い出す隔離チャンバを構成する技術、ポート、隔離チャンバ及び流路を収容及び画定するハウジング（針管支持体2）を構成する技術、が開示されている。

引用文献1-2に記載のものは、採血分野という同一の技術分野に属する。

引用文献1に記載のものにおいて、引用文献2に記載の技術を参考として、本願の請求項1に係る発明と同様の空気透過性血液バリアとハウジングを具備するよう構成することは、当業者にとって容易である。

[請求項2, 4について]

引用文献2の[0012]-[0013]を参照。

[請求項3について]

サンプル針に密封材を配置することは、設計的な事項といえる。

[請求項5について]

引用文献2の[0011]参照。

[請求項6について]

引用文献1の図5を参照。

[請求項7-10について]

引用文献1-2の記載を含め既述の説示を参照。

●理由2（明確性）について

・請求項 1-10

請求項1-10の記載は、以下の点で不明確である。よって、請求項1-10に係る発明は、明確でない。

（1）請求項1の記載について

請求項1の「患者の血液サンプル、少なくとも汚染物質を含む前記血液サンプルの第1の部分」との記載は、「少なくとも汚染物質を含む」ことが「血液サンプル」に係っているのか、「前記血液サンプルの第1の部分」に係っているのか、日本語として不明確である。引用項においても同様。

（2）請求項4，7の記載について

請求項4，7の「前記血液サンプルの後続の部分」との記載は、いかなる部分に「後続」するものを特定しているのか不明確である。引用項においても同様。

<引用文献等一覧>

1. 米国特許出願公開第2008/0145933号明細書
2. 特開2001-000424号公報

<先行技術文献調査結果の記録>	
・調査した分野	I P C A 6 1 B 5 / 0 0 - 5 / 3 9 8 D B 名
・先行技術文献	特開昭58-025146号公報 特表平09-504726号公報 特開平02-224742号公報 米国特許出願公開第2011/0306899号明細書

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません

。

＜補正をする際の注意＞

（１）明細書、特許請求の範囲について補正をする場合は、補正により記載を変更した個所に下線を引いてください（特許法施行規則様式第１３備考６、７）。

（２）補正は、この出願の外国語書面の翻訳文（又は誤訳訂正書による補正後の明細書、特許請求の範囲若しくは図面）に記載した事項の範囲内で行わなければなりません。また、意見書で、各補正事項について補正が適法なものである理由を、根拠となる翻訳文（又は誤訳訂正書による補正後の明細書、特許請求の範囲若しくは図面）の記載箇所を明確に示したうえで主張してください。

（３）特許請求の範囲について補正をする際には、特許法第１７条の２第４項に違反する補正とならないよう、注意してください。

この拒絶理由通知の内容に関するお問合せ又は面接のご希望がありましたら、次の連絡先までご連絡ください。電子メール等で補正案等の送付を希望される場合は、その旨を電話でお知らせください。

審査第一分析診断（医学診断） 岡崎 潤
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APPLICATION # **18/494,622** RECEIPT DATE / TIME **06/27/2024 05:37:33 PM Z ET** ATTORNEY DOCKET # **069366-0577657_KUR2C05US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9839	FILED BY	Trent Tercenio
PATENT CENTER #	66136962	FILING DATE	10/25/2023
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. ROGERS
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 66

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069366-0577657_KUR2C05US-A-NPL-047.pdf	6	Non Patent Literature	170 KB
069366-0577657_KUR2C05US-A-NPL-046.pdf	4	Non Patent Literature	735 KB
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069366-0577657_KUR2C05US-A-NPL-030.pdf	B17C00E83D4FCE3C45F4B431B181BA04D18C41160232C48D6511DFD96F9AEE8ED68B5359D78511CDAAE4C5B74933BF14FCE30D4A28159F4A404E9D2F8E742345
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069366-0577657_KUR2C05US_Transmittal-Letter.pdf	23EBEF6126D2C6CAEDD5083CC39A7FAAA7D1BA9C70A153C671EB6B5B82F2F8DF4965F78C5FBAD73A9C1A3EE46F73FE8DDC47BB878B4D1DCE4ECB370819776A63
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as

described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 1

Notice of Allowance
(Divisional)

Application Serial No.: 2021-214177
Drafting Date: June 16, 2023
Examiner: Naoya TAKAGI 3611 2Q00
Title of the Invention: BLOOD SAMPLE OPTIMIZATION SYSTEM AND
BLOOD CONTAMINANT SEQUESTRATION DEVICE
AND METHOD
Number of Claims: 20
Applicant(s): KURIN, INC.
Agent: MURAKOSHI, Satoshi

A decision is hereby made to grant patent right to the above identified patent application on the ground that no cause for rejecting the application has been found in the examination.

This is to certify that all the above-referenced items are identical to the JPO's official record.

Certificated: June 19, 2023

Administrative Official of Ministry of Economy, Trade and Industry, Takashi SATO

Note: Applicant must pay Issue Fee within 30 days from the mailing date indicated above.

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 2

- Type of Application: Divisional Application
- Cited References: Yes
- Grace Period under Patent Act Article 30: No
- Amendment to Title of the Invention: No
- Deposit of Biological Material : N/A

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 3/E

Reference Information

Application Serial No.: 2021-214177

- FI

A61B 5/15 200

- Search Fields (IPC, DB Name):

A61B 5/15-5/157

- References Cited :

Japanese Patent Application Publication No.2013-240628	(JP,A)
Japanese Patent Application Publication No.2016-504075	(JP,A)
International Patent Application Publication No.2014/058945	(WO,A1)
US Patent Application Publication No.2005/0245885	(US,A1)

- Non-patent literatures:

特許査定
(分割)

特許出願の番号	特願 2 0 2 1 - 2 1 4 1 7 7
起案日	令和 5 年 6 月 1 6 日
特許庁審査官	▲高▼木 尚哉 3 6 1 1 2 Q 0 0
発明の名称	流体分流デバイス、及び流体分流サンプリングシステム
請求項の数	2 0
特許出願人	クリン インコーポレイテッド
代理人	村越 智史 (ほか 4 名)

この出願については、拒絶の理由を発見しないから、特許査定をします。

上記はファイルに記録されている事項と相違ないことを認証する。

認証日 令和 5年 6月19日 経済産業事務官 佐藤 隆

注意：この書面を受け取った日から 3 0 日以内に特許料の納付が必要です。

- ・出願種別 分割
- ・参考文献 有
- ・特許法第30条適用 無
- ・発明の名称の変更 無

- ・菌寄託

参考情報

特許出願の番号 特願 2 0 2 1 - 2 1 4 1 7 7

・ F I

A 6 1 B 5 / 1 5 2 0 0

・ 調査した分野 (I P C , D B 名)

A 6 1 B 5 / 1 5 - 5 / 1 5 7

・ 参考特許文献

特開 2 0 1 3 - 2 4 0 6 2 8	(J P , A)
特表 2 0 1 6 - 5 0 4 0 7 5	(J P , A)
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米国特許出願公開第 2 0 0 5 / 0 2 4 5 8 8 5	(U S , A 1)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	18494622
	Filing Date	10/25/2023
	First Named Inventor	Bobby ROGERS
	Art Unit	3791
	Client Number	069366
Page 1 of 1	Matter Number	0577657_KUR2C05US

GENERAL
<p>Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.</p> <p>Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention, nor is it intended to constitute an admission that such information is "analogous prior art".</p> <p>In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.</p>

TIMING
<p>In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.</p>

CERTIFICATION STATEMENT
<p>No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).</p>

FEE
<p>No fee is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).</p>

ADDITIONAL COMMENTS

SIGNATURE			
Signature	/Benjamin F. Hudson/	Date	2024-06-27
Name	Benjamin F. Hudson	Registration Number	71,474

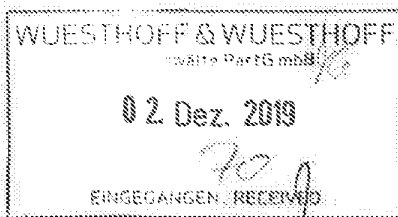


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Questions about this communication ?
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Wuesthoff & Wuesthoff
Patentanwälte PartG mbB
Schweigerstraße 2
81541 München
ALLEMAGNE



Date	02.12.19
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Reference EPA-148 105	Application No./Patent No. 19200766.4 - 1132
Applicant/Proprietor Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the European search report (R. 61 EPC) or the partial European search report/ declaration of no search (R. 63 EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

The following have been approved:

☐ Abstract

☒ Title

☒ The Abstract was modified and the definitive text is attached to this communication.

The following figure(s) will be published together with the abstract: 15C

Refund of search fee

If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued once the date of publication of the European search report has been mentioned in the European Patent Bulletin (R. 69(1), R. 70(2) EPC).





EUROPEAN SEARCH REPORT

Application Number
EP 19 20 0766

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29) * the whole document *	1-14	INV. A61B5/15 A61B5/153 A61B5/154
A	WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHER LLOYD [US]; BR) 29 December 2011 (2011-12-29) * paragraph [0070] * * figure 15 * * abstract *	1-14	
A	US 2009/227953 A1 (TAN CHEE LEONG [SG] ET AL) 10 September 2009 (2009-09-10) * the whole document *	1-14	
A	JP H08 257018 A (NISSHO KK) 8 October 1996 (1996-10-08) * abstract; figures *	1-14	
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A	US 3 648 684 A (BARNWELL CLEORA W ET AL) 14 March 1972 (1972-03-14) * abstract; figures *	1-14	A61B
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A	US 4 056 101 A (GEISSLER ULRICH C ET AL) 1 November 1977 (1977-11-01) * abstract; figures *	1-14	
		-/--	
The present search report has been drawn up for all claims			
Place of search Berlin		Date of completion of the search 18 November 2019	Examiner Schultz, Ottmar
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

EPO FORM 1503 03.02 (P04C01)



EUROPEAN SEARCH REPORT

Application Number
EP 19 20 0766

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	US 2013/317391 A1 (BULLINGTON GREGORY J [US] ET AL) 28 November 2013 (2013-11-28) * paragraphs [0084] - [0094] * * figures 16-18 * *****	1-14	
			TECHNICAL FIELDS SEARCHED (IPC)
The present search report has been drawn up for all claims			
Place of search Berlin		Date of completion of the search 18 November 2019	Examiner Schultz, Ottmar
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

EPO FORM 1500 01/02 (P040201)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 19 20 0766

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

18-11-2019

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			US 2019209066 A1	11-07-2019

EPO FORM P4452

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

TITLE: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE

APPLICANT: Kurin, Inc.

IPC CLASSIFICATION: A61B5/15, A61B5/153, A61B5/154

EXAMINER: Schultz, Ottmar

CONSULTED DATABASES: EPDOC, WPI, COMBI, TXT+

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150389, A61B5/150473, A61B5/150572, A61B5/153, A61B5/154

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:
See claims.



ABSTRACT / ZUSAMMENFASSUNG / ABRÉGÉ

19200766.4

Blood sample optimization systems and methods are described that reduce or eliminate contaminants in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device (1500) located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber (1508) for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel (1506) that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

Datum
Date cf Form 1507
Date

Blatt
Sheet 1
Feuille

Anmelde-Nr:
Application No: 19 200 766.4
Demande n°:

The examination is being carried out on the **following application documents**

Description, Pages

1-43 as originally filed

Claims, Numbers

1-14 as originally filed

Drawings, Sheets

1/50-50/50 as originally filed

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Reference is made to the following document; the numbering will be adhered to in the rest of the procedure.

D1: WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996.

- 1 The present application does not meet the requirements of Article 52(1) EPC, because the subject-matter of claims 1 and 6 are not new in the sense of Article 54(1) and (2) EPC.

The reasons are as follows:

- 1.1 Document D1 discloses (the references in parentheses applying to this document) all the features of claim 1, namely:

"A blood sequestration device (see figure 1: ref. sign 10 "*closed system blood sampling device*") **comprising;**

an inlet port (see figure 1: ref. sign 14 "*cannula tip*");

a junction (see fig. 1: the area where the bore 36 connects with bore 18) **connected with the inlet port;**

a sequestration chamber (see figure 1: ref. sign 22 "*blood disposal chamber*") **having a vent** (see figure 1: ref. sign 30 "*liquid tight, air permeable, hydrophobic membrane*") **comprising an air permeable blood barrier;**

a sampling channel (see figure 1: ref. sign 36 "bore") having a proximal end connected with the inlet port via the junction and a distal end connected with an outlet port (see fig. 1: ref. sign 42 "luer"); and

a housing (see fig. 1) that houses and defines the inlet port, the junction, the sequestration chamber, and the sampling channel, and the outlet port,

whereby the sequestration chamber (see figure 1: ref. sign 22 "blood disposal chamber") is connected (see fig. 1) with the inlet port via the junction which is configured to direct (see page 3, lines 1 to 4: "... It also feeds an initial fraction of withdrawn blood to a communicating blood disposal chamber which has an air permeable liquid sealed end ...") the first portion of blood to the sequestration chamber (see figure 1: ref. sign 22 "blood disposal chamber"), and the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood".

Claim 1 is thus not novel (Art. 54(1)(2) EPC).

- 1.2 Document D1 also discloses (the references in parentheses applying to this document) all the features of claim 1, namely:

"A system of a blood sequestration device (see figures 1, 2: ref. sign 10 "closed system blood sampling device"), a blood sampling pathway (see figures 2: ref. sign 50 "venipuncture device") having a patient needle, and a sample collection device (see figures 2: ref. sign 70 "syringe"), the blood sequestration device comprising;

an inlet port (see figure 1: ref. sign 14 "cannula tip") connected with the patient needle;

a junction (see fig. 1: the area where the bore 36 connects with bore 18) connected with the inlet port opposite the blood sampling pathway;

a sequestration chamber (see figure 1: ref. sign 22 "blood disposal chamber") having a vent (see figure 1: ref. sign 30 "liquid tight, air permeable hydrophobic membrane") comprising an air permeable blood barrier;

a sampling channel (see figure 1: ref. sign 36 "bore") having a proximal end connected with the inlet port; and

an outlet port (see fig. 1: ref. sign 42 "luer") connected with a distal end of the sampling channel and with the sample collection device; and

a housing (see fig. 1) that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel,

whereby the sequestration chamber is connected with the inlet port and the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with blood".

Claim 6 is thus not novel (Art. 54(1)(2) EPC).

- 2 The dependent claims 2 to 5 and 7 to 14 do not appear to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to novelty (Art. 54(1)(2), EPC) and/or inventive step (Article 56, EPC), the reasons being as follows:

Ad claims 2, 12, 13: Not novel, see D1, figure 1;

Ad claims 3, 4: Not novel, see D1, figures 1, 2;

Ad claims 5, 14: Not inventive to design the housing from two parts, see D1, figure 1;

Ad claims 7, 8, 9, 10, 11: Not novel, see D1, figures 2.

- 3 Further objections:

- 3.1 The closest prior art (see document D1) is not acknowledged in the description (Rule 42(1)(b) EPC).

- 3.2 Claim-like clauses appended at the end of the description (see pages 39 to 43) must also be deleted prior to grant, since they otherwise may lead to unclarity as to the actual scope of protection (Guidelines F-IV, 4.4).

- 3.3 "Incorporation by reference" is not an option in the European procedure since the concerned subject-matter does not fall within the scope of the claims (Article 84 EPC); the description thus requires amendment in this respect at paragraph [0001].

- 4 It is not at present apparent which part of the application could serve as a basis for a new, allowable claim.

- 5 If, however, filing an amended set of claims, **arguments in support of inventive step in the form of a problem-solution approach according to the Guidelines G-VII, 5 should be provided in an accompanying letter.**

- 6 Since the present description will not be consistent with the subject-matter as defined by such an amended set of claims, **to expedite the examining procedure** the applicant should then at the same time bring **all affected passages** of entire description into conformity with such an amended set of claims, i.e. the applicant should limit the application to the embodiment of the invention, namely as defined by an amended independent claim, and to the preferred embodiments, namely as defined by amended dependent claims.

In this respect, it is noted that terms like "*... may ...*", "*... can ...*", etc. as used throughout the description are not allowed if the related feature is part of the invention as defined by the independent claims. **Appropriate amendments are required.**

It is noted that anything denoted "*... embodiment ...*" and "*... invention ...*" must fall under the scope of protection sought, otherwise it is not an embodiment and not an invention.

Therefore, all the terms like "*... aspect of the invention ...*", "*... embodiment ...*", "*... invention ...*", "*... variation of the invention ...*", etc. related to all further inventions and further features or methods not covered by the amended set of claims should be replaced by the term "*... **example not being part of the invention** ...*", if not then the remaining embodiments are to be excised from the amended set of claims, description and drawings or to be denoted not forming part of the present invention but represent background art that is useful for understanding the invention (see Guidelines F-IV, 4.3(iii)).

The subject-matter concerning the embodiments to be excised may be made the subject of one or more divisional applications according to Rule 36 EPC.

- 7 Care should then also be taken during revision of the description and the claims not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

Intermediate generalisations should also be avoided (Art. 123(2) EPC and Guidelines H-V, 3.2.1).

Datum
Date of Form 1507
Date

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Sheet 5
Feuille

Anmelde-Nr:
Application No: 19 200 766.4
Demande n°:

To make sure that the new set of claims meets the requirements of Art. 123(2) EPC and Guidelines H-V, 3.2.1, the applicant is requested to double check and provide basis for the amendments by references to the application as filed in the accompanying letter in his own interest.

+++++



European Patent Office
80298 MUNICH
GERMANY

Questions about this communication?
Contact Customer Services at www.epo.org/contact



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Date	26.07.2023
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Reference KUR-002EP3	Application No./Patent No. 23155927.9 - 1122 / 4215114
Applicant/Proprietor Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the European search report (R. 61 EPC) or the partial European search report/ declaration of no search (R. 63 EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

The following have been approved:

☐ Abstract ☐ Title

☒ The Abstract was modified and the definitive text is attached to this communication.

The following figure(s) will be published together with the abstract: 23B

Refund of search fee

If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued once the date of publication of the European search report has been mentioned in the European Patent Bulletin (R. 69(1), R. 70(2) EPC).



Datum
Date cf Form 1507
Date

Blatt
Sheet 1
Feuille

Anmelde-Nr:
Application No: 23 155 927.9
Demande n°:

The examination is being carried out on the **following application documents**

Description, Pages

1-35 as originally filed

Claims, Numbers

1-16 filed in electronic form on 20-02-2023

Drawings, Sheets

1/50-50/50 as originally filed

Reference is made to the following document; the numbering will be adhered to in the rest of the procedure.

D1 WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29)

1. The amendments filed with the letter dated 20-02-2023 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 123(2) EPC. The amendments concerned are the following: claims 1-16 relate to a device while the application as filed as well as in particular paragraphs [0051],[0125],[0126] relate to a blood sequestration device.

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claim 1 is not new within the meaning of Article 54(1) and (2) EPC.

D1 discloses a device (10) comprising:

an inlet port (14);

an outlet port (42);

a chamber (22) connected with the inlet port (14) and configured to receive a first portion of blood the chamber (22) including an air permeable material (30) that seals at least partially upon contact with a portion of the first portion of blood (see p.7 I.172-174); and

a sampling channel (36) having a proximal end connected with the inlet port (14, see fig. 1) and a distal end connected with the outlet port (42, see fig.1).

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

3. Dependent claims 2-16 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to novelty and/or inventive step.

3.1 The features of claims 2,9,10,13,15 are merely some straightforward possibilities which the skilled person would select, depending on the circumstances, without exercising inventive skill, in order to solve the problem posed.

3.2 The subject matter of claim 3 is already known from D1 (p.7 I.172-174).

3.3 The subject matter of claim 4 is already known from D1 (p.7 I.188,189).

3.4 The subject matter of claim 5 is already known from D1 (fig. 1).

3.5 The subject matter of claims 6,7 is already known from D1 (p.5 I.2).

3.6 The subject matter of claim 8 is already known from D1 (p.4 I.25: adsorbing material 24).

3.7 The subject matter of claims 11,12,14 is already known from D1 (fig.1).

3.8 The subject matter of claim 16 is already known from D1 (fig.2).

4. The applicant **should bring the description into conformity** with the claims on file (Article 84 EPC). In particular should features that are present in the independent claim(s) not be referred to as options in the form of e.g. "in some instances", "in some embodiments", "in a preferred embodiment" and so forth, but be clearly identified as forming part of the invention. **This applies to the description as a whole**, not only to the introductory part. The "Summary of The Invention" should likewise be amended, i.e. recitation of superseded claims be removed or adapted to the wording of the new claims. Please also note that no method is claimed.

5. To meet the requirements of Rule 42(1)(b) EPC, the document D1 should be identified in the description and the relevant background art disclosed therein should be briefly discussed, observing that references to the prior art introduced after filing must be purely factual.

6. In order to meet the requirements of Rule 43(1) EPC, the independent claim should be properly cast in the two-part form, with those features which in combination are part of the prior art being placed in the preamble (see Guidelines F-IV, 2.2). Arguments in support of inventive step should be presented in an accompanying letter.

If the applicant is of the opinion that a two-part form of claim would be inappropriate he is invited to provide reasons in his reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of the independent claim are known from the prior art (see Guidelines F-IV, 2.3.2).

7. The vague and imprecise statements used in the description at paragraph [0128] imply that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 84 EPC) when used to interpret them (see the Guidelines, F-IV, 4.4). These statements should therefore be amended to remove this inconsistency.

8. "Incorporation by reference" is not an option in the European procedure; the description thus requires amendments in this respect at paragraph.

9. The unit inch expressed in paragraphs [0084],[0090],[0105] does not meet the requirements of Rule 49(10) EPC and should be replaced by the appropriate SI unit (see Guidelines F-II, Annex 2). The present expression should, however, be retained in parentheses after the replacement expression.

10. Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage, **not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).**

11. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant should **clearly identify the amendments made**, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (**see Guidelines H-IV**).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

12. Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).

13. Amendments should be made by filing replacement pages. Unnecessary recasting of the description should be avoided. An amended abstract is not required. The applicant should also take account of the requirements of Rule 50(1) EPC. According to Rule 50(1) in conjunction with Rule 49(8) EPC, amendments shall be typed or printed. Handwritten amendments may only be made in documents other than those replacing application documents (Rule 50(2) EPC); they may, for example, be used to fulfil the requirements of Rule 137(4) EPC (identifying amendments and indicating basis for them).

14. In order to expedite the procedure, the applicant is requested to deal with all of the raised objections and to **perform all necessary amendments along with the first response to this communication.**



EUROPEAN SEARCH REPORT

Application Number
EP 23 15 5927

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29) * the whole document *	1-16	INV. A61B5/15 A61B5/153 A61B5/154

A	WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHER LLOYD [US]; BR) 29 December 2011 (2011-12-29) * paragraph [0070] * * figure 15 * * abstract *	1-16	

A	US 2009/227953 A1 (TAN CHEE LEONG [SG] ET AL) 10 September 2009 (2009-09-10) * the whole document *	1-16	

A	JP H08 257018 A (NISSHO KK) 8 October 1996 (1996-10-08) * abstract; figures *	1-16	

A	US 4 416 291 A (KAUFMAN JOSEPH [US]) 22 November 1983 (1983-11-22) * column 5, line 40 - line 52; figure 7 *	1-16	TECHNICAL FIELDS SEARCHED (IPC) A61B

The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 18 July 2023	Examiner Coja, Michael
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

1
EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 23 15 5927

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

18-07-2023

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
WO 9605875	A1	29-02-1996	AT	208640 T		15-11-2001
			AU	686450 B2		05-02-1998
			CA	2173331 A1		29-02-1996
			DE	69523887 T2		29-08-2002
			EP	0725658 A1		14-08-1996
			JP	H09504726 A		13-05-1997
			US	5947932 A		07-09-1999
			WO	9605875 A1		29-02-1996

WO 2011162772	A1	29-12-2011	NONE			

US 2009227953	A1	10-09-2009	US	2009227953 A1		10-09-2009
			US	2010262038 A1		14-10-2010
			US	2012330187 A1		27-12-2012

JP H08257018	A	08-10-1996	NONE			

US 4416291	A	22-11-1983	AU	549400 B2		23-01-1986
			BR	8202753 A		19-04-1983
			EP	0070356 A2		26-01-1983
			ES	8307509 A1		01-07-1983
			JP	S649011 B2		16-02-1989
			JP	S5825146 A		15-02-1983
			MX	151907 A		02-05-1985
			NZ	200914 A		31-05-1984
			US	4416291 A		22-11-1983
			ZA	822891 B		30-03-1983
			ZA	822892 B		30-03-1983

Information on Search Strategy

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

EP 23 15 5927

TITLE: BLOOD SAMPLE CONTAMINANT SEQUESTRATION DEVICE

APPLICANT: Kurin, Inc.

IPC CLASSIFICATION: A61B5/15, A61B5/153, A61B5/154

EXAMINER: Coja, Michael

CONSULTED DATABASES: EPODOC, WPI, COMBI, TXT+

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150389, A61B5/150473, A61B5/150572, A61B5/153, A61B5/154, A61B5/150251

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:



European Patent Office
80298 MUNICH
GERMANY

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Date	22.04.2024
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Reference KUR-008EP1	Application No./Patent No. 21818838.1 - 1122 / 4158303 PCT/US2021035294
Applicant/Proprietor Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the supplementary European search report (Art. 153(7) EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

Refund of the search fee

If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued shortly (R. 70(2) EPC).



Datum
Date cf Form 1507
Date

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Sheet 1
Feuille

Anmelde-Nr:
Application No: 21 818 838.1
Demande n°:

The examination is being carried out on the **following application documents**

Description, Pages

1-49 as published

Claims, Numbers

1-15 filed in electronic form on 01-09-2023

Drawings, Sheets

1/81-81/81 as published

Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

- D1 WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US])
5 December 2019 (2019-12-05)
- D2 WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US])
21 March 2019 (2019-03-21)

1. The amendments filed with the letter dated 01-09-2023 introduce subject-matter which extend beyond the content of the application as filed, contrary to Article 123(2) EPC. The amendments concerned are the following:

- removal of the features "**a displaceable plug between the inlet and the sample path that is displaced by the subsequent pressure differentials to allow the subsequent portions of the fluid to be conveyed through the sample path**" in claim 1.

Indeed these features appear to be described as essential throughout the original description and figures (see also claim 6 of the original application and Guidelines H-V. 3.1). Furthermore no alternatives for these features are presented in the application as originally filed.

The applicant is invited to indicate where the basis for claim 1 can be found in the original application as filed.

Further amendments appear to be contrary to Article 123(2) EPC:

- features **"wherein the displaceable plug (3119) is hollowed out towards the sample path (3118) or hollowed out away from the sample path (3118)"** in claim 10
- features **"wherein the device (3100) is configured to allow a free flow of fluid from the inlet (3112) to the sample path (3118) when the displaceable plug (3119) moves into a receptacle"** in claim 15

No basis for these amendments could be found in the original application.

The applicant is invited to indicate where the basis for the dependent claims 10 and 15 as well as for the dependent claims 2-9 and 11-14 can be found in the original application as filed.

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claim 1 is not new within the meaning of Article 54(1) and (2) EPC.

2.1 D1 discloses **a device** (see fig.11-14: 600;700) **comprising:**

an inlet (612);

an outlet (616);

a sample path (654;754) **connected between the inlet and the outlet;**

a chamber (614) **connected between the inlet and the outlet, the chamber having an air permeable fluid resistor** (615) **proximate the outlet** (see par.[0148]: "The flow controller 615 can be any suitable shape, size, and/or configuration and can be configured to selectively control, permit, allow, and/or transfer a flow of fluid therethrough. For example, as described above, the flow controller 615 can be a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid (e.g., bodily fluid)."), **the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of a fluid sample to displace air therein through the air permeable fluid resistor and the outlet** (see par.[0158]: "Thus, when a negative pressure is generated within a portion of the device 700 (e.g., in response to coupling a fluid collection device to an outlet of the device 700), an initial volume of bodily fluid can flow into a sequestration chamber of the device 700 (e.g., a sequestration portion of the device 700, a sequestration flow path, a sequestration reservoir or container, etc.), as

described in detail above with reference to the device 600."), **with subsequent portions of the fluid sample conveyed by the sample path from the inlet to the outlet** (see par.[0160]:" Thus, a subsequent volume of bodily fluid that is substantially free of contaminants can flow through the device 700 and into the fluid collection device coupled thereto."); **and a displaceable plug (676;775) which, when displaced, allows the subsequent portions of the fluid sample to be conveyed through the sample path.**

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

2.2 Furthermore, the document D2 also disclose all the features of claim 1. For further details, see the relevant parts thereof as cited in the Search Report.

3. The dependent claims 2 to 15 seem not to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC in respect of novelty and/or inventive step, defining either features already known from any of D1-D2 or straightforward possibilities from which the person skilled in the art would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

4. The applicant **should bring the description into conformity** with the claims on file (Article 84 EPC). In particular should features that are present in the independent claim(s) not be referred to as options in the form of e.g. "in some instances", "in some embodiments", "in a preferred embodiment" and so forth, but be clearly identified as forming part of the invention. **This applies to the description as a whole**, not only to the introductory part. The "Summary of The Invention" should likewise be amended, i.e. recitation of superseded claims be removed or adapted to the wording of the new claims. Please also note that no method is claimed.

5. To meet the requirements of Rule 42(1)(b) EPC, the documents D1 and D2 should be identified in the description and the relevant background art disclosed therein should be briefly discussed, observing that references to the prior art introduced after filing must be purely factual.

6. In order to meet the requirements of Rule 43(1) EPC, the independent claim should be properly cast in the two-part form, with those features which in combination are part of the prior art being placed in the preamble (see Guidelines F-IV, 2.2). Arguments in support of inventive step should be presented in an accompanying letter.

If the applicant is of the opinion that a two-part form of claim would be inappropriate he is invited to provide reasons in his reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of the independent claim are known from the prior art (see Guidelines F-IV, 2.3.2).

7. The features of the claims should be provided with **reference signs placed in parentheses** to increase the intelligibility of the claims (Rule 43(7) EPC). This applies to both the preamble and characterising portion (see Guidelines F-IV, 4.19).

8. The vague and imprecise statements (e.g. "any modifications", "spirit of the invention") used in the description at paragraphs [0065],[0194],[0212] imply that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 84 EPC) when used to interpret them (see the Guidelines, F-IV, 4.4). These statements should therefore be amended to remove this inconsistency.

9. "Incorporation by reference" is not an option in the European procedure; the description thus requires amendments in this respect at paragraph [0001].

10. The unit inch expressed in paragraphs [0095],[0101],[0117],[0158] does not meet the requirements of Rule 49(10) EPC and should be replaced by the appropriate SI unit (see Guidelines F-II, Annex 2). The present expression should, however, be retained in parentheses after the replacement expression.

11. Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage, **not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).**

12. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant should **clearly identify the amendments made**, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (**see Guidelines H-IV**).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

13. Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).

14. Amendments should be made by filing replacement pages. Unnecessary recasting of the description should be avoided. An amended abstract is not required. The applicant should also take account of the requirements of Rule 50(1) EPC. According to Rule 50(1) in conjunction with Rule 49(8) EPC, amendments shall be typed or printed. Handwritten amendments may only be made in documents other than those replacing application documents (Rule 50(2) EPC); they may, for example, be used to fulfil the requirements of Rule 137(4) EPC (identifying amendments and indicating basis for them).

15. In order to expedite the procedure, the applicant is requested to deal with all of the raised objections and to **perform all necessary amendments along with the first response to this communication**.

Information on Search Strategy

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

EP 21 81 8838

TITLE: FLUID OPTIMIZATION AND CONTAMINANT CONTAINMENT DEVICE AND METHOD USING DISPLACEABLE PLUG

APPLICANT: Kurin, Inc.

IPC CLASSIFICATION: G01N1/10, G01N1/02, A61B5/15, A61B5/00, A61M39/00, A61M39/06, B01L3/00, G01N1/18, A61B5/154

EXAMINER: Coja, Michael

CONSULTED DATABASES: EPDOC, WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150221, A61B5/150251

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

SUPPLEMENTARY EUROPEAN SEARCH REPORT

Application Number
EP 21 81 8838

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05) * the whole document *	1-15	INV. G01N1/10 G01N1/02 A61B5/15 A61B5/00
X	WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 21 March 2019 (2019-03-21) * paragraph [1070] - paragraph [1092]; figures 2-5 *	1-15	A61M39/00 A61M39/06 B01L3/00 G01N1/18 A61B5/154
A	US 2017/020427 A1 (ROGERS BOBBY E [US] ET AL) 26 January 2017 (2017-01-26) * the whole document *	1-15	
A	US 2018/353117 A1 (BULLINGTON GREGORY J [US] ET AL) 13 December 2018 (2018-12-13) * the whole document *	1-15	
A	US 2019/175087 A1 (BULLINGTON GREGORY J [US] ET AL) 13 June 2019 (2019-06-13) * the whole document *	1-15	TECHNICAL FIELDS SEARCHED (IPC)
A	US 2008/145933 A1 (PATTON RICHARD G [US]) 19 June 2008 (2008-06-19) * the whole document *	1-15	A61B
The supplementary search report has been based on the last set of claims valid and available at the start of the search.			
Place of search The Hague		Date of completion of the search 10 April 2024	Examiner Coja, Michael
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

2

EPO FORM 1503 03.82 (P04C04)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 21 81 8838

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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10-04-2024

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 21 81 8838

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10-04-2024

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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EP 21 81 8838

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10-04-2024

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US21/35294

A. CLASSIFICATION OF SUBJECT MATTER

IPC - G01N 1/10; G01N 1/02; A61B 5/15; A61B 5/00; A61M 39/00; A61M 39/06; B01L 3/00; G01N 1/18 (2021.01)

CPC - G01N 1/10; B01L 3/0203; A61B 5/15; G01N 1/02; A61B 5/15; A61B 5/150992; A61M 39/06; B01L 3/02; B01L 3/0289; B01L 3/0296; G01N 1/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGY INC) 05 December 2019; paragraphs [0021], [0036], [0148]-[0160]; figures 11-14	1-10, 14, 16-18
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Y		11-13, 15, 19-20
Y	WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGY INC) 21 March 2019; paragraphs [1146], [1149]-[1150]; figures 23-24	11-13, 15, 19-20

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

04 August 2021 (04.08.2021)

Date of mailing of the international search report

SEP 28 2021

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: James Scott Nolan
P.O. Box 371710
San Diego, CA 92110
United States Of America

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

SEP 28 2021

Applicant's or agent's file reference
KURIN8PCT

FOR FURTHER ACTION

Sec paragraph 2 below

International application No.

PCT/US21/35294

International filing date (day/month/year)

01 June 2021 (01.06.2021)

Priority date (day/month/year)

01 June 2020 (01.06.2020)

International Patent Classification (IPC) or both national classification and IPC

IPC - G01N 1/10; G01N 1/02; A61B 5/15; A61B 5/00; A61M 39/00; A61M 39/06; B01L 3/00; G01N 1/18 (2021.01)

CPC - G01N 1/10; B01L 3/0203; A61B 5/15; G01N 1/02; A61B 5/15; A61B 5/150992; A61M 39/06; B01L 3/02; B01L 3/0289; B01L 3/0296; G01N 1/18

Applicant Kurin, Inc.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion

04 August 2021 (04.08.2021)

Authorized officer

Shane Thomas

PCT Help Desk

Telephone No. 571-272-4300

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US21/35294

Box No. 1 Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed:
 - ☐ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US21/35294

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	11-13, 15, 19-20	YES
	Claims	1-10, 14, 16-18	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-10, 14, 16-18 lack novelty under PCT Article 33(2) as being anticipated by (NAME). WO 2019/232196 A1 to Magnolia Medical Technologies, INC. (herein "Magnolia'196").

As to claim 1, Magnolia'196 discloses a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source (devices and methods for procuring bodily fluid samples with reduced contaminants; paragraphs [0007], [0021]), a first portion of the fluid sample potentially having contaminants (fluid samples with reduced contaminants such as dermally residing microbes and/or other contaminants exterior to the bodily fluid source; paragraphs [0007], [0021]), the fluid sample optimization device (similar devices 600 and 700; paragraphs [0149], [0158]; figures 11-14) comprising: an inlet configured to connect with the fluid source (device 600 includes an inlet 612 and comparable IN for device 700; paragraph [0148]; figures 11-14); an outlet configured to connect with the fluid collection device (an outlet 616 and comparable OUT for device 700; paragraph [0148]; figures 11-14); a sample path connected between the inlet and the outlet (fluid flow path 654 and 754 (sample path); paragraphs [0148], [0158]; figures 11-14); a contaminant containment reservoir connected between the inlet and the outlet (a sequestration chamber 614 with a comparable section shown in device 700, shown between inlet and the outlet; paragraphs [0148], [0158]; figures 11-14), the contaminant containment reservoir having an air permeable fluid resistor proximate the outlet (sequestration chamber 614 in fluid communication with flow controller 615, a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid, with comparable structures shown in device 700; paragraphs [0148], [0158]; figures 11-14), the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (negative pressure within the fluid flow path 654 is transferred and/or exerted through the flow restrictor 631 and is operable in drawing an initial flow of bodily fluid from the inlet 612, through at least a portion of the fluid flow path 613, and into the sequestration chamber 614; paragraph [0154], [0158]; figures 11-14), the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet (sequestration chamber 614 in fluid communication with flow controller 615, a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid, with comparable structures shown in device 700; paragraphs [0148], [0158]; figures 11-14), such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir (volume of bodily fluid that is sufficient to fully wet or saturate the flow controller 615 and the flow controller 615 in its second or sealed state, the flow controller 615 substantially sequesters, blocks, isolates, separates, segregates, and/or otherwise prevents a flow of fluid (e.g., gas and liquid) through the flow controller 615, thereby sequestering and/or fluidically isolating the sequestration chamber 614 from the fluid flow path 654, and comparable structures for device 700; paragraphs [0155], [0158]; figures 11-14), subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet (when the flow controller 615 is placed in its second or sealed state, at least a portion of the negative pressure otherwise being exerted through the flow controller 615 is instead exerted on a concave side or surface of the diaphragm 676 or 776 and opens barriers 675 or 775 to define an opening which fluid can flow from inlet to outlet; paragraphs [0157]-[0158]; figures 11-14); and a displaceable plug between the inlet and the sample path that is displaced by the subsequent pressure differentials to allow the subsequent portions of the fluid to be conveyed through the sample path (barriers 675 and 775 are forced open when a negative pressure is generated within a portion of the device 700; paragraphs [0157]-[0158], [0160]; figures 11-14).

As to claim 2, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 1, and Magnolia'196 further discloses further comprising a housing that houses and defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir (a fluid control device includes a housing, specifically first portion 624 and the second portion 625 can be collectively disposed in a housing; paragraphs [0021], [0149]).

As to claim 3, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 1, and Magnolia'196 further discloses wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (flow controller 615 can be a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid, or its first state is at a permeable state and is saturated to a sealed state; paragraphs [0148], [0155]).

As to claim 4, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 1, and Magnolia'196 further discloses wherein the contaminant containment reservoir includes a main basin and a channel connecting the main basin and the inlet (the inlet 612 via the fluid flow path 613 feeds into sequestration chamber 614, with comparable structures shown in device 700; paragraphs [0148], [0158]; figures 11-14).

----Continued in Supplemental Box----

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US21/35294

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

---Continued From Box V. 2: Citations and Explanations---.

As to claim 5, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 1, and Magnolia'196 further discloses wherein each pressure differential is provided by a vacuum pressure from the fluid collection device (a fluid collection device configured to define or produce a vacuum, to produce negative pressures in device 600; paragraphs [0036], [0152]).

As to claim 6, Magnolia'196 discloses a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source (devices and methods for procuring bodily fluid samples with reduced contaminants; paragraphs [0007], [0021]), a first portion of the fluid sample potentially having contaminants (fluid samples with reduced contaminants such as dermally residing microbes and/or other contaminants exterior to the bodily fluid source; paragraphs [0007], [0021]), the fluid sample optimization device (similar devices 600 and 700; paragraphs [0149], [0158]; figures 11-14) comprising: an inlet configured to connect with the fluid source (device 600 includes an inlet 612 and comparable IN for device 700; paragraph [0148]; figures 11-14); an outlet configured to connect with the fluid collection device (an outlet 616 and comparable OUT for device 700; paragraph [0148]; figures 11-14); a sample path connected between the inlet and the outlet (fluid flow path 654 and 754 (sample path); paragraphs [0148], [0158]; figures 11-14), the sample path further having a displaceable plug that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path (barriers 675 or 775, in a first state, fluidically isolates at least a portion of the fluid flow path 654 from other portions of the device 600 or 700, causing contaminants to be sequestered; paragraphs [0153], [0157]-[0158], [0160]; figures 11-14); and a contaminant containment reservoir connected between the inlet and the outlet (a sequestration chamber 614 with a comparable section shown in device 700, shown between inlet and the outlet; paragraphs [0148], [0158]; figures 11-14), the contaminant containment reservoir further having an air permeable fluid resistor proximate the outlet (sequestration chamber 614 in fluid communication with flow controller 615, a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid, with comparable structures shown in device 700; paragraphs [0148], [0158]; figures 11-14), the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (negative pressure within the fluid flow path 654 is transferred and/or exerted through the flow restrictor 631 and is operable in drawing an initial flow of bodily fluid from the inlet 612, through at least a portion of the fluid flow path 613, and into the sequestration chamber 614; paragraph [0154], [0158]; figures 11-14), the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet (sequestration chamber 614 in fluid communication with flow controller 615, a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid, with comparable structures shown in device 700; paragraphs [0148], [0158]; figures 11-14), such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir (volume of bodily fluid that is sufficient to fully wet or saturate the flow controller 615 and the flow controller 615 in its second or sealed state, the flow controller 615 substantially sequesters, blocks, isolates, separates, segregates, and/or otherwise prevents a flow of fluid (e.g., gas and liquid) through the flow controller 615, thereby sequestering and/or fluidically isolating the sequestration chamber 614 from the fluid flow path 654, and comparable structures for device 700; paragraphs [0155], [0158]; figures 11-14), subsequent portions of the fluid sample displace the displaceable plug and are conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet (when the flow controller 615 is placed in its second or sealed state, at least a portion of the negative pressure otherwise being exerted through the flow controller 615 is instead exerted on a concave side or surface of the diaphragm 676 or 776 and opens barriers 675 or 775 to define an opening which fluid can flow from inlet to outlet; paragraphs [0157]-[0158]; figures 11-14).

As to claim 7, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 6, and Magnolia'196 further discloses further comprising a housing that houses and defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir (a fluid control device includes a housing, specifically first portion 624 and the second portion 625 can be collectively disposed in a housing; paragraphs [0021], [0149]).

As to claim 8, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 6, and Magnolia'196 further discloses wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (flow controller 615 can be a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid, or its first state is at a permeable state and is saturated to a sealed state; paragraphs [0148], [0155]).

As to claim 9 The fluid sample optimization device in accordance with claim 6, wherein the contaminant containment reservoir includes a tortuous path (the inlet 612 via the fluid flow path 613 (tortuous path) feeds into sequestration chamber 614, with comparable structures shown in device 700; paragraphs [0148], [0158]; figures 11-14).

As to claim 10, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 6, and Magnolia'196 further discloses wherein each pressure differential is provided by a vacuum pressure provided by the fluid collection device (a fluid collection device configured to define or produce a vacuum, to produce negative pressures in device 600; paragraphs [0036], [0152]).

As to claim 14, Magnolia'196 discloses a fluid sample optimization device for optimizing a fluid sample (devices and methods for procuring bodily fluid samples with reduced contaminants; paragraphs [0007], [0021]), a first portion of the fluid sample potentially having contaminants (fluid samples with reduced contaminants such as dermally residing microbes and/or other contaminants exterior to the bodily fluid source; paragraphs [0007], [0021]), the fluid sample optimization device (similar devices 600 and 700; paragraphs [0149], [0158]; figures 11-14) comprising: an inlet (device 600 includes an inlet 612 and comparable IN for device 700; paragraph [0148]; figures 11-14); an outlet (an outlet 616 and comparable OUT for device 700; paragraph [0148]; figures 11-14); a contaminant containment reservoir connected between the inlet and the outlet (a sequestration chamber 614 with a comparable section shown in device 700, shown between inlet and the outlet; paragraphs [0148], [0158]; figures 11-14), the contaminant containment reservoir having an air permeable fluid resistor proximate the outlet (sequestration chamber 614 in fluid communication with flow controller 615, a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid, with comparable structures shown in device 700; paragraphs [0148], [0158]; figures 11-14), the contaminant containment reservoir being arranged to receive, when a pressure

---Continued Within the Next Supplemental Box---.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US21/35294

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

-***-Continued from previous Supplemental Box-***-

differential is applied between the inlet and the outlet (negative pressure within the fluid flow path 654 is transferred and/or exerted through the flow restrictor 631 and is operable in drawing an initial flow of bodily fluid from the inlet 612, through at least a portion of the fluid flow path 613, and into the sequestration chamber 614; paragraph [0154], [0158]; figures 11-14), a first portion of the fluid sample to displace air therein through the air permeable fluid resistor and the outlet (sequestration chamber 614 in fluid communication with flow controller 615, a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid, with comparable structures shown in device 700; paragraphs [0148], [0158]; figures 11-14), such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir (volume of bodily fluid that is sufficient to fully wet or saturate the flow controller 615 and the flow controller 615 in its second or sealed state, the flow controller 615 substantially sequesters, blocks, isolates, separates, segregates, and/or otherwise prevents a flow of fluid (e.g., gas and liquid) through the flow controller 615, thereby sequestering and/or fluidically isolating the sequestration chamber 614 from the fluid flow path 654, and comparable structures for device 700; paragraphs [0155], [0158]; figures 11-14); and a sample path connected between the inlet and the outlet (fluid flow path 654 and 754 (sample path); paragraphs [0148], [0158]; figures 11-14), the sample path further including a displaceable plug that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path during receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir (barriers 675 or 775, in a first state, fluidically isolates at least a portion of the fluid flow path 654 from other portions of the device 600 or 700, causing contaminants to be sequestered; paragraphs [0153], [0157]-[0158], [0160]; figures 11-14), wherein subsequent portions of the fluid sample are conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet (when the flow controller 615 is placed in its second or sealed state, at least a portion of the negative pressure otherwise being exerted through the flow controller 615 is instead exerted on a concave side or surface of the diaphragm 676 or 776 and opens barriers 675 or 775 to define an opening which fluid can flow from inlet to outlet; paragraphs [0157]-[0158]; figures 11-14).

As to claim 16, Magnolia'196 discloses, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 14, and Magnolia'196 further discloses comprising a housing that houses and defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir (a fluid control device includes a housing, specifically first portion 624 and the second portion 625 can be collectively disposed in a housing; paragraphs [0021], [0149]).

As to claim 17, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 14, and Magnolia'196 further discloses wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (flow controller 615 can be a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid, or its first state is at a permeable state and is saturated to a sealed state; paragraphs [0148], [0155]).

As to claim 18, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 14, and Magnolia'196 further discloses wherein the contaminant containment reservoir includes a main basin fluidically connected with the inlet by a conduit (the inlet 612 via the fluid flow path 613 feeds into sequestration chamber 614, with comparable structures shown in device 700; paragraphs [0148], [0158]; figures 11-14).

Claims 11-13, 15, and 19-20 lack an inventive step under PCT Article 33(3) as being obvious over Magnolia'196 in view of WO 2019/055487 A1 to Magnolia Medical Technologies, INC. (herein "Magnolia'487").

As to claim 11, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 6, and Magnolia'196 further discloses wherein the displaceable plug is fit into a portion of the sample path (barrier 775 provides a seal to the outlet flow path 754 and is moved linearly to provide flow, barrier is shown fit into a cavity of the device; paragraph [0159]-[0160]; figures 13-14). Magnolia'196 does not disclose a friction-fit. Magnolia'487 discloses a friction-fit (actuator rod 862, with ends 863 and 864 set into recesses in body 851 where the travel of the actuator is stopped by the recess (friction fit); paragraphs [1146], [1149]-[1150]; figures 23-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Magnolia'196 invention to provide a friction-fit, as taught by Magnolia'487, in order to provide a path for the flow diverter (Magnolia'487: paragraph [1149]).

As to claim 12, Magnolia'196 and Magnolia'487, in combination, disclose the fluid sample optimization device in accordance with claim 11, but Magnolia'196 does not disclose wherein the portion of the sample path in which the displaceable plug is friction-fit includes a seat. Magnolia'487 discloses a portion of the sample path in which the displaceable plug is friction-fit includes a seat (actuator rod 862, includes seals 865 that are shown as o-rings seated into the actuator; paragraphs [1146], [1149]-[1150]; figures 23-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Magnolia'196 invention to provide wherein the portion of the sample path in which the displaceable plug is friction-fit includes a seat, as taught by Magnolia'487, in order to provide a path for the flow diverter (Magnolia'487: paragraph [1149]).

As to claim 13, Magnolia'196 and Magnolia'487, in combination, disclose the fluid sample optimization device in accordance with claim 12, but Magnolia'196 does not disclose wherein the seat comprises an elastomeric O-ring. Magnolia'487 discloses the seat comprises an elastomeric O-ring (actuator rod 862, includes seals 865 that are shown as (elastomeric) o-rings seated into the actuator; paragraphs [1146], [1149]-[1150]; figures 23-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Magnolia'196 invention to provide wherein the portion of the sample path in which the displaceable plug is friction-fit includes a seat, as taught by Magnolia'487, in order to provide a path for the flow diverter (Magnolia'487: paragraph [1149]).

As to claim 15, Magnolia'196 discloses, Magnolia'196 discloses the fluid sample optimization device in accordance with claim 14, and Magnolia'196 further discloses wherein the displaceable plug is initially secured in the sample path proximate the inlet (barrier 775 provides a seal to the outlet flow path 754 and is moved linearly to provide flow, barrier is shown fit into a cavity of the device; paragraph

-***-Continued Within the Next Supplemental Box-***-

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US21/35294

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

-***-Continued from previous Supplemental Box-***-

[0159]-[0160]; figures 13-14). Magnolia'196 does not disclose by an elastomeric seat. Magnolia'487 discloses an elastomeric seat (actuator rod 862, includes seals 865 that are shown as (elastomeric) o-rings seated into the actuator; paragraphs [1146], [1149]-[1150]; figures 23-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Magnolia'196 invention to provide an elastomeric seat, as taught by Magnolia'487, in order to provide a path for the flow diverter (Magnolia'487: paragraph [1149]).

As to claim 19, Magnolia'196 and Magnolia'487, in combination, disclose the fluid sample optimization device in accordance with claim 15, and Magnolia'196 discloses wherein the displaceable plug is fit into a portion of the sample path (barrier 775 provides a seal to the outlet flow path 754 and is moved linearly to provide flow, barrier is shown fit into a cavity of the device; paragraph [0159]-[0160]; figures 13-14). Magnolia'196 does not disclose a friction-fit. Magnolia'487 discloses a friction-fit (actuator rod 862, with ends 863 and 864 set into recesses in body 851 where the travel of the actuator is stopped by the recess (friction fit); paragraphs [1146], [1149]-[1150]; figures 23-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Magnolia'196 invention to provide a friction-fit, as taught by Magnolia'487, in order to provide a path for the flow diverter (Magnolia'487: paragraph [1149]).

As to claim 20, Magnolia'196 and Magnolia'487, in combination, disclose the fluid sample optimization device in accordance with claim 19, but Magnolia'196 does not disclose wherein the displaceable plug is formed of an elastomeric material. Magnolia'487 discloses a displaceable plug is formed of an elastomeric material (actuator rod 862, includes seals 865 that are shown as (elastomeric) o-rings seated into the actuator; paragraphs [1146], [1149]-[1150]; figures 23-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Magnolia'196 invention to provide wherein the displaceable plug is formed of an elastomeric material, as taught by Magnolia'487, in order to provide a path for the flow diverter (Magnolia'487: paragraph [1149]).

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

拒絶理由通知書

特許出願の番号	特願 2 0 2 1 - 2 1 4 1 7 7
起案日	令和 4 年 1 1 月 2 9 日
特許庁審査官	▲高▼木 尚哉 3 6 1 1 2 Q 0 0
特許出願人代理人	三好 秀和（ほか 3 名） 様
適用条文	第 3 6 条第 6 項第 1 号（サポート要件） 第 3 6 条第 6 項第 2 号（明確性）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から 3 か月以内に意見書を提出してください。

理由

1. （サポート要件）この出願は、特許請求の範囲の記載が下記の点で、特許法第 3 6 条第 6 項第 1 号に規定する要件を満たしていない。
2. （明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第 3 6 条第 6 項第 2 号に規定する要件を満たしていない。

記

●理由 1（サポート要件）について

- ・請求項 1 - 2 0
- ・備考

本願の発明の詳細な説明には、本願発明の課題として、段落[0004]には、「血液培養を行うための血液サンプルの採取は、現代の患者ケアの重要な要素であり、正確な診断を提供することによって患者の結果に良い影響を与えることも、不必要な抗菌療法を長引かせ、入院期間を長くし、コストを増加させることによって結果に悪影響を与えることもある。」と記載され、段落[0007]には、「偽陽性の血液培養は、一般的に、不十分なサンプリング技術の結果である。それらは、必要でないときに抗生物質を使用させ、病院費及び患者の不安を増大させる。血液培養は、皮膚内への針刺しから採取され、その後で血液のサンプルを取り込むためにバキュテナー（登録商標）が取り付けられる。汚染は、穿刺部位及びその周辺の皮膚領域の不適切又は不完全な消毒によって生じ得る。それはまた、挿入

中の針による皮膚のくりぬきから、くりぬかれた皮膚細胞と関連する汚染物質とがサンプル中に引き込まれることで生じることもある。」と記載されており、血液培養のための血液サンプルの採取において、血液が汚染されることが記載されている。

そして、当該課題を解決するための手段として、段落[0014]には、「採血経路と接続される血液隔離デバイス」を備えることが記載されている。

そうすると、本願の発明の詳細な説明には、一貫して、汚染を避ける対象が「血液」であることが記載されていると言える。

しかしながら、本願の請求項1には、「流体分流デバイス」と記載されているのみであって、「流体」として「血液」を用いることが特定されていない。

よって、請求項1には、発明の詳細な説明に記載された、発明の課題を解決するための手段が反映されておらず、請求項1に係る発明は、発明の詳細な説明に記載した範囲を超えることとなる。

上記と同様の理由により、請求項8、請求項15は、発明の詳細な説明に記載した範囲を超えることとなる。

よって、請求項1－20に係る発明は、発明の詳細な説明に記載したものではない。

●理由2（明確性）について

・請求項 15－20

・備考

請求項15には、「前記チャンバ、前記サンプリング流路及び前記分岐点は、流体の第1の部分が前記チャンバに流れ込んで前記チャンバを満たし、前記空気透過孔を通して前記チャンバ内の空気を追い出すように、及び、流体の第2の部分が前記チャンバ及び前記チャンバ内に隔離された流体の第1の部分を迂回し、前記出口ポートに向かって前記サンプリング流路に導かれるように寸法設定されかつ構成される」ことが記載されているが、「前記空気透過孔を通して前記チャンバ内の空気を追い出すように、」との記載が、「流体の第1の部分」についての記載であるのか、あるいは、「流体の第2の部分」についての記載であるのか明らかでない。（上記記載の「流体の第1の部分が前記チャンバに流れ込んで前記チャンバを満たし、前記空気透過孔を通して前記チャンバ内の空気を追い出すように、」が「流体の第1の部分が前記チャンバに流れ込んで、前記空気透過孔を通して前記チャンバ内の空気を追い出すように、前記チャンバを満たし、」を意味するのであれば、そのように記載されたい。）

したがって、請求項15－20に係る発明は明確でない。

<先行技術文献調査結果の記録>

- ・調査した分野 I P C A 6 1 B 1 / 0 0 - 1 / 3 2
 G 0 2 B 2 3 / 2 4 - 2 3 / 2 6
- ・先行技術文献 特開 2 0 1 3 - 2 4 0 6 2 8 号公報
 特表 2 0 1 6 - 5 0 4 0 7 5 号公報
 国際公開第 2 0 1 4 / 0 5 8 9 4 5 号
 米国特許出願公開第 2 0 0 5 / 0 2 4 5 8 8 5 号明細書

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません。
。

この拒絶理由通知の内容に関するお問合せ又は面接のご希望がありましたら次の連絡先までご連絡ください。電子メール等で補正案等の送付を希望される場合は、その旨を電話でお知らせください。

審査第一部分析診断 医学診断(PA2J) 高木尚哉
T E L . 0 3 - 3 5 8 1 - 1 1 0 1 内線 3 2 9 2

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 1

Notice of Allowance
(Divisional)

Application Serial No.: 2021-214177
Drafting Date: June 16, 2023
Examiner: Naoya TAKAGI 3611 2Q00
Title of the Invention: BLOOD SAMPLE OPTIMIZATION SYSTEM AND
BLOOD CONTAMINANT SEQUESTRATION DEVICE
AND METHOD
Number of Claims: 20
Applicant(s): KURIN, INC.
Agent: MURAKOSHI, Satoshi

A decision is hereby made to grant patent right to the above identified patent application on the ground that no cause for rejecting the application has been found in the examination.

This is to certify that all the above-referenced items are identical to the JPO's official record.

Certificated: June 19, 2023

Administrative Official of Ministry of Economy, Trade and Industry, Takashi SATO

Note: Applicant must pay Issue Fee within 30 days from the mailing date indicated above.

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 2

- | | |
|---|------------------------|
| • Type of Application: | Divisional Application |
| • Cited References: | Yes |
| • Grace Period under Patent Act Article 30: | No |
| • Amendment to Title of the Invention: | No |
| • Deposit of Biological Material : | N/A |

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 3/E

Reference Information

Application Serial No.: 2021-214177

- FI

A61B 5/15 200

- Search Fields (IPC, DB Name):

A61B 5/15-5/157

- References Cited :

Japanese Patent Application Publication No.2013-240628	(JP,A)
Japanese Patent Application Publication No.2016-504075	(JP,A)
International Patent Application Publication No.2014/058945	(WO,A1)
US Patent Application Publication No.2005/0245885	(US,A1)

- Non-patent literatures:

特許査定
(分割)

特許出願の番号	特願 2 0 2 1 - 2 1 4 1 7 7
起案日	令和 5 年 6 月 1 6 日
特許庁審査官	▲高▼木 尚哉 3 6 1 1 2 Q 0 0
発明の名称	流体分流デバイス、及び流体分流サンプリングシステム
請求項の数	2 0
特許出願人	クリン インコーポレイテッド
代理人	村越 智史 (ほか 4 名)

この出願については、拒絶の理由を発見しないから、特許査定をします。

上記はファイルに記録されている事項と相違ないことを認証する。

認証日 令和 5年 6月19日 経済産業事務官 佐藤 隆

注意：この書面を受け取った日から 3 0 日以内に特許料の納付が必要です。

- ・出願種別 分割
- ・参考文献 有
- ・特許法第30条適用 無
- ・発明の名称の変更 無

- ・菌寄託

参考情報

特許出願の番号 特願 2 0 2 1 - 2 1 4 1 7 7

・ F I

A 6 1 B 5 / 1 5 2 0 0

・ 調査した分野 (I P C , D B 名)

A 6 1 B 5 / 1 5 - 5 / 1 5 7

・ 参考特許文献

特開 2 0 1 3 - 2 4 0 6 2 8	(J P , A)
特表 2 0 1 6 - 5 0 4 0 7 5	(J P , A)
国際公開第 2 0 1 4 / 0 5 8 9 4 5	(W O , A 1)
米国特許出願公開第 2 0 0 5 / 0 2 4 5 8 8 5	(U S , A 1)

・ 参考図書雑誌



UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	KURIN4CIP	6468
158174	7590	08/04/2022		
Kurin, Inc. P.O. Box 371710 San Diego, CA 92137			EXAMINER ABOUELELA, MAY A	
			ART UNIT	PAPER NUMBER
			3791	
			NOTIFICATION DATE	DELIVERY MODE
			08/04/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficeaction@appcoll.com
jsnolan1@hotmail.com
kurin@virtualipsupport.com

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 06/24/2020, 07/03/2020 and 09/18/2020. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

4. Claim 11 is objected to because of the following informalities: the phrase "in inlet port" in line 2 should be amended to read --an inlet port--. Appropriate correction is required.

5. Claim 11 is objected to because of the following informalities: the phrase "the vent further being further configured to" in line 8 should be amended to read --the vent further being configured to--. Appropriate correction is required.

6. Claim 12 is objected to because of the following informalities: the phrase “it” in line 3 should be amended to read –air--. Appropriate correction is required.

7. Claim 13 is objected to because of the following informalities: the phrase “a return” in line 2 should be amended to read –the return--. Appropriate correction is required.

8. Claim 18 is objected to because of the following informalities: the phrase “a patient” in line 4 should be amended to read –the patient--. Appropriate correction is required.

9. Claim 18 is objected to because of the following informalities: the phrase “at subsequent” in line 8 should be amended to read –a subsequent--. Appropriate correction is required.

10. Claim 19 is objected to because of the following informalities: the phrase “a return” in line 3 should be amended to read –the return--. Appropriate correction is required.

Claim Interpretation

11. The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

- (A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;
- (B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g., “means for”) or another linking word or phrase, such as “configured to” or “so that”; and
- (C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step”) in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word “means,” but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform

the recited function and the generic placeholder is not preceded by a structural modifier.

Such claim limitation(s) is/are:

Limitation “closure mechanism” in claim 12, the claim does not recite enough structure that corresponds to the claimed “closure mechanism”, however the specification disclose (the closure mechanism 3710 is a raised portion that is raised from an outer surface of the housing, par.215, the closure mechanism simply defines a surface to interface with another object, such as a human fingertip, a cotton swab, a piece of tape, or any other object, to seal any vents, apertures, openings, holes, par.216, closure mechanism in the form of a cap 3180 to enclose and/or seal air-permeable blood barrier and/or air vent, par.219).

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

12. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-20 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Claim 18 recites the limitation "the patient needle" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "the sample needle" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s)

because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1-20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 7-13 of co-pending Application No.17/094692, claims 1-20 of co-pending Application No.17/538990, claims 1-20 of U.S Patent Application

No.11311219, claims 1-16 of U.S Patent Application No. 9820682, claims 1-23 of U.S Patent Application No.10143412, and claims 1-2 of U.S Patent Application No.

11185266. Although the claims at issue are not identical, they are not patentably distinct from each other because the copending and patent applications and the instance application are claiming a common subject matter including: a blood sequestration device comprising; an inlet path; an outlet path; a sequestration chamber connected with the inlet path by a junction and being configured to receive a first portion of blood through the inlet path, the first blood portion is inhibited to return to the inlet path; and a sampling channel connected between the inlet path and the outlet path, the sampling channel being configured to convey subsequent amounts of blood between the inlet path and the outlet path.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

<i>Notice of References Cited</i>	Application/Control No. 16/819,033		Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA		Art Unit 3791	Page 1 of 4

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*	B	US-9138572-B2	09-2015	Zeytoonian; Paul	A61M39/26	1/1
*	C	US-8568371-B2	10-2013	Siopes; William	A61M39/26	251/903
*	D	US-8540663-B2	09-2013	Davey; Christopher T.	A61M1/30	604/93.01
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*	F	US-20160174888-A1	06-2016	Berthier; Erwin	A61B5/150503	600/573
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*	J	US-20040147855-A1	07-2004	Marsden, Stewart	A61B5/150496	600/576
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*	L	US-8535241-B2	09-2013	Bullington; Gregory	A61B10/0045	604/249
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*	B	US-20030105414-A1	06-2003	Leong, Alvin Tan Chee	A61B5/15003	600/576
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	Filing Date	2020-03-13
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	
	Attorney Docket Number	KURIN4CIP

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4444203	A	1984-04-24	Engelman	
	2	6398743	B1	2002-06-04	Halseth et al.	

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Application Number	16819033
Filing Date	2020-03-13
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	
Attorney Docket Number	KURIN4CIP

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Art Unit	3791
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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/JSN/	Date (YYYY-MM-DD)	2020-09-18
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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	1	4349035	A	1982-09-14	Thomas et al.	
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	1	20180271425	A1	2018-09-27	Kurin, Inc.	
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	3	20180353117	A1	2018-12-13	Magnolia Medical Technologies, Inc.	

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	1	International Search Report and Written Opinion dated 19 June 2020, for PCT application no. PCTUS2020/023617.	

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That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/JSN/	Date (YYYY-MM-DD)	2020-07-01
Name/Print	James S. Nolan	Registration Number	53,393

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16819033
	Filing Date	2020-03-13
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	
	Attorney Docket Number	KURIN4CIP

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	10010282	B2	2018-07-03	Rogers et al.	
	2	10143412	B2	2018-12-04	Rogers et al.	
	3	3648684	A	1972-03-14	Barnwell et al.	
	4	3741197	A	1973-06-26	Sanz et al.	
	5	3817240	A	1974-06-18	Ayres	
	6	3874367	A	1975-04-01	Ayres	
	7	3886930	A	1975-06-03	Ryan	
	8	4056101	A	1977-11-01	Geissler et al.	

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9	4057050	A	1977-11-08	Sarstedt	
10	4106497	A	1978-08-15	Percarpio	
11	4154229	A	1979-05-15	Nugent	
12	4207870	A	1980-06-17	Eldridge	
13	4412548	A	1983-11-01	Hoch	
14	4416290	A	1983-11-22	Lutkowski	
15	4813433	A	1989-03-21	Downey	
16	5222502	A	1993-06-29	Kurose	
17	5520193	A	1996-05-28	Suzuki et al.	
18	5749857	A	1998-05-12	Cuppy	
19	6569117	B1	2003-05-27	Ziv et al.	

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20	8070725	B2	2011-12-06	Christensen	
21	8197420	B2	2012-06-12	Patton	
22	8523826	B2	2013-09-03	Layton Jr.	
23	8535241	B2	2013-09-17	Bullington et al.	
24	8540663	B2	2013-09-24	Davey et al.	
25	8568371	B2	2013-10-29	Siopes et al.	
26	8603009	B2	2013-12-10	Tan et al.	
27	8864684	B2	2014-10-21	Bullington et al.	
28	9022951	B2	2015-05-05	Bullington et al.	
29	9060724	B2	2015-06-23	Bullington et al.	
30	9138572	B2	2015-09-22	Zeytoonian et al.	

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	31	9155495	B2	2015-10-13	Bullington et al.	
	32	9204864	B2	2015-12-08	Bullington et al.	
	33	9820682	B2	2017-11-21	Rogers et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20020004647	A1	2002-01-10	Leong	
	2	20030105414	A1	2003-06-05	Leong	
	3	20030208151	A1	2003-11-06	Kraus et al.	
	4	20040054333	A1	2004-03-18	Theeuwes et al.	
	5	20040073171	A1	2004-04-15	Rogers et al.	
	6	20040147855	A1	2004-07-29	Marsden	

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7	20050004524	A1	2005-01-06	Newby et al.	
8	20050005635	A1	2005-01-13	Metais	
9	20050007524	A1	2005-01-13	Luo et al.	
10	20050240161	A1	2005-10-27	Crawford	
11	20070088279	A1	2007-04-19	Shue et al.	
12	20080145933	A1	2008-06-19	Patton	
13	20080167577	A1	2008-07-10	Weilbacher et al.	
14	20080319346	A1	2008-12-25	Crawford et al.	
15	20090227953	A1	2009-09-10	Tan et al.	
16	20100010372	A1	2010-01-14	Brown et al.	
17	20100057004	A1	2010-03-04	Christensen et al.	

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18	20130317391	A1	2013-11-28	Bullington et al.	
19	20140039348	A1	2014-02-06	Bullington et al.	
20	20140107564	A1	2014-04-17	Bullington et al.	
21	20140155782	A1	2014-06-05	Bullington et al.	
22	20140276578	A1	2014-09-18	Bullington et al.	
23	20150246352	A1	2015-09-03	Bullington et al.	
24	20150342510	A1	2015-12-03	Bullington et al.	
25	20160017488	A1	2016-01-21	Kobayashi et al.	
26	20160174888	A1	2016-06-23	Berthier et al.	
27	20160361006	A1	2016-12-15	Bullington et al.	
28	20170020427	A1	2017-01-26	Rogers et al.	

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29	20170020428	A1	2017-01-26	Rogers et al.
30	20170065733	A1	2017-03-09	Bullington et al.
31	20180140240	A1	2018-05-24	Bullington et al.
32	20180177445	A1	2018-06-28	Rogers et al.
33	20180353117	A1	2018-12-13	Bullington et al.
34	20190159711	A1	2019-05-30	Rogers et al.

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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	1665986	EP	B1	2009-06-03	Bennett et al.		
	2	3324845	EP	A1	2018-05-30	Rogers et al.	Equivalent to WO2017/019552	
	3	3562397	EP	A1	2019-11-06	Rogers et al.	Equivalent to WO2018/125929	

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4	3622890	EP	A1	2020-03-18	Rogers et al.	
5	3622890	EP	A1	2019-10-01	Bobby E. Rogers	×
6	2012016496	JP	A	2012-01-26	Akiyama et al.	☐
7	2019534792	JP	A	2019-12-05	Seilinger et al.	☐
8	2020000340	JP	A	2020-01-09	Omura et al.	☒
9	5789869	JP	B2	2015-10-07	Suzuki, Tatsutoshi et al.	☒
10	5825146	JP	B2	2015-12-02	Karasawa et al.	☒
11	5867238	JP	B2	2016-02-24	Najiyanto et al.	☒
12	6643474	JP	B2	2020-02-12	Rogers, et al.	☒
13	H08257018	JP	A	1996-10-08	Higaki et al.	☒
14	H09504726	JP	A	1997-05-13	Desecki et al.	☐

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15	S5825146	JP	A	1983-02-15	Jiyosefu	☒
16	S5867238	JP	A	1983-04-21	Edowaado et al.	☐
17	2011162772	WO	A1	2011-12-29	Fischel et al.	☐
18	2013181352	WO	A1	2013-12-05	Bullington et al.	☐
19	2017019552	WO	A1	2017-02-02	Rogers et al.	☐
20	2018125929	WO	A1	2018-07-05	Rogers et al.	☐
21	9605875	WO	A1	1996-02-29	Desecki et al.	☐

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NON-PATENT LITERATURE DOCUMENTS

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	BULLINGTON, et al, Systems and Methods for Sample Collection with Reduced Hemolysis, Exhibit H in Provisional Application No. 62/517,681, dated 6/9/2017, 131 pages	
	2	Communication Under Rule 71(3) EPC dated 22 April 2020 for EP application no. 17840467.9	

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3	European Patent Application No. EP19200766.4 extended European Search Report dated December 2, 2019, 11 pages.
4	European Patent Office; Communication pursuant to Article 94(3) EPC; dated October 31, 2018.
5	Examination Report No. 1 dated 29 April 2020, for Australian Patent Application No. 2016297849.
6	International Search Report and Written Opinion for PCT/US16/43709, Dated October 19, 2016.
7	International Search Report/Written Opinion for PCT/US17/68569 dated 25 April 2018.
8	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application number JP2018-523384, dated July 23, 2019.

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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Signature	/JSN/	Date (YYYY-MM-DD)	2020-06-24
Name/Print	James S. Nolan	Registration Number	53393

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/094,692	11/10/2020	Bobby E. ROGERS	KURIN4CON	8012
158174	7590	11/04/2022		
Kurin, Inc. P.O. Box 371710 San Diego, CA 92137			EXAMINER ABOUELELA, MAY A	
			ART UNIT 3791	PAPER NUMBER
			NOTIFICATION DATE 11/04/2022	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficeaction@appcoll.com
jsnolan1@hotmail.com
kurin@virtualipsupport.com

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Objections

2. Claim 14 is objected to because of the following informalities: the phrase “into chamber” in line 8 should be amended to read –into the chamber--. Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1-18 and 20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S Patent Application No. 10827964. Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent Application and the instance application are claiming a common subject matter including: a blood sequestration/optimization device comprising; an inlet port; an outlet port; a chamber connected with the inlet port, the sequestration chamber having a vent configured to allow air to be displaced by a first portion of blood entering the inlet port and into sequestration chamber; a plug/closure to enclose the vent to inhibit air from reentering the sequestration chamber; a sampling

channel having a proximal end connected with the inlet port and a distal end connected with the outlet port, the sampling channel being configured to convey subsequent portions of blood past the sequestration chamber and to the outlet port after the first portion of blood has entered the sequestration chamber; and a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is

available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

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*	B	US-4412548-A	11-1983	Hoch; Louis	A61B5/150213	600/577
*	C	US-5222502-A	06-1993	Kurose; Katsutoshi	A61B5/150732	600/584
*	D	US-5520193-A	05-1996	Suzuki; Issei	A61B5/1545	604/126
*	E	US-20100057004-A1	03-2010	Christensen; Kelly D.	A61M39/22	604/122
*	F	US-20070088279-A1	04-2007	Shue; Ming-Jeng	A61M25/0693	604/168.01
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*	H	US-20040054333-A1	03-2004	Theeuwes, Felix	A61M5/14276	604/248
*	I	US-9022951-B2	05-2015	Bullington; Gregory	A61B10/0048	600/576
*	J	US-6569117-B1	05-2003	Ziv; David	A61M39/02	604/246
*	K	US-3741197-A	06-1973	Sanz; Manuel C.	A61B5/150267	600/583
*	L	US-20100010372-A1	01-2010	BROWN; LEROY R.	A61B5/15003	600/573
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*	D	US-9877675-B2	01-2018	Baid; Rishi	A61B5/150389	1/1
*	E	US-4444203-A	04-1984	Engelman; Allan	A61B5/150496	600/576
*	F	US-20070083162-A1	04-2007	O'Reagan; James	A61M39/26	604/167.03
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*	I	US-9155495-B2	10-2015	Bullington; Gregory J.	A61B5/150633	1/1
*	J	US-20160008579-A1	01-2016	Burkholz; Jonathan Karl	A61M5/158	604/164.08
*	K	US-20120016266-A1	01-2012	Burkholz; Jonathan Karl	A61B5/150992	600/581
*	L	US-4436098-A	03-1984	Kaufman; Joseph	A61B5/1545	604/199
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*	E	US-20160174888-A1	06-2016	Berthier; Erwin	A61B5/150503	600/573
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*	J	US-8864684-B2	10-2014	Bullington; Gregory J.	A61B10/0048	600/576
*	K	US-8535241-B2	09-2013	Bullington; Gregory	A61B5/150946	604/249
*	L	US-20040073171-A1	04-2004	Rogers, Bobby E.	A61M39/26	604/164.13
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*	C	US-9060724-B2	06-2015	Bullington; Gregory J.	A61B5/150099	1/1
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*	E	US-20020004647-A1	01-2002	Leong, Alvin Tan Chee	A61B5/1545	604/168.01
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<i>Search Notes</i> 	Application/Control No. 17/094,692	Applicant(s)/Patent Under Reexamination ROGERS et al.
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CPC - Searched*		
Symbol	Date	Examiner
A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503	10/13/2022	MA

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

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Search Notes		
Search Notes	Date	Examiner
class/subclass search, text search, inventor name search	10/13/2022	MA

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	
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PE2E SEARCH - Search History (Prior Art)

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L77	86	("2007/0083162").URP N.	(USPAT)	OR	OFF	OFF	2017/09/28 01:59 PM
L78	1	("15140443").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 01:59 PM
L79	9	("2008/0145933").URP N.	(USPAT)	OR	OFF	OFF	2017/09/28 02:04 PM
L80	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 02:20 PM
L81	1071	L80 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 02:20 PM
L82	78	L81 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 02:21 PM
L83	282596	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/09/28 04:01 PM
L84	6183	L83 AND (A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/09/28 04:01 PM
L85	387	L84 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:01 PM
L86	362	L85 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:02 PM
L87	12	("2005/0010189").URP N.	(USPAT)	OR	OFF	OFF	2017/09/28 04:03 PM
L88	1363	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:04 PM
L89	74	L88 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:05 PM
L90	21	("3965910" "3996923"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2017/09/28

		"4131127" "4301811" "4450854" "4506691" "4819684" "5147333" "5393035" "5636975").PN. OR ("6569117").URPN.	USOCR)				04:09 PM
L91	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:12 PM
L92	18	L91 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:12 PM
L93	9	("2008/0145933").URP N.	(USPAT)	OR	OFF	OFF	2017/09/28 04:13 PM
L95	67	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:23 PM
L96	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:25 PM
L97	4	L96 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:25 PM
L98	3	L97 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:26 PM
L99	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:50 PM
L100	13	L99 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:50 PM
L101	255	("1779451" "2004050" "2700385" "2836942" "2854976" "2953243" "3021942" "3073307" "3074542" "3255873" "3294231" "3323523" "3329146" "3333682" "3367488" "3382865" "3485239" "3537452" "3585984" "3610240" "3658061" "3664879" "3817240" "3828775" "3859998" "3874367" "3886930" "3890971" "3904033" "3934722" "3968876" "4106497" "4108175" "4113090" "4139009" "4154229" "4166450" "4175008" "4193400" "4207870" "4269186" "4300678" "4312362" "4317445" "4340068" "4375849" "4398544" "4409990" "4412548" "4416290" "4416291" "4418703" "4430082" "4436098" "4444203" "4592744"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/01/09 04:51 PM

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		"4659330"	"4664249"				
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		"4679571"	"4681567"				
		"4695274"	"4702738"				
		"4723943"	"4728320"				
		"4728321"	"4731059"				
		"4735311"	"4735618"				
		"4737144"	"4738663"				
		"4743233"	"4746008"				
		"4747836"	"4747837"				
		"4772272"	"4778453"				
		"4781697"	"4782841"				
		"4788986"	"4790828"				
		"4793484"	"4795432"				
		"4795443"	"4801295"				
		"4804372"	"4813426"				
		"4816022"	"4816024"				
		"4819659"	"4820277"				
		"4826490"	"4826491"				
		"4838871"	"4842587"				
		"4844089"	"4846796"				
		"4850968"	"4850976"				
		"4850977"	"4850978"				
		"4850994"	"4850996"				
		"4858607"	"4863434"				
		"4863435"	"4863436"				
		"4865592"	"4867746"				
		"4872552"	"4874383"				
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		"4892521"	"4894052"				
		"4900309"	"4909791"				
		"4909792").PN. OR					
		("4921096"	"4927018"				
		"4944397"	"4966591"				
		"4971068"	"4976699"				
		"4982842"	"5011475"				
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		"5032116"	"5033476"				
		"5055102"	"5069225"				
		"5078693"	"5078698"				
		"5092845"	"5112327"				
		"5116325"	"5120319"				
		"5122121"	"5135509"				
		"5137518"	"5139489"				
		"5151089"	"5154285"				
		"5181523"	"5188611"				
		"5197954"	"5201794"				
		"5207653"	"5217025"				
		"5222502"	"5232454"				
		"5232455"	"5242411"				
		"5242417"	"5277311"				
		"5290246"	"5295969"				
		"5303713"	"5306259"				
		"5312369"	"5401251"				
		"5405332"	"5423765"				

		"5450856" "5462534" "5485854" "5486163" "5490841" "5496281" "5509907" "5520193" "5533984" "5542932" "5584816" "5599313" "5599318" "5603699" "5632732" "5643219" "5662617" "5665075" "5669889" "5693022" "5697914" "5702369" "5733265" "5755701" "5807351" "5830190" "5836920" "5885249" "5893844" "5913846" "5984895" "5993426" "6059737" "6077244" "6077253" "6080137" "6096006" "6110160" "6120482" "6156010" "6190370" "6261263" "6511439" "6533760" "6964658" "7160267" "RE31086").PN. OR ("7615033").URPN.					
L102	215	L101 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:51 PM
L103	1347	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:11 PM
L104	17	L103 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L105	19	("2009/0312711").URP N.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L106	11	("2007/0106220").URP N.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L107	288967	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L108	6321	L107 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L109	121	L108 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:17 PM
L110	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:31 PM
L111	6	L110 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:31 PM
L113	71	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:31 PM
L114	0	("15140443").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:38 PM

L115	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:38 PM
L116	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:40 PM
L117	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 01:56 PM
L118	854	L117 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:56 PM
L119	91	L118 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:57 PM
L120	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:06 PM
L121	1074	L120 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L122	80	L121 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L123	301210	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L124	6556	L123 AND (A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L125	3664	L124 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L126	12749	"19" and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L127	117	L125 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L128	1348	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:16 PM
L129	75	L128 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:17 PM
L130	1	("20120291564").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:21 PM
L131	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:25 PM
L132	18	L131 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:25 PM
L133	98	("20020002349" "20020183651" "20030055381" "20030208151" "20040010228" "20040054333" "20040147855" "20050004524"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:44 PM

		"20050240161" "20050245885" "20050281713" "20060287639" "20080108954" "20080145933" "2707953" "3013557" "3098016" "3382865" "3405706" "3494351" "3577980" "3648684" "3848579" "3937211" "4057050" "4133863" "4166450" "4340067" "4370987" "4444203" "4459997" "4509534" "4657160" "4676256" "4865583" "4890627" "4988339" "5009847" "5097842" "5108927" "5122129" "5269317" "5330464" "5360011" "5429610" "5450856" "5507299" "5577513" "5762633" "5865812" "5882318" "5922551" "6016712" "6057105" "6159164" "6210909" "6364890" "6387086" "6403381" "6626884" "6692479" "6746420" "6913580" "7044941" "7087047" "7335188" "7744573" "8197420" "8231546" "8337418").PN. OR ("8535241").URPN.					
L134	307	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:47 PM
L135	23	("4166450").PN. OR ("4412548").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L136	307	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L137	4	("2007/0088279").URP N.	(USPAT)	OR	ON	ON	2018/07/24 02:48 PM
L138	1	(14/990763).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:58 PM
L139	9	(blood and sequest\$5 and junction and first and portion and sampl\$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 03:07 PM

L140	1	(15/287421).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/25 09:39 PM
L141	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/26 11:56 AM
L142	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:24 PM
L143	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:25 PM
L144	34	("20020004647" "20030105414" "20040054333" "20040073171" "20040147855" "20050004524" "20050240161" "20070088279" "20080145933" "20100057004" "20130317391" "20160174888" "3817240" "3874367" "3886930" "4057050" "4106497" "4154229" "4207870" "4412548" "5222502" "5520193" "5749857" "6569117" "8197420" "8523826" "8535241" "8540663" "8568371" "8864684" "9022951" "9060724" "9138572" "9204864").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 05:53 PM
L145	272	((("ROGERS") near3 ("Bobby")) OR ((("KANG") near3 ("Gino")) OR ((("STROUP") near3 ("David")) OR ((("COCHRAN") near3 ("Jonas")) OR ((("DEPTALA") near3 ("Arthur")) OR ((("DETLOFF") near3 ("John")) OR ((("POGUE") near3 ("Lonnie")) OR ((("MACOWSKI") near3 ("Brian")) OR ((("GARRETT") near3 ("Chad")))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/11/07 05:57 PM
L146	9	L145 and (blood near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 05:58 PM
L147	34	("20020004647" "20030105414" "20040054333" "20040073171" "20040147855" "20050004524" "20050240161" "20070088279" "20080145933" "20100057004" "20130317391" "20160174888" "3817240" "38743	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 06:26 PM

		67 "3886930 "405705 0 "4106497 "4154229" "4207870 "4412548 "5 5222502 "5520193 "5 749857 "6569117 "81 97420 "8523826 "853 5241 "8540663 "8568 371 "8864684 "90229 51 "9060724 "913857 2 "9204864").PN.					
L148	5	L147 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 06:29 PM
L149	6	("2010/0057004").URP N.	(USPAT)	OR	ON	ON	2019/11/07 06:40 PM
L150	0	L149 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:20 PM
L151	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:21 PM
L152	4	L151 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L153	1766	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:21 PM
L154	13	L153 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L155	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:22 PM
L156	48	L155 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:22 PM
L157	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L158	17	L157 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:43 PM
L159	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L160	6	L159 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L161	333030	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L162	6981	L161 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L163	139	L162 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L164	117	L163 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:45 PM
L165	1	L146 and (enclos\$3 near4 mechanism)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:51 PM
L166	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/08 04:57 PM

L167	1	(15/139716).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/11 12:09 PM
L168	1	(15/520430).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 11:02 AM
L169	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:11 PM
L170	1	("20120253321").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:13 PM
L171	1	(15/861959).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:14 PM
L172	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 02:17 PM
L173	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:14 PM
L174	1	("20080167577").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:19 PM
L175	4	("2008/0167577").URP N.	(USPAT)	OR	ON	ON	2019/12/09 03:30 PM
L176	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:31 PM
L177	39	(US-20040073171-\$ or US-20160174888-\$ or US-20050240161-\$ or US-20040147855-\$ or US-20130317391-\$ or US-20050004524-\$ or US-20030105414-\$ or US-20020004647-\$ or US-20100057004-\$ or US-20070088279-\$ or US-20080145933-\$ or US-20040054333-\$ or US-20100010372-\$ or US-20080319346-\$ or US-20080167577-\$).did. or (US-9138572-\$ or US-8568371-\$ or US-8540663-\$ or US-8523826-\$ or US-8197420-\$ or US-4057050-\$ or US-8864684-\$ or US-8535241-\$ or US-5749857-\$ or US-9060724-\$ or US-9204864-\$ or US-3817240-\$ or US-3874367-\$ or US-3886930-\$ or US-4106497-\$ or US-4154229-\$ or US-4207870-\$ or US-4412548-\$ or US-5222502-\$ or US-5520193-\$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:37 PM

L178	8	9022951-\$ or US-6569117-\$ or US-3741197-\$ or US-8603009-\$).did. ("20040054333" "8197420" "9855001" "9861306" "10045724" "10028687" "8337418" "10028689").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:42 PM
L179	100	("20020002349" "20020183651" "20030055381" "20040010228" "20040054333" "20040147855" "20050004524" "20050240161" "20050245885" "20050281713" "20060287639" "2707953" "3013557" "3098016" "3382865" "3405706" "3494351" "3577980" "3648684" "3848579" "3937211" "4057050" "4133863" "4166450" "4340067" "4370987" "4444203" "4459997" "4509534" "4676256" "4865583" "4890627" "4988339" "5009847" "5097842" "5108927" "5122129" "5269317" "5360011" "5429610" "5450856" "5507299" "5577513" "5762633" "5882318" "5922551" "6016712" "6057105" "6159164" "6210909" "6364890" "6387086" "6403381" "6692479" "6746420" "6913580" "7044941" "7087047").PN. OR ("8197420").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 03:43 PM
L180	70	L179 and (blood near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 03:43 PM
L181	43	L180 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 03:44 PM
L182	270	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR ((("MIAZGA") near3	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/12/09 04:13 PM

L183	335813	("Jay")) OR (("GAW") near3 ("Shan"))).INV. (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L184	7259	L183 AND (A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L185	325	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 04:33 PM
L186	594	L184 and (flash\$6 and seal\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L187	476	L186 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L188	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:14 PM
L189	1123	L188 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L190	1013	L189 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L191	10	L190 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:16 PM
L192	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:23 PM
L193	1143	L192 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L194	1038	L193 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L195	3	L194 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L196	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:24 PM
L197	618	L196 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L198	557	L197 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L199	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:25 PM
L200	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:31 PM
L201	219	L200 and ((blood or	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09

L202	199	fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4)) L201 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	05:33 PM 2019/12/09 05:33 PM
L203	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:36 PM
L204	44	L203 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:37 PM
L205	1	(15/508871).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/10 11:58 AM
L206	342199	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/03/16 12:53 PM
L207	4239	L206 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:53 PM
L208	146	L207 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:54 PM
L209	101	L208 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:55 PM
L210	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:38 PM
L211	1123	L210 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:38 PM
L212	1013	L211 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L213	22	L212 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L214	108	("20020193748" "20030093009" "20030105414" "20030220614" "20030229315" "20040059302" "20040092872" "20040193120" "20050004524" "20050065482" "20050124944" "20050187493" "20050245868" "20050245869" "20050245870" "20050245879" "20050245885"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 01:46 PM

L215	26	"20060036219" "20060224122" "20070106220" "20070106224" "20070167914" "20080086085" "20080177202" "20080319345" "20080319346" "20090204026" "20100262038" "4106497" "4207870" "4305406" "4572210" "4573976" "4641663" "4795443" "4840619" "4894055" "4900307" "4994046" "5015241" "5195985" "5215534" "5222502" "5242417" "5246428" "5256153" "5295970" "5303713" "5312372" "5336199" "5348544" "5356392" "5411492" "5439449" "5466223" "5501675" "5542932" "5599313" "5662617" "5665075" "5672161" "5676658" "5702369" "5704920" "5733265" "5755522" "5957892" "5984899" "6149629" "6224576" "6254575" "6261263" "6298541" "6344032" "6436086" "6440104" "6524277" "6533760" "6592556" "6623456" "6635032" "6648855" "6695819" "6699217" "6712792" "6780169" "6837877" "6869415" "6984223" "7001363" "7128726" "7147624" "7160267" "7163526" "7223258" "7226432" "7396343" "7428773" "7537581" "7766879" "D422700" "D442280" "D604836" "D604837" "D604838" "D604839" "D605287").PN. OR ("8603009").URPN. L214 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:47 PM
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L216	27	("2008/0319346").URP N.	(USPAT)	OR	ON	ON	2020/03/16 01:47 PM
L217	23	("2003/0105414").URP N.	(USPAT)	OR	ON	ON	2020/03/16 01:48 PM
L218	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:52 PM
L219	1143	L218 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L220	25	L219 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L221	353695	((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:54 PM
L222	3643	L221 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L223	1926	L222 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L224	785	L223 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:56 PM
L225	7046	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 02:32 PM
L226	14	L225 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:35 PM
L227	1352	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:36 PM
L228	135	L227 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L229	19	L228 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L230	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:47 PM
L231	3	L230 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:47 PM
L232	19	("2008/0145933").URP N.	(USPAT)	OR	ON	ON	2020/03/16 02:48 PM
L233	795	(600/576).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:58 PM
L234	71	L233 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:58 PM

L235	57	L234 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:59 PM
L236	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:12 PM
L237	11	L236 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:12 PM
L238	45	("20040054333" "20050 240161" "4412548" "57 49857" "8197420" "985 5001" "9861306" "2002 0004647" "2010005700 4" "3741197" "2004007 3171" "3874367" "4057 050" "4106497" "81974 20" "8535241" "854066 3" "8603009" "8864684" "10045724" "3817240" "10028687" "20030105 414" "5222502" "55201 93" "6569117" "856837 1" "20040147855" "200 70088279" "200801459 33" "20100010372" "38 86930" "8523826" "906 0724" "9204864" "8337 418" "20050004524" "2 0080167577" "2008031 9346" "20130317391" " 4154229" "9022951" "1 0028689" "2016017488 8" "4207870" "9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:13 PM
L239	6	("2008/0167577").URP N.	(USPAT)	OR	ON	ON	2020/03/16 03:13 PM
L240	118	("3500828" "3670729" "3714945" "3977400" "3994293" "3995619" "4106491" "4200096" "4468224" "4531987" "4549554" "4735215" "4828548" "4874373" "4893635" "4894052" "4907599" "4944308" "4994042" "5129884" "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 03:15 PM
L241	6	("2008/0167577").URP N.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 03:15 PM
L242	274	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2020/03/16 03:25 PM

L243	61	L242 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:25 PM
L244	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:47 PM
L245	0	(14/502498).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:11 PM
L246	1	("20110082383").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L247	1	("8150506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L252	1	(15/057214).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/17 11:28 AM
L253	348964	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L254	7453	L253 AND (A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L255	155	L254 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:23 PM
L256	77	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:35 PM
L257	343953	(blood same (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:40 PM
L258	11	L256 and (blood same (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:41 PM
L259	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:50 PM
L260	121	("3500828" "3670729" "3714945" "3977400" "3994293" "3995619" "4106491" "4200096" "4468224" "4531987" "4549554" "4735215" "4828548" "4874373" "4893635" "4894052" "4907599" "4944308" "4994042" "5129884" "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:19 PM
L261	32	L260 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:20 PM
L262	1	("3648684").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L263	1	("4056101").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L264	329	(600/577).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/06/10

L265	11	L264 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	06:39 PM 2020/06/10 06:39 PM
L266	29	("2008/0319346").URP N.	(USPAT)	OR	ON	ON	2020/06/10 06:40 PM
L267	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:40 PM
L268	72	L267 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:40 PM
L269	1767	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:44 PM
L270	31	L269 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:45 PM
L271	77	("4676249" "4787891" "4850960" "4874382" "4886067" "4886500" "4900307" "4904242" "4917102" "4950252" "4955862" "5046508" "5116353" "5125718" "5129884" "5163911" "5217435" "5290244" "5295974" "5314503" "5318585" "5330432" "5360410" "5366441" "5376075" "5395337" "5531692" "5695475" "5695479" "5702367" "5735813" "5749857" "5788654" "5800395" "5846226" "5871470" "5882342" "5919172" "5935108" "5935113" "5989220" "6050976" "6077244" "6099504" "6126641" "6162195").PN. OR ("6398743").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:46 PM
L272	18	L271 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:46 PM
L273	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:48 PM
L274	7050	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:49 PM
L275	14	L274 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:49 PM
L276	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:51 PM
L277	7	L276 and ((blood or	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10

L278	1368	fluid\$4) near4 (sequest\$5 or flash\$4)) (604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	06:51 PM 2020/06/10 06:52 PM
L279	135	L278 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:52 PM
L280	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 07:08 PM
L281	3	L280 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 07:08 PM
L282	20	("2008/0145933").URP N.	(USPAT)	OR	ON	ON	2020/06/10 07:08 PM
L286	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 08:56 PM
L287	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:16 PM
L288	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:17 PM
L289	100	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/03/01 09:17 PM
L290	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:36 PM
L291	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:39 PM
L292	180	((("ROGERS") near3 ("Bobby"))).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/03/02 12:19 PM
L293	11	L292 and (blood near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 12:20 PM
L294	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:47 PM
L295	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:49 PM
L296	1	("20020048170").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:36 PM
L297	1	("20040174525").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:49 PM
L298	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:09 PM
L299	27321	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/03/02 03:17 PM

L300	4594	A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc. L299 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:27 PM
L301	3762	L300 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:28 PM
L302	257	L301 and (air near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L303	420	L301 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L304	1	("20110167658").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:30 PM
L305	5	("2015/0306288").URP N.	(USPAT)	OR	ON	ON	2021/03/02 04:15 PM
L306	1	(16/208559).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 04:32 PM
L307	2	("2009/0043225").URP N.	(USPAT)	OR	ON	ON	2021/03/02 04:49 PM
L308	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/03/02 05:00 PM
L309	1363	L308 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:00 PM
L310	73	L309 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L311	73	L310 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L312	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:34 PM
L313	711	L312 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L314	58	L313 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L315	58	L314 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L316	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:42 PM
L317	277	L316 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:42 PM

L318	20	L317 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:43 PM
L319	336	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/03/02 05:44 PM
L320	210	L319 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L321	196	L320 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L322	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:48 PM
L323	1208	L322 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L324	73	L323 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L325	73	L324 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:49 PM
L326	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:59 PM
L327	271	L326 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L328	10	L327 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L329	268	L327 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L330	182	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/07/08 02:22 PM
L331	27660	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/07/08 03:27 PM
L332	4684	L331 and ((blood or fluid\$4) near4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:28 PM

L333	3769	(sequest\$5 or sampl\$4 or flash\$4 or collect\$4)) L332 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L334	579	L333 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L335	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:54 PM
L336	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:56 PM
L337	337	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:19 PM
L338	211	L337 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L339	196	L338 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L340	37	L339 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L341	221	("20010021827" "20020004650" "20020055716" "20020072715" "20020103464" "20020103465" "20020107488" "20020151856" "20020193748" "20030028171" "20030036730" "20030050608" "20030055385" "20030078544" "20030093009" "20030105414" "20030114797" "20030120222" "20030176842" "20030181873" "20030191438" "20030199827" "20030216687" "20030220614" "20030229315" "20030229316" "20040024370" "20040059302" "20040092872" "20040102740" "20040111068" "20040193120"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"20040204681" "20040210197" "20050004524" "20050059936" "20050065482" "20050124944" "20050165353" "20050187493" "20050228345" "20050245868" "20050245869" "20050245870" "20050245879" "20050245885" "20050283093" "20060015073" "20060036217" "20060036219" "20060079847" "20060129064" "20060189934" "20060189936" "20060224122" "20060270947" "20060276756" "20070021724" "20070027430" "20070106220" "20070106224" "20070167914" "20070282275" "20080015513" "20080086085" "20080177202" "20080221528" "20080269691" "20080306452" "20080319345" "20080319346" "20090204026" "20090227896" "20100063455" "20100191189" "20100262038" "20110118674" "4106497" "4207870" "4305406" "4572210" "4573976" "4641663" "4795443" "4813426" "4840619" "4887998" "4894055" "4900307" "4923477" "4994046" "5015241" "5195985" "5215534" "5219333" "5222502" "5242417" "5246428" "5256153").PN. OR ("5295970" "5295975"					
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		"5439449"	"5466223"				
		"5501675"	"5542932"				
		"5549558"	"5595566"				
		"5599313"	"5607402"				
		"5662617"	"5665075"				
		"5669889"	"5672161"				
		"5676658"	"5681295"				
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		"5718239"	"5733265"				
		"5755522"	"5769826"				
		"5795336"	"5879337"				
		"5893845"	"5910130"				
		"5921964"	"5957892"				
		"5984899"	"6149629"				
		"6171284"	"6183445"				
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		"6261263"	"6261265"				
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		"6419658"	"6436086"				
		"6440104"	"6471677"				
		"6475191"	"6485469"				
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		"6554807"	"6575939"				
		"6592556"	"6623456"				
		"6623461"	"6635032"				
		"6641555"	"6648855"				
		"6648856"	"6659983"				
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		"6811545"	"6835190"				
		"6837877"	"6846302"				
		"6860872"	"6869415"				
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		"7001363"	"7083600"				
		"7101355"	"7128726"				
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		"7226432"	"7361159"				
		"7396343"	"7428773"				
		"7524308"	"7537581"				
		"7670320"	"7727190"				
		"7766879"	"7938808"				
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L342	115	"D604838" "D604839" "D605287" "RE35539" "RE43473").PN. OR ("9615783").URPN. ("20020193748" "20030093009" "20030105414" "20030220614" "20030229315" "20040059302" "20040092872" "20040193120" "20050004524" "20050065482" "20050124944" "20050187493" "20050245868" "20050245869" "20050245870" "20050245879" "20050245885" "20060036219" "20060224122" "20070106220" "20070106224" "20070167914" "20080086085" "20080177202" "20080319345" "20080319346" "20090204026" "20100262038" "4106497" "4207870" "4305406" "4572210" "4573976" "4641663" "4795443" "4840619" "4894055" "4900307" "4994046" "5015241" "5195985" "5215534" "5222502" "5242417" "5246428" "5256153" "5295970" "5303713" "5312372" "5336199" "5348544" "5356392" "5411492" "5439449" "5466223" "5501675" "5542932" "5599313" "5662617" "5665075" "5672161" "5676658" "5702369" "5704920" "5733265" "5755522" "5957892" "5984899" "6149629" "6224576" "6254575" "6261263" "6298541" "6344032" "6436086" "6440104" "6524277" "6533760"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM
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L343	148	"6592556" "6623456" "6635032" "6648855" "6695819" "6699217" "6712792" "6780169" "6837877" "6869415" "6984223" "7001363" "7128726" "7147624" "7160267" "7163526" "7223258" "7226432" "7396343" "7428773" "7537581" "7766879" "D422700" "D442280" "D604836" "D604837" "D604838" "D604839" "D605287").PN. OR ("8603009").URPN. ("20020193748" "20030105414" "20030229315" "20040059302" "20040092872" "20050004524" "20050187493" "20050245868" "20050245869" "20050245870" "20050245885" "20060036219" "20070106220" "20070167914" "20080086085" "20080177202" "4106497" "4207870" "4305406" "4573976" "4641663" "4795443" "4840619" "4894055" "4900307" "4994046" "5015241" "5195985" "5215534" "5222502" "5242417" "5256153" "5295970" "5303713" "5312372" "5336199" "5348544" "5356392" "5411492" "5439449" "5466223" "5501675" "5542932" "5672161" "5676658" "5702369" "5704920" "5755522" "5984899" "6149629" "6261263" "6298541" "6436086" "6440104" "6524277" "6533760" "6592556" "6623456" "6635032" "6648855" "6699217" "6712792" "6780169" "6837877" "6869415" "6984223"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM
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L344	41	"7001363" "7128726" "7147624" "7160267" "7163526" "7223258" "7226432" "7396343" "7428773" "D422700" "D442280").PN. OR ("7766879").URPN. ("2735430" "2798487" "3187749" "3240209" "3585984" "3817240" "4166450" "4207870" "4295477" "4312362").PN. OR ("4436098").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:22 PM
L345	163	L341 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:22 PM
L346	163	L345 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:23 PM
L347	22	("2005/0283093").URP N.	(USPAT)	OR	ON	ON	2021/07/08 04:23 PM
L348	163	L345 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L349	163	L348 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L350	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/08 04:37 PM
L351	1363	L350 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:37 PM
L352	1346	L351 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L353	136	L352 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L354	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:41 PM
L355	711	L354 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L356	699	L355 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L357	123	L356 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L358	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:44 PM
L359	277	L358 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM

L360	260	or flash\$4 or collect\$4)) L359 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L361	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:46 PM
L362	1208	L361 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:46 PM
L363	1194	L362 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L364	1194	L363 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L366	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:05 PM
L367	319	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR ("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/02/02 03:14 PM
L368	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:35 PM
L369	190	((("ROGERS") near3 ("Bobby"))).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 03:36 PM
L370	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:41 PM
L371	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L372	1	("9060725").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L373	1	("9060724").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:43 PM
L374	1	("9022950").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L375	1	("9022951").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L376	1	("10292633").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:46 PM
L377	1	("10433779").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:47 PM
L378	1	("10436554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:48 PM
L379	1	("10736554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L380	1	("10912506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L381	1	("10010282").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2022/02/02

L382	1	(16/376745).APP.	USOCR) (US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	03:49 PM 2022/02/02 03:50 PM
L383	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:51 PM
L384	276	(600/579).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:52 PM
L385	204	L384 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 03:53 PM
L386	37427	(A61B5/150221 or A61B5/15003 or A61B5/150236 or A61B5/150244 or A61B5/150251 or A61B5/150389 or A61B5/150503 or A61B5/150992 or A61B5/153 or A61B5/155 or A61B10/0048 or A61B10/0051 or A61B10/007 or A61B2010/0061 or A61B2010/0077 or A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 04:35 PM
L387	7279	L386 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L388	4442	L387 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L389	874	L388 and (seal\$4 near4 (member or mechanism\$4 or vent\$4 or elastic\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:38 PM
L390	26	("2008/0145933").URP N.	(USPAT)	OR	ON	ON	2022/02/02 04:52 PM
L391	44	("2008/0319346").URP N.	(USPAT)	OR	ON	ON	2022/02/02 04:59 PM
L392	385	L386 and ((blood or fluid) near4 (seal\$4 near4 (member or mechanism\$4 or vent\$4 or elastic\$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L393	171	L392 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L394	355	(604/103).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 05:52 PM
L395	7	L394 and ((blood or fluid) near4 (seal\$4 near4 (member or mechanism\$4 or vent\$4 or elastic\$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:52 PM

L396	1	(16/328127).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/03 12:00 PM
L397	0	"1020130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L398	8	"20130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L399	14	"2013021595"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:18 PM
L400	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/04 07:10 PM
L401	1	(15/746656).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/05 11:48 AM
L402	0	(17/388440).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/07 09:34 AM
L403	1	("20050048465").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2022/02/07 09:34 AM
L404	196	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:08 PM
L405	16	L404 and (blood near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L406	16	L404 and ((blood or chamber) near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L407	16	L406 and (junct\$4 or bypass\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L408	16	L406 and junct\$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L409	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:54 PM
L410	4525	L409 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4 or flush\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:55 PM
L411	3810	L410 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:56 PM
L412	820	L411 and ((vent\$4 or	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18

L413	22445	open\$4 or apertur\$4) near4 air) (A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	03:57 PM 2022/05/18 05:51 PM
L414	4603	L413 and ((blood or fluid\$4 or chamber) same (sequest\$5 or sampl\$4 or flash\$4 or collect\$4 or flush\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:51 PM
L415	511	L414 and ((junct\$4 or bypass\$4 or divert\$4) near4 (blood or fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:52 PM
L416	355	L415 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:53 PM
L417	1	(16/819033).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:10 PM
L418	1	(17/094692).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L419	1	(17/538990).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
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L421	1	("11185266").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:30 PM
L422	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:31 PM
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L425	38	424 AND (closur\$4 OR enclos\$4)	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:42 PM

L426	42781	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/13 01:47 PM
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L429	519	428 AND ((closur\$4 OR enclos\$4 OR pug\$4) near5 (vent OR open\$4 OR air))	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:54 PM
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L435	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13

							02:34 PM
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PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N94	1	(port and sequest\$5 and junction and chamber and sampl\$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:15 PM
N112	3	(port and sequest\$5 and chamber and sampl\$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:39 PM
N248	4	(blood and fluid\$4 and inlet and outlet and port and reservoir and allow and initial\$4 and sequest\$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N249	4	(blood and fluid\$4 and inlet and outlet and port and reservoir and allow\$4 and initial\$4 and sequest\$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N250	495	(blood and fluid\$4 and allow\$4 and initial\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N251	107	(blood and fluid\$4 and allow\$4 and initial\$4 and subsequent\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N283	9	((blood or fluid\$4) and sequestrat\$4 and chamber and sampl\$4 and vent\$4 and air\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N284	530	((blood or fluid\$4) and chamber and sampl\$4 and vent\$4 and air\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N285	84	((blood or fluid\$4) and chamber and cap and sampl\$4 and vent\$4 and air\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:32 PM
N365	6	(port and sequest\$5 and junction and chamber and sampl\$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:49 PM

Bibliographic Data

Application No: 17/094,692

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/

Examiner's Signature

Initials

Title:

BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH
ONE-WAY AIR VALVE AND AIR-PERMEABLE BLOOD
BARRIER WITH CLOSURE MECHANISM

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/10/2020	600	3791	KURIN4CON
RULE			

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CONTINUING DATA

This application is a CON of 15893518 02/09/2018 PAT 10827964

15893518 has PRO of 62467016 03/03/2017

15893518 has PRO of 62457764 02/10/2017

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

02/02/2021

** SMALL ENTITY **

STATE OR COUNTRY

UNITED STATES

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FILING FEE RECEIVED

\$830

Annex to EPO Form 2004, Communication pursuant to Rule 71(3) EPC

Bibliographical data of European patent application No. 19 200 766.4

For the intended grant of the European patent, the bibliographical data are set out below, for information:

Title of invention:

- BLUTPROBENOPTIMIERUNGSSYSTEM SOWIE VORRICHTUNG ZUR SEQUESTRIERUNG VON BLUTKONTAMINANTEN
- BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE
- SYSTÈME D'OPTIMISATION D'ÉCHANTILLON DE SANG ET DISPOSITIF DE SÉQUESTRATION DE CONTAMINANTS DU SANG

Classification: INV. A61B5/15 A61B5/153 A61B5/154

Date of filing: 22.07.2016

Priority claimed:

- US / 24.07.2015 / USP201562196797
- US / 07.10.2015 / USP201562238636
- US / 04.04.2016 / USP201662318194
- US / 27.04.2016 / USA201615140448
- US / 27.04.2016 / USA201615140443

Contracting States*
for which fees have
been paid:

AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU
LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

Extension States*
for which fees have
been paid:

Validation States*
for which fees have
been paid:

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- *) If the time limit for the payment of designation fees according to Rule 39(1) EPC has not yet expired and the applicant has not withdrawn any designation, **all Contracting States/Extension States/Validation States** are currently still deemed to be designated. See also Rule 71a(3) EPC and, if applicable, the above Note to users of the automatic debiting procedure.
- **) If two or more applicants have designated different Contracting States, this is indicated here.



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Application No. 19 200 766.4 - 1122	Ref. KUR-19054-P-EP	Date 31.08.2022
Applicant Kurin, Inc.		

Communication under Rule 71(3) EPC

1. Intention to grant

You are informed that the examining division intends to grant a European patent on the basis of the above application, with the text and drawings and the related bibliographic data as indicated below.

A copy of the relevant documents is enclosed.

1.1 In the text for the Contracting States:

AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT
RO RS SE SI SK SM TR

Description, Pages

2, 3, 5, 7-37 as originally filed

1, 4, 4a filed in electronic form on

18-09-2020

Claims, Numbers

1-14 filed in electronic form on

18-09-2020

Drawings, Sheets

1/50-50/50 as originally filed

With the following amendments to the above-mentioned documents proposed by the division

Description, Pages 1, 4, 4a, 5, 7, 9, 23, 25, 29, 31, 34

Delete Previous: 6

Comments**DESCRIPTION**

Page 1: Deletion of irrelevant and/or superfluous information (Rule 48(1)(c) EPC, Guidelines F-II, 7.4)

Pages 4, 5, 7, 9, 29, 34: Description adapted to the claims (Art. 84 EPC)

Pages 4(a), 5, 7: Description adapted to amended claims (Art. 84 EPC)

Page 6: (PAGE DELETED) - Description adapted to amended claims (Art. 84 EPC)

Pages 23, 25, 31: Insertion of SI/metric units (Rule 49(10) EPC)

Pages 38-43: (PAGE DELETED) -

1.2 Bibliographic data

The title of the invention in the three official languages of the European Patent Office, the international patent classification, the designated contracting states, the registered name(s) of the applicant(s) and the other bibliographic data are shown on **EPO Form 2056** (enclosed).

2. Invitation

You are invited, **within a non-extendable period of four months** of notification of this communication,

2.1 to EITHER approve the text communicated above and verify the bibliographic data (Rule 71(5) EPC)

(1) by filing a translation of the claim(s) in the other two official languages of the EPO

	Fee code	EUR
(2a) by paying the fee for grant including the fee for publication: minus any amount already paid (Rule 71a(5) EPC):	007	990.00 0.00
Total amount:		990.00
(3) by paying additional claims fees under Rule 71(4) EPC; number of claims fees payable: 0 minus any amount already paid (Rule 71a(5) EPC):	016	0.00 0.00
Total amount:		0.00

Important: If the translations of the claims and fees have already been filed and paid respectively in reply to a previous communication under Rule 71(3) EPC, e.g. in the case of resumption of examination after approval (see Guidelines C-V, 6), **agreement as to the text to be granted** (Rule 71a(1) EPC) must be expressed within the same time limit (e.g. by approving the text and verifying the bibliographic data, by confirming that grant proceedings can go ahead with the documents on file and/or by stating which translations of the claims already on file are to be used).

Note 1: See "Notes concerning fee payments" below.

Note 2: Any overpaid "minus" amounts will be refunded when the decision to grant (EPO Form 2006A) has been issued.

Note 3: For the calculation of the grant fee under Article 2(2), No. 7, RFees (old fee structure), the number of pages is determined on the basis of a clean copy of the application documents, in which text deleted as a result of any amendments by the examining division is not shown.

Such clean copy is made available via on-line file inspection only.

2.2 OR, in the case of disapproval, to request reasoned amendments or corrections to the text communicated above or keep to the latest text submitted by you (Rule 71(6) EPC).

In this case the translations of the claims and fee payments mentioned under point 2.1 above are NOT due.

The terms "amendment(s)" and "correction(s)" refer only to amendments or corrections of the application documents and not of other documents (e.g. bibliographic data, the designation of the inventor, etc.).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the examining division requesting that you correct this deficiency (Rule 137(4) EPC).

2.3 Bibliographic data

Where you request a change or correction of bibliographic data in response to the Rule 71(3) communication, this will **not** cause the sending of a further communication under Rule 71(3) EPC. You will still have to pay the fees and file translations in reply to the Rule 71(3) communication in the case of 2.1 above, unless you also file a reasoned request for amendments or corrections in response to the Rule 71(3) communication (see case 2.2 above).

3. Loss of rights

If neither of the two possible actions above (see points 2.1 or 2.2) is performed in due time, the European patent application will be deemed to be withdrawn (Rule 71(7) EPC).

4. Further procedure

4.1 In the case of point 2.1 above

- 4.1.1** The decision to grant the European patent will be issued, and the **mention of the grant** of the patent will be published in the European Patent Bulletin, if the requirements concerning the translation of the claims and the payment of all fees are fulfilled and there is agreement as to the text to be granted (Rule 71a(1) EPC).

Note on payment of the renewal fee:

If a renewal fee becomes due before the next possible date for publication of the mention of the grant of the European patent, publication will be effected only after the renewal fee and any additional fee have been paid (Rule 71a(4) EPC).

Under Article 86(2) EPC, the obligation to pay renewal fees to the European Patent Office terminates with the payment of the renewal fee due in respect of the year in which the mention of the grant of the European patent is published.

Note on payment of the designation fee(s):

If the designation fee(s) become(s) due after the communication under Rule 71(3) EPC, the mention of the grant of the European patent will not be published until these fees have been paid (Rule 71a(3) EPC).

- 4.1.2** After publication, the **European patent specification** can be downloaded free of charge from the EPO publication server <https://data.epo.org/publication-server>.

4.1.3 Filing of translations in the contracting states

As regards translation requirements prescribed by the contracting states under Article 65(1) EPC, please consult the website of the European Patent Office

www.epo.org → Law & practice → Legal texts, National law relating to the EPC

www.epo.org → Law & practice → All Legal texts → London Agreement

In the case of a valid extension or validation

As regards translation requirements prescribed by the extension or validation states, please consult the website of the European Patent Office

www.epo.org → Law & practice → Legal texts, National law relating to the EPC

Failure to supply a prescribed translation in a contracting state, or in an extension or validation state may result in the patent being deemed to be void *ab initio* in the state concerned (Art. 65(3) EPC).

4.2 In the case of 2.2 above

If the present communication under Rule 71(3) EPC is based on an auxiliary request and, within the time limit, you maintain the main request or a higher ranking request which is not allowable, the application will be refused (Art. 97(2) EPC).

If the examining division gives its consent to the requested amendments or corrections, it will issue a new communication under Rule 71(3) EPC; otherwise, it shall resume the examination proceedings (Rule 71(6) EPC).

5. Filing of a divisional application

Any divisional application relating to this European patent application must be filed directly with the European Patent Office in Munich, The Hague or Berlin and will be in the language of the proceedings for the present application, or if the latter was not in an official language of the EPO, the divisional application may be filed in the language of the present application as filed (see Article 76(1) and Rule 36(2) EPC). Any such divisional application must be filed while the present application is still pending (Rule 36(1) EPC; Guidelines A-IV, 1.1.1).

6. Notes concerning fee payments**6.1 Making payments**

For payments made via deposit account, please note that as from 1 December 2017 debit orders will only be carried out if filed in an electronically processable format (xml), using an accepted means of filing as laid down in the Arrangements for deposit accounts (ADA), published in the Supplementary publication in the Official Journal.

All relevant information related to the modes of payment of fees to the EPO can be retrieved from the EPO website at "**Making Payments**".

6.2 Information concerning fee amounts

Procedural fees are usually adjusted every two years, on even years, with effect from 1 April. Therefore, before making a payment, parties should verify the amounts actually due on the date of payment using the applicable version of the Schedule of fees and expenses, published as a Supplement to the Official Journal of the EPO, available on the EPO website (www.epo.org) at www.epo.org/schedule-of-fees. The "Schedule of fees" table allows the viewing, downloading and searching of individual fee amounts, both current and previous.

6.3 Note to users of the automatic debiting procedure

The fee for grant, including the fee for publication, and any additional claims fees due under Rule 71(4) EPC will be debited automatically on the date of filing of the translations of the claims, or on the last day of the period of this communication. However, if the designation fee(s) become(s) due as set out in Rule 71a(3) EPC and/or a renewal fee becomes due as set out in Rule 71a(4) EPC, these should be paid separately by another permitted way of payment in order not to delay the publication of the mention of the grant. The same applies in these circumstances to the payment of extension and validation fees. The same applies in these circumstances to the payment of extension and validation fees.

Examining Division:

Chairman:	Kakoullis, Marios
2nd Examiner:	Przykutta, Andreas
1st Examiner:	Nielsen, Michael



Acquaviva, Laure
For the Examining Division
Tel. No.: +49 89 2399 - 5656

Enclosures: Text intended for grant
 EPO Form 2056



Application No.:

EP19200766

Intention to grant a European patent

Electronically authenticated

31.08.2022

Date

Marios Kakoullis

Chairperson

Michael Nielsen

1st examiner

Andreas Przykutta

2nd examiner



**~~BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT
SEQUESTRATION DEVICE AND METHOD~~**

~~CROSS-REFERENCE TO RELATED APPLICATIONS~~

5 [0001] This application claims the benefit of priority of U.S. Non-Provisional
Application Serial No. 15/140,443, filed on April 27, 2016 and titled "BLOOD SAMPLE
OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND
METHOD" and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April
27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD
10 CONTAMINANT SEQUESTRATION DEVICE AND METHOD", both of which claim
priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015
and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S.
Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled
"BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING";
15 and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and
titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT
SEQUESTRATION DEVICE AND METHOD".

BACKGROUND

20 [0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on
the other hand, is bacteraemia in the presence of clinical symptoms and signs such
as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are
associated with a high mortality and an increased incidence and duration of hospital
stay and associated costs. Many bacteraemias, sepsis, fungaemias and other
pathogens actually occur within a hospital or other healthcare settings with

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catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles.

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01.10.2019

Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination,

20% or more of skin organisms are located deep within the dermis and are unaffected by antiseptics. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

5 [0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

10 [0012a] WO 96/05875 A1 discloses a blood sampling device comprising a bifurcated capillary tube which has a first branch having a cannula shaped end for withdrawing and conveying blood to a blood collection zone for storing a quantity of withdrawn blood and feeding an initial fraction of withdrawn blood to a blood disposal chamber having an air permeable liquid sealed end; and a second branch
15 connected to the blood collection zone which terminates in an opening adapted to receive a blood withdrawal device.

SUMMARY

[0013] This document presents systems and methods 2 (a method is not claimed) 2 for reducing blood

20 culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

25 [0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to

accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is 2 provided, comprising; an inlet port; a junction connected with the inlet port; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with an outlet port; and a housing that houses and defines the inlet port, the junction, the sequestration chamber, the sampling channel, and the outlet port, wherein the sequestration chamber is connected with the inlet port via the junction which is configured to direct a first portion of blood to the sequestration chamber, wherein the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood. 2

~~presented. The blood~~

~~sequestration device includes an inlet port and an outlet port. The blood~~

~~5 sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable~~

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~~blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.~~

[0016] In another aspect, a ~~2~~  system of a blood sequestration device, a blood sampling pathway having a patient needle, and a sample collection device is provided, the blood sequestration device comprising; an inlet port connected with the patient needle; a junction connected with the inlet port opposite the blood sampling pathway; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port; and an outlet port connected with a distal end of the sampling channel and with the sample collection device; and a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel, wherein the sequestration chamber is connected with the inlet port and the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with blood.  2

~~blood sequestration device connected with a~~

~~blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.~~

[0017] ~~In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration~~



f.

~~device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.~~

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~~sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.~~

[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims. 2 ■ The invention is best illustrated by figures 16A to 19B. ■ 2

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

[0024] FIG. 1 illustrates a blood sample optimization system.

[0025] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0026] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0027] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0028] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0030] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

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- [0031]** FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.
- [0032]** FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.
- [0033]** FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.
- [0034]** FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.
- [0035]** FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.
- [0036]** FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.
- [0037]** FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminants of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.
- [0038]** FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.
- [0039]** FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.
- [0040]** FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.
- [0041]** FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

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[0042] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0043] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0044] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0045] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0046] FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0047] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0048] This document describes blood sample optimization systems and

methods  (a method is not claimed)  

for reducing or eliminating contaminants in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient

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needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0049] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0050] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

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[0051] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0052] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

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[0053] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0054] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0055] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

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[0056] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminant, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0057] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0058] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable

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blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0059] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0060] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0061] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is

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added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0062] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0063] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0064] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone

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to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0065] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indicator or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0066] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

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[0067] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0068] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0069] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable

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blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0070] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0071] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a

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sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0072] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0073] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0074] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0075] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can

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be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0076] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0077] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0078] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with

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one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0079] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0080] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0081] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved,

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and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0082] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0083] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminants of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port

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1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0084] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately ≥ 0.114 cm (0.045 inches), ~~≥ 0.045 inches,~~ but can have a diameter of between ≥ 0.0254 cm (0.01 inches) ~~≥ 0.01 inches~~ or less to ≥ 0.508 cm (0.2 inches) ~~≥ 0.2 inches~~ or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0085] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0086] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration

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chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0087] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0088] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion

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pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0089] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0090] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately ≥ 0.114 cm (0.045 inches), ~~≥ 0.045 inches,~~ but can have a diameter of between ≥ 0.0254 cm (0.01 inches) ~~≥ 0.01 inches~~ or less to ≥ 0.508 cm (0.2 inches) ~~≥ 0.2 inches~~ or more.

[0091] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some

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implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0092] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0093] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0094] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port

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1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0095] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel

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1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0097] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0098] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0099] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00100] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial

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groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00101] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00102] After a venipuncture by a patient needle of a patient (not  shown, not claimed),   ~~shown~~,

which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure

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overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00103] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00104] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS.

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16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00105] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately ≥ 0.114 cm (0.045 inches), ≥ 0.045 inches, but can have a diameter of between ≥ 0.0254 cm (0.01 inches) ≥ 0.01 inches or less to ≥ 0.508 cm (0.2 inches) ≥ 0.2 inches or more.

[00106] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00107] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need

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for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00108] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00109] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00110] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

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[00111] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17D and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00112] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00113] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00114] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other

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pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00115] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00116] In ~~2~~ **FIG. 2** use (neither use nor method is claimed), ~~use~~ **FIG. 2** the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-

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filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00117] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00118] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00119] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

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[00120] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00121] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00122] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00123] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

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[00124] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00125] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

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Amended claims

1. A blood sequestration device (1500) comprising;
an inlet port (1502);
5 a junction (1607) connected with the inlet port (1502);
a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);
a sampling channel (1506) having a proximal end connected with the inlet port (1502) via the junction (1607), and a distal end connected with an outlet port (1504); and
10 a housing (1501) that houses and defines the inlet port (1502), the junction (1607), the sequestration chamber (1508), the sampling channel (1506), and the outlet port (1504),
wherein the sequestration chamber (1508) is connected with the inlet port (1502) via the junction (1607) which is configured to direct a first portion of blood to the sequestration chamber (1508),
15 characterized in that the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood.
20
2. The blood sequestration device (1500) in accordance with claim 1, wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).
- 25 3. The blood sequestration device (1500) in accordance with claim 1 or 2, further comprising a blood sampling pathway connected with the inlet port (1502) opposite the junction (1607), and
wherein the inlet port (1502) defined by the housing (1501) has a cross-sectional geometry consistent with the blood sampling pathway.
30
4. The blood sequestration device (1500) in accordance with one of the preceding claims, wherein the sampling channel (1506) defined by the housing (1501) has a cross-sectional geometry consistent with the inlet port (1502).
- 35 5. The blood sequestration device (1500) in accordance with one of claims 2 to 4, wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520)

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defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

6. A system of a blood sequestration device (1500), a blood sampling pathway
5 having a patient needle, and a sample collection device, the blood sequestration device (1500) comprising;
an inlet port (1502) connected with the patient needle;
a junction (1607) connected with the inlet port (1502) opposite the blood sampling pathway;
10 a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);
a sampling channel (1506) having a proximal end connected with the inlet port (1502); and
an outlet port (1504) connected with a distal end of the sampling channel
15 (1506) and with the sample collection device; and a housing (1501) that houses and defines the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506),
characterized in that the sequestration chamber (1508) is connected with the inlet port (1502) and the air permeable blood barrier (1512) includes an air
20 permeable material that seals at least partially upon contact with blood.
7. The system in accordance with claim 6, wherein the inlet port (1502) is connected with the patient needle via a first portion of the blood sampling pathway.
- 25 8. The system in accordance with claim 6 or 7, wherein the outlet port (1504) is connected with the sample collection device via a second portion of the blood sampling pathway.
9. The system in accordance with one of claims 6 to 8, wherein the sequestration
30 chamber (1508) includes a sequestration channel defined in the housing (1501).
10. The system in accordance with claim 9, wherein the sequestration channel has a proximal end connected with the inlet port (1502), and a distal end having the vent (1510) comprising an air permeable blood barrier (1512).
35
11. The system in accordance with one of claims 6 to 10, wherein the sequestration chamber (1508) and the sampling channel (1506) are connected with

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the inlet port (1502) by the junction (1607) that is configured to direct a first portion of blood to the sequestration chamber (1508).

5 12. The system in accordance with one of claims 6 to 11, wherein the sampling channel (1506) has a substantially uniform cross-sectional geometry that is consistent with the blood sampling pathway.

10 13. The system in accordance with claim 12, wherein the sequestration chamber (1506) includes a sequestration chamber that has a cross-sectional area that is larger than the cross-sectional geometry of the sampling channel (1506).

15 14. The system in accordance with claim 7, member (1520), wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520) defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

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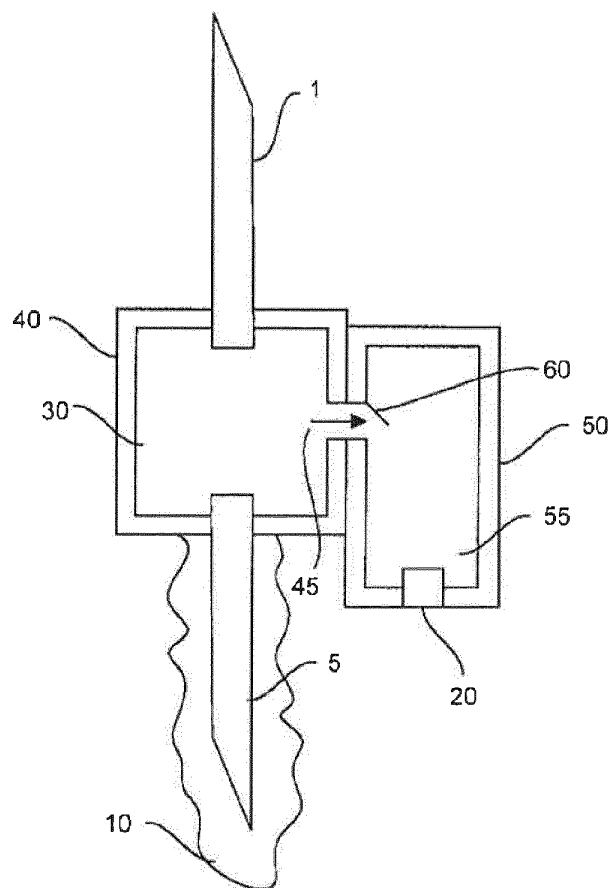


FIG. 1

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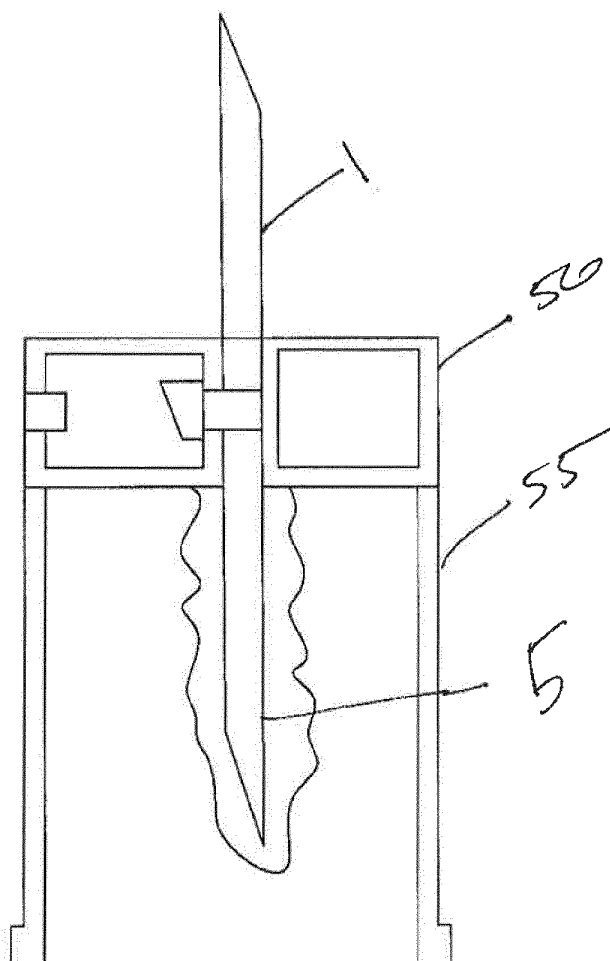
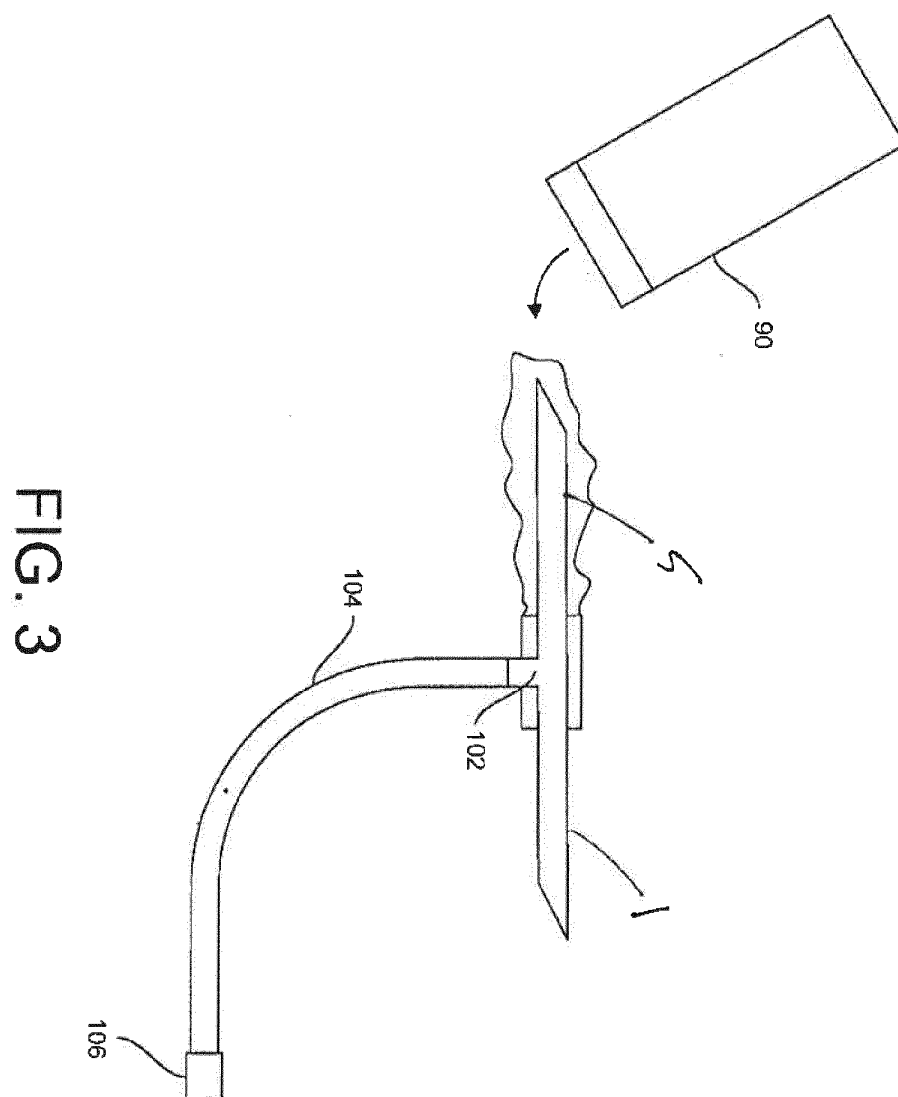


FIG. 2

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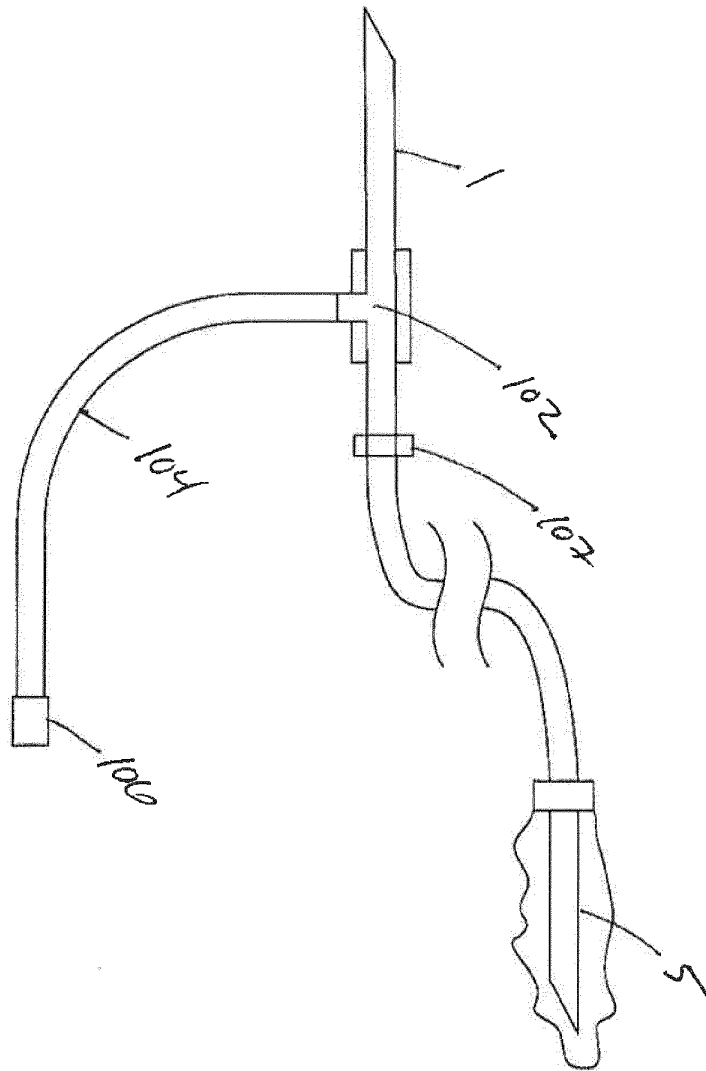


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FIG. 4



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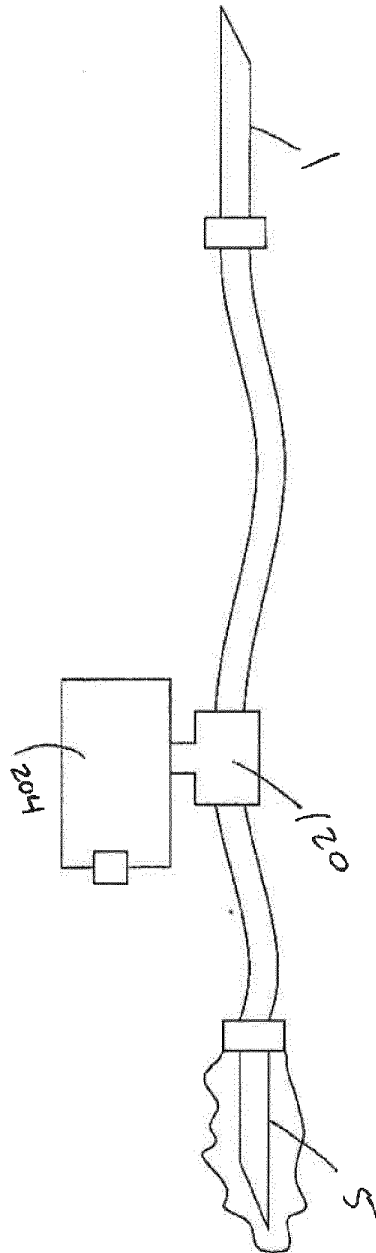


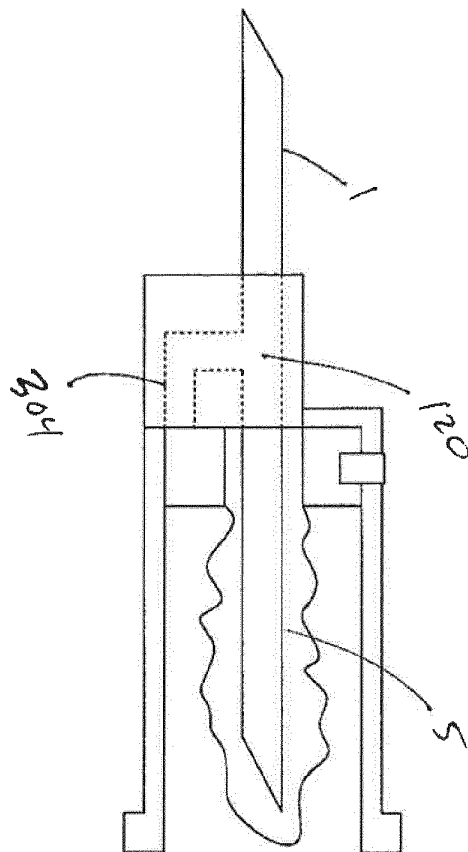
FIG. 5

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FIG. 6



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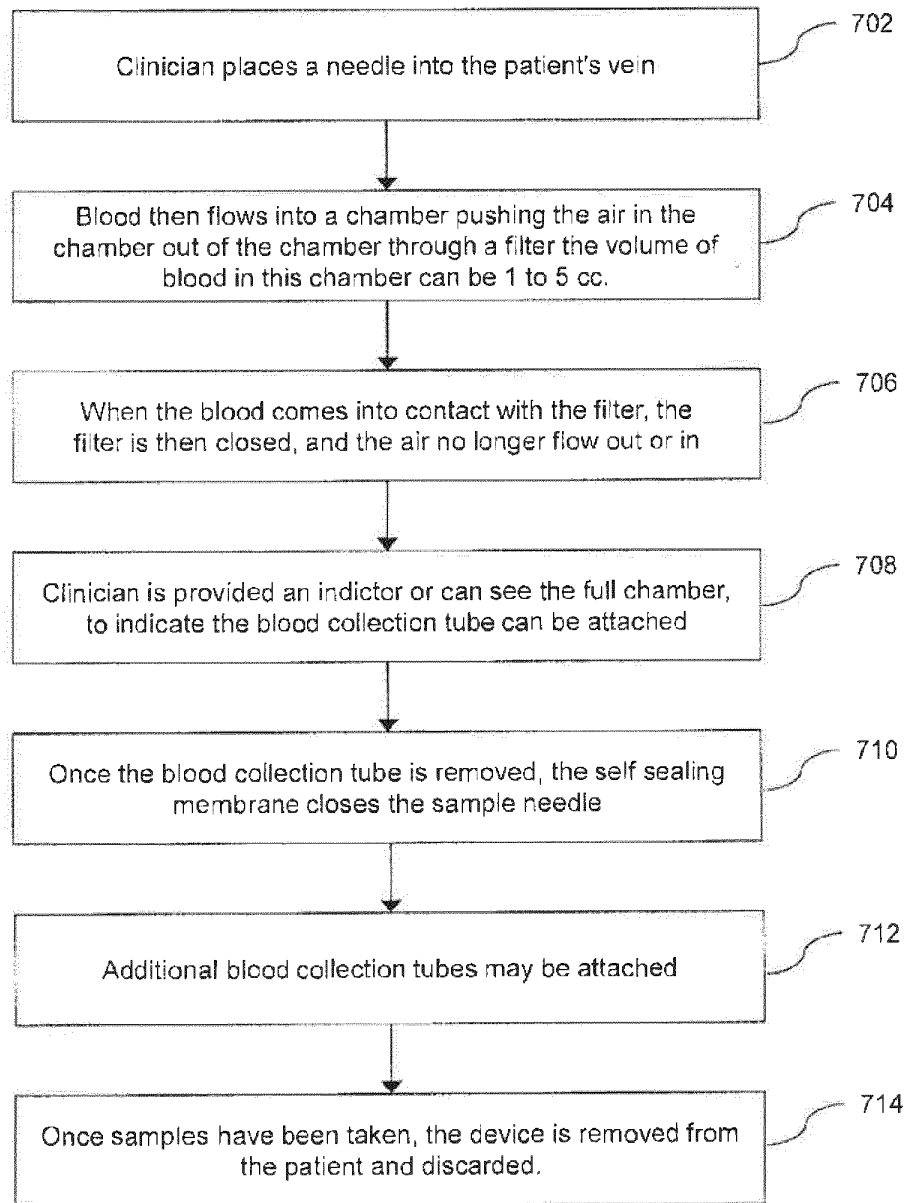


FIG. 7

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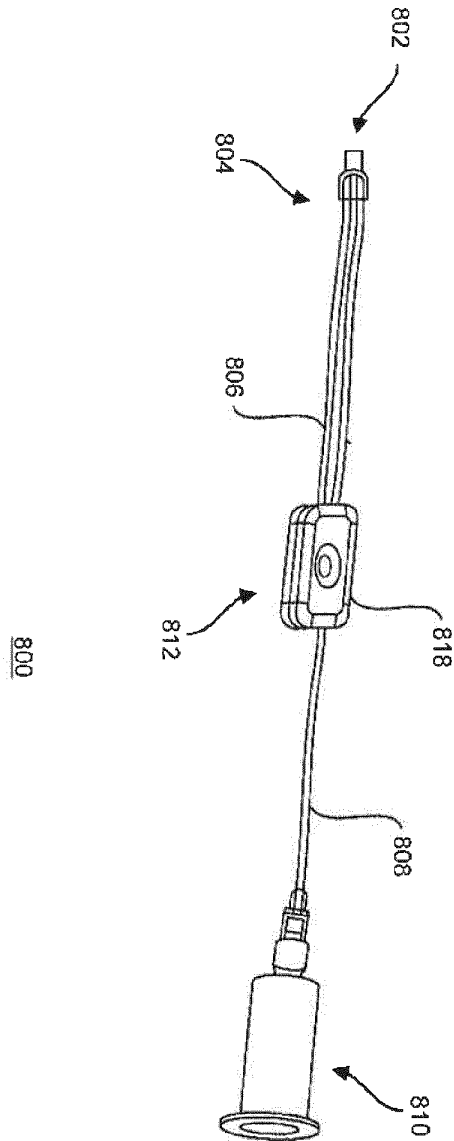


FIG. 8A

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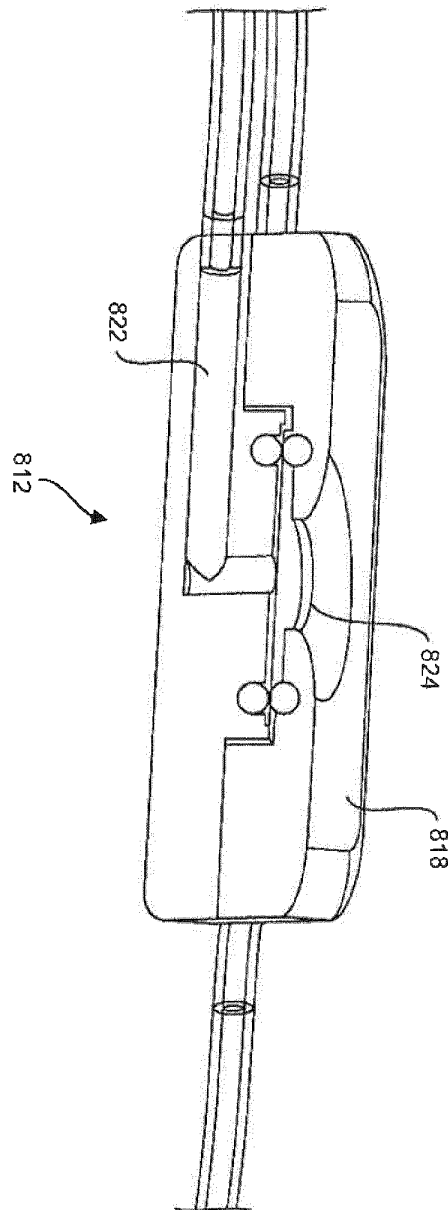


FIG. 8B

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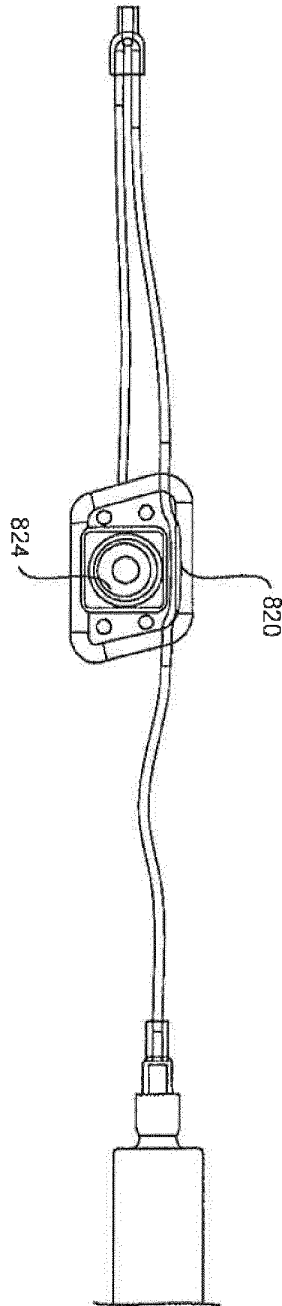


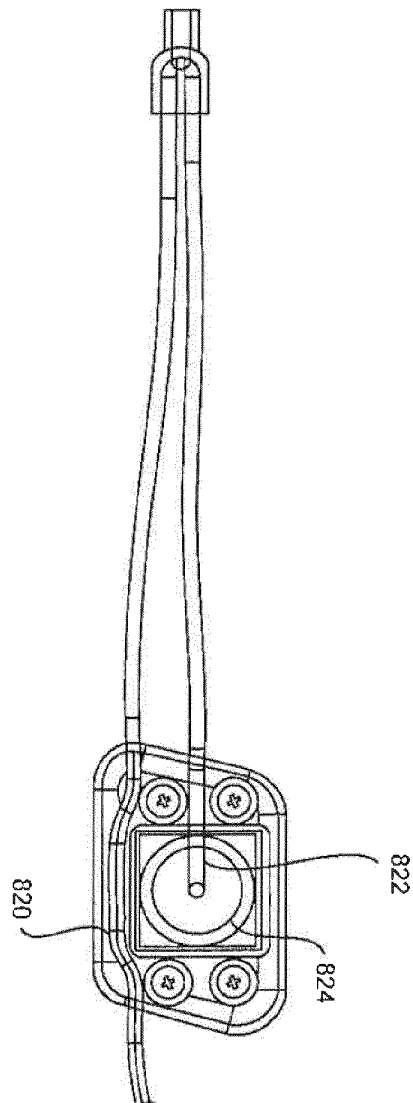
FIG. 8C

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FIG. 8D

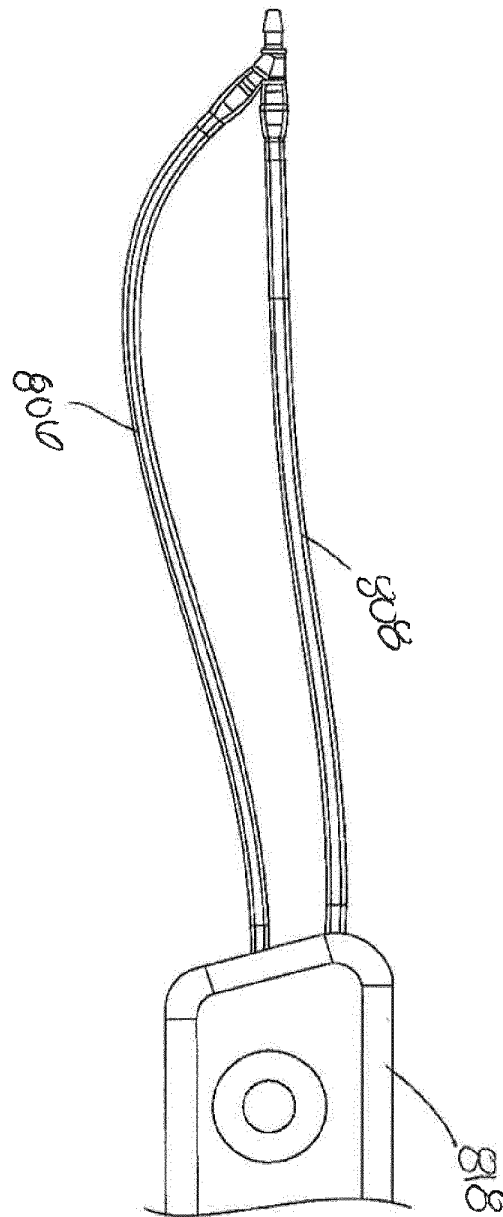


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FIG. 8E

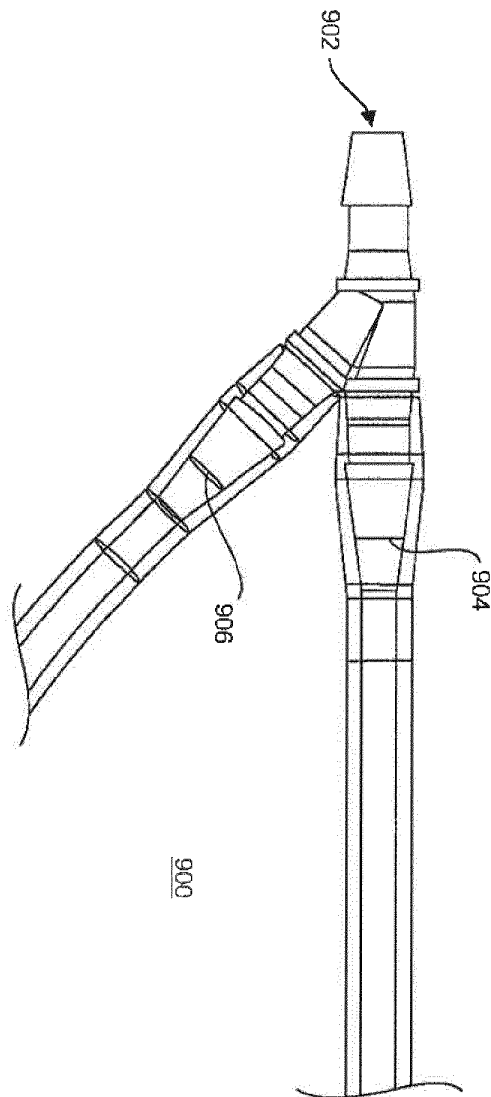


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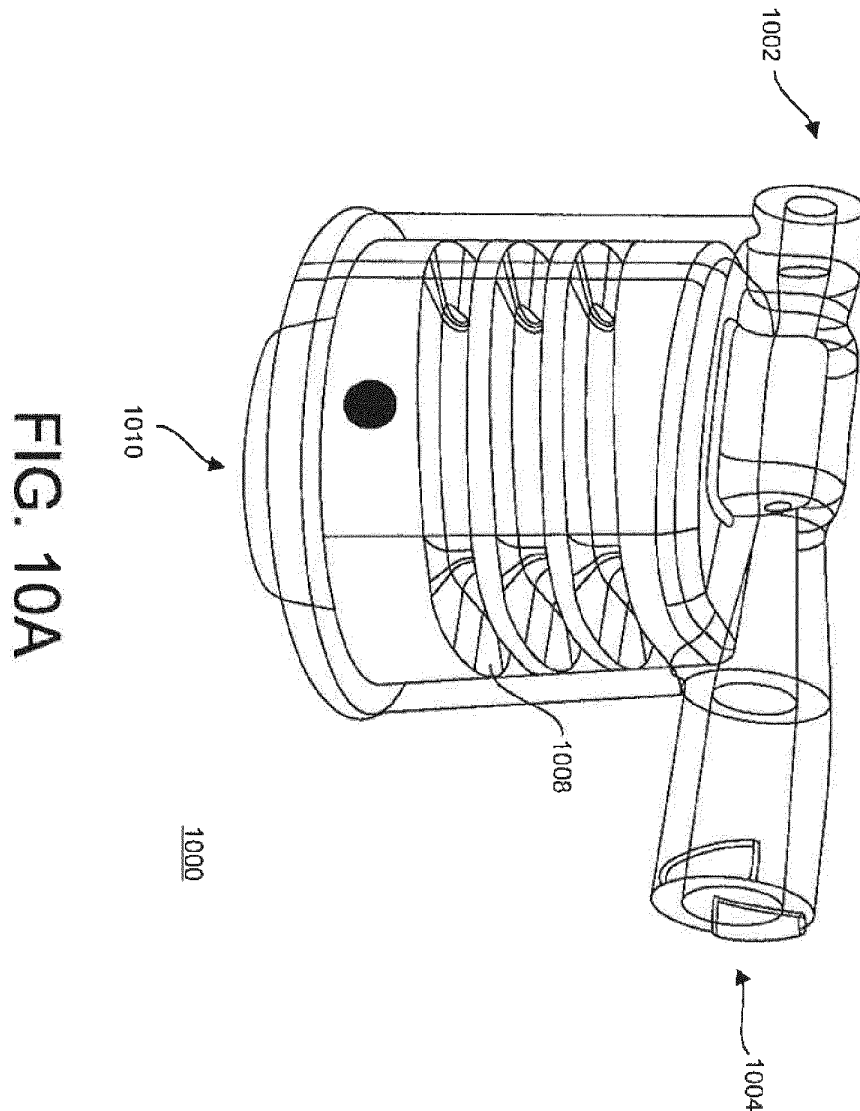
FIG. 9



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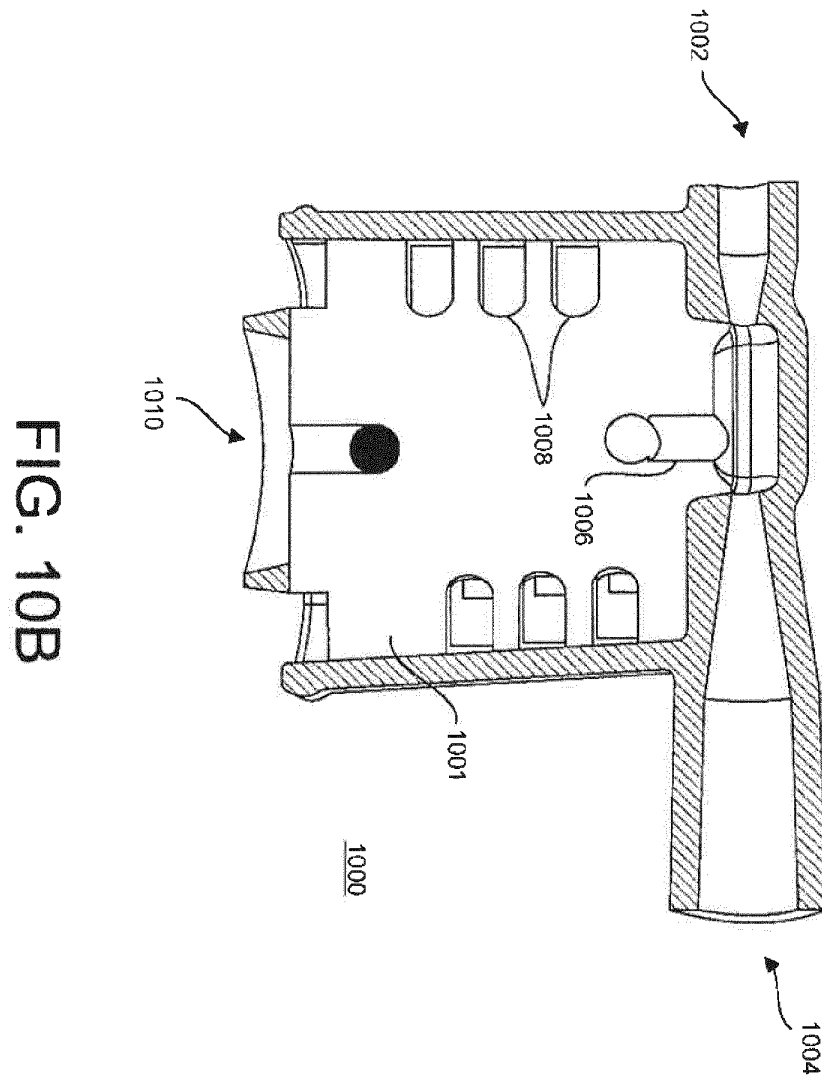
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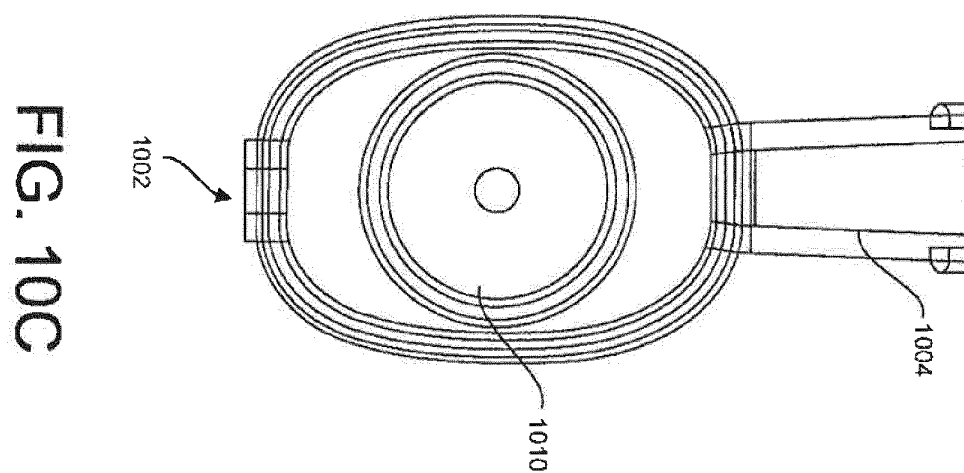
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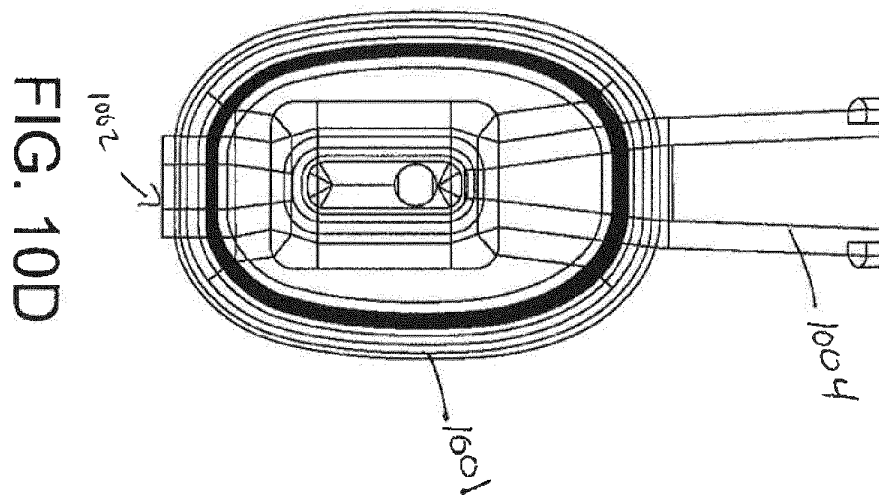
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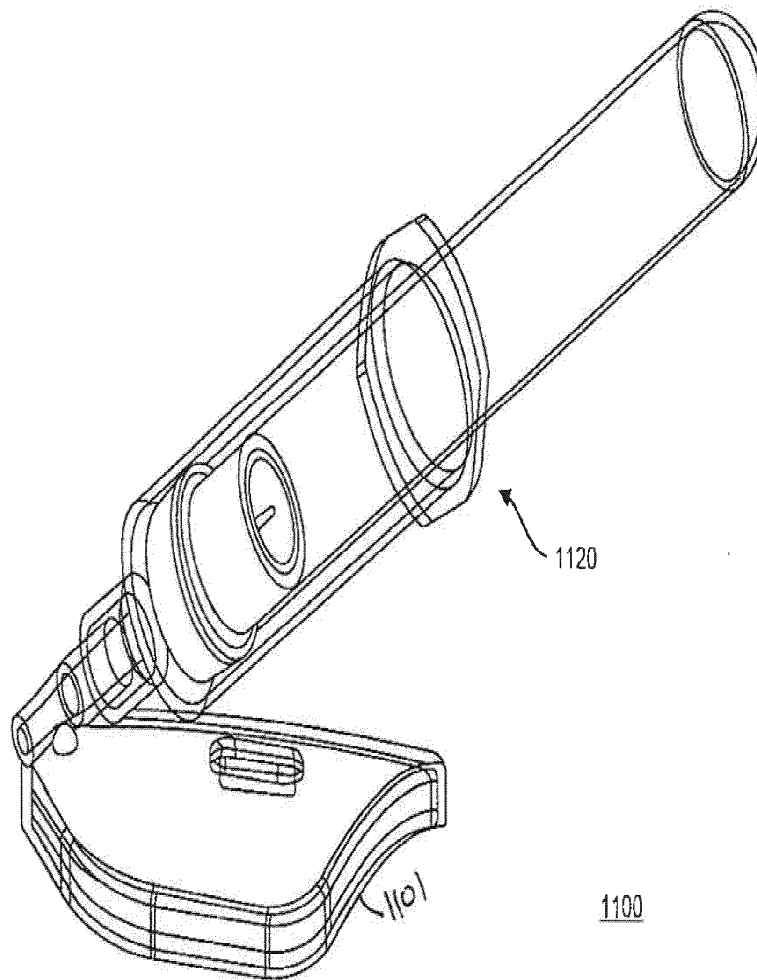


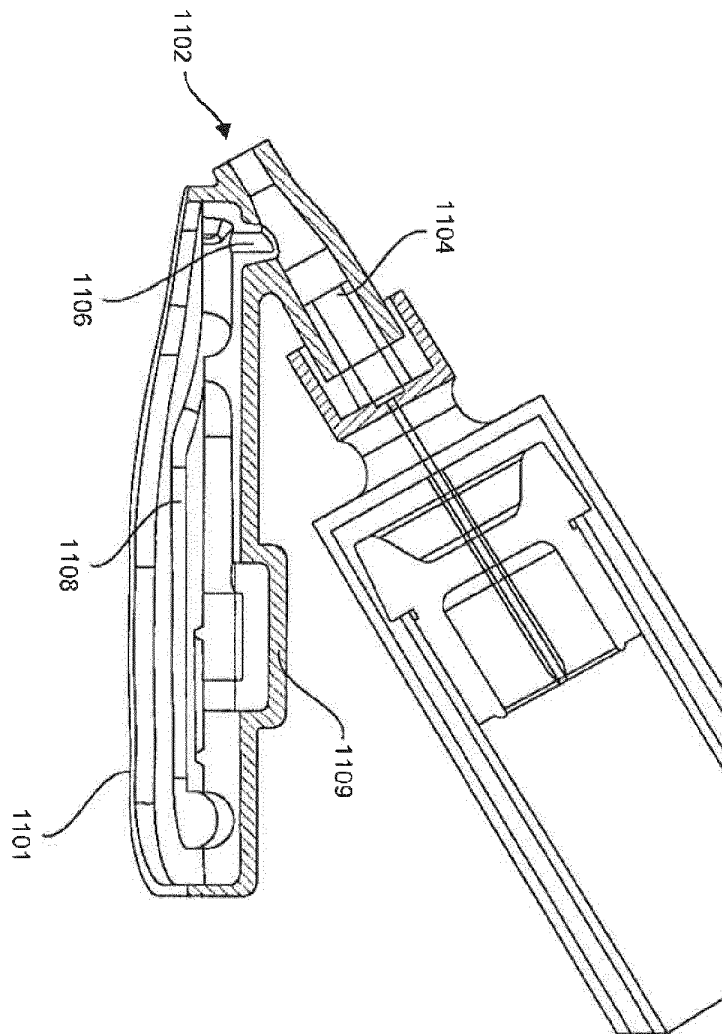
FIG. 11A

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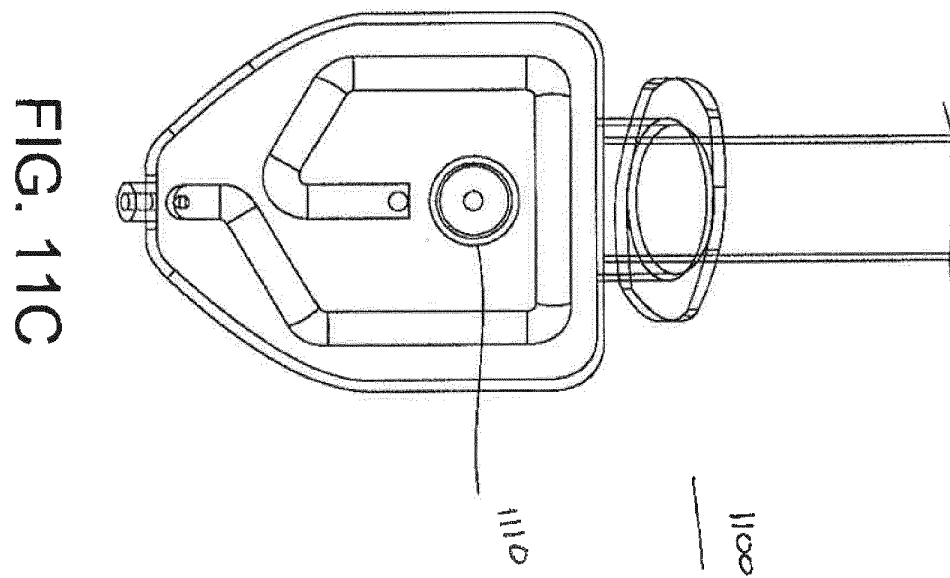
FIG. 11B



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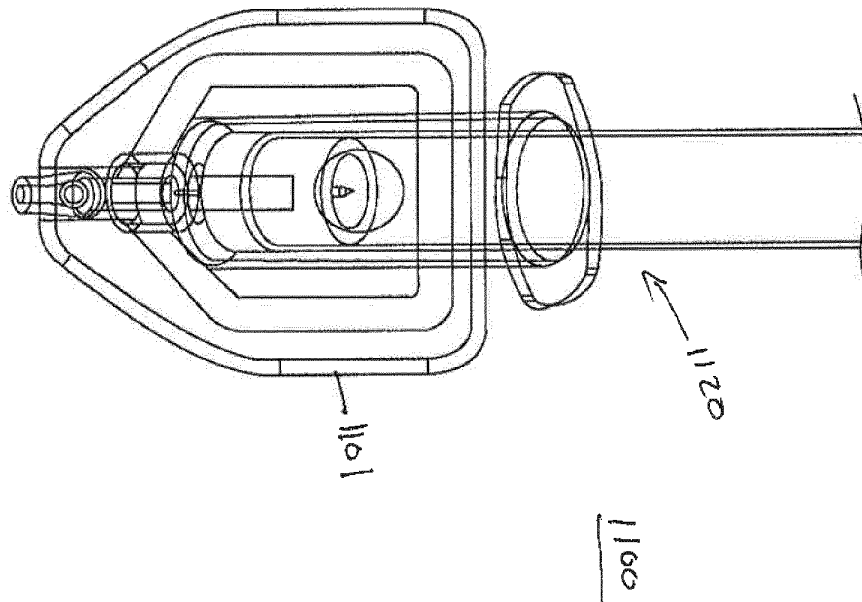


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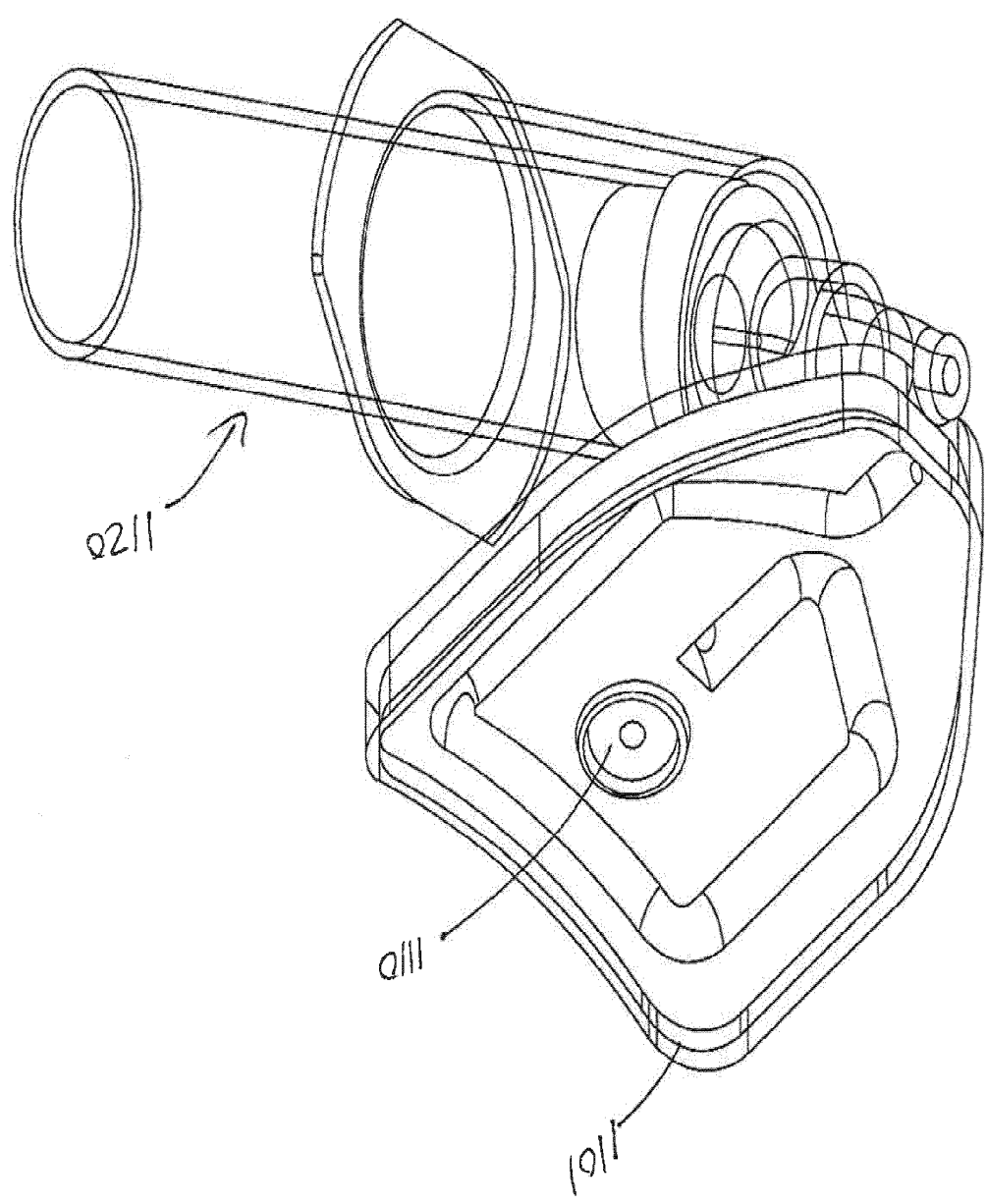
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FIG. 11D



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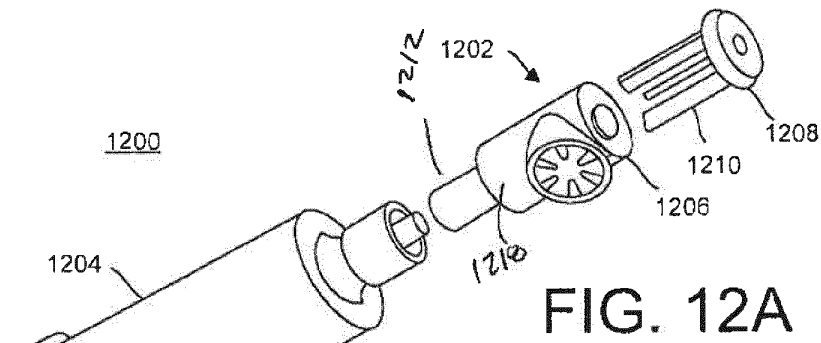
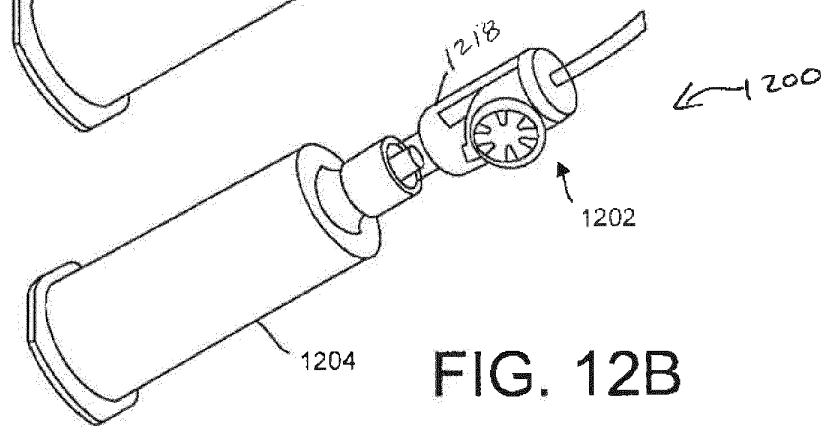
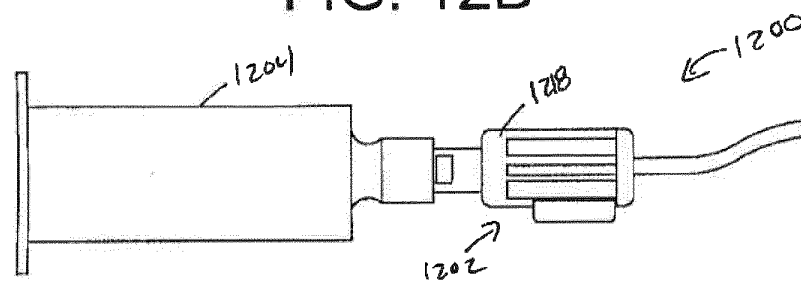
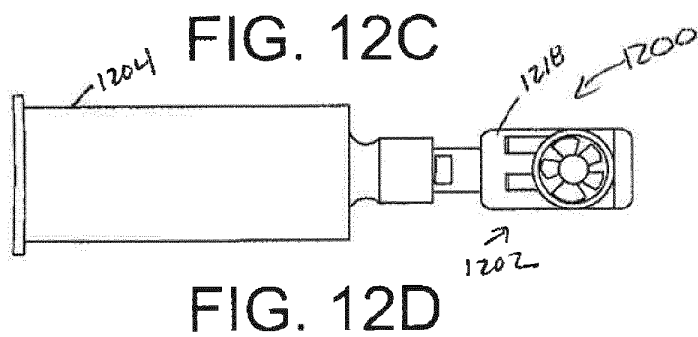
FIG. 11E



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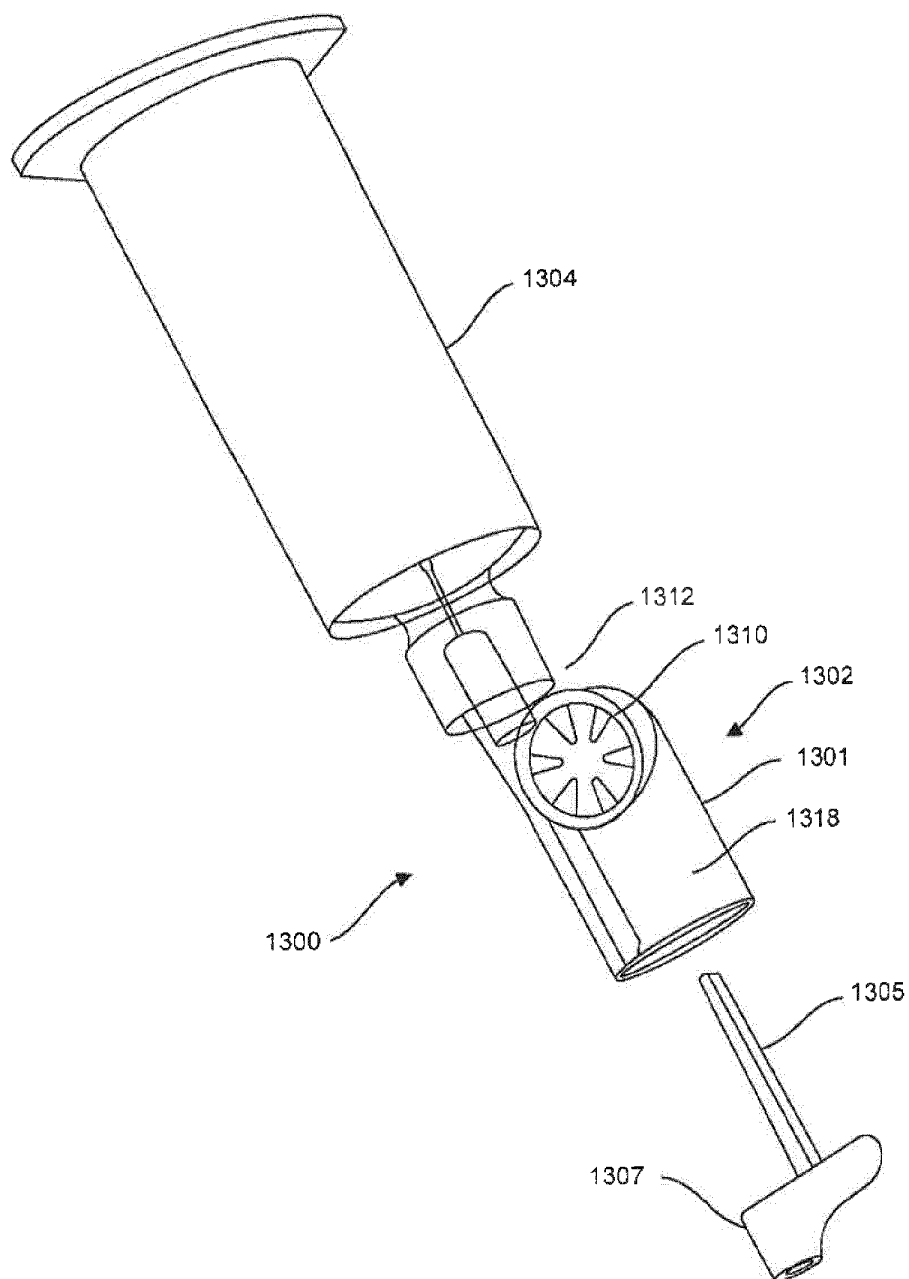


FIG. 13A

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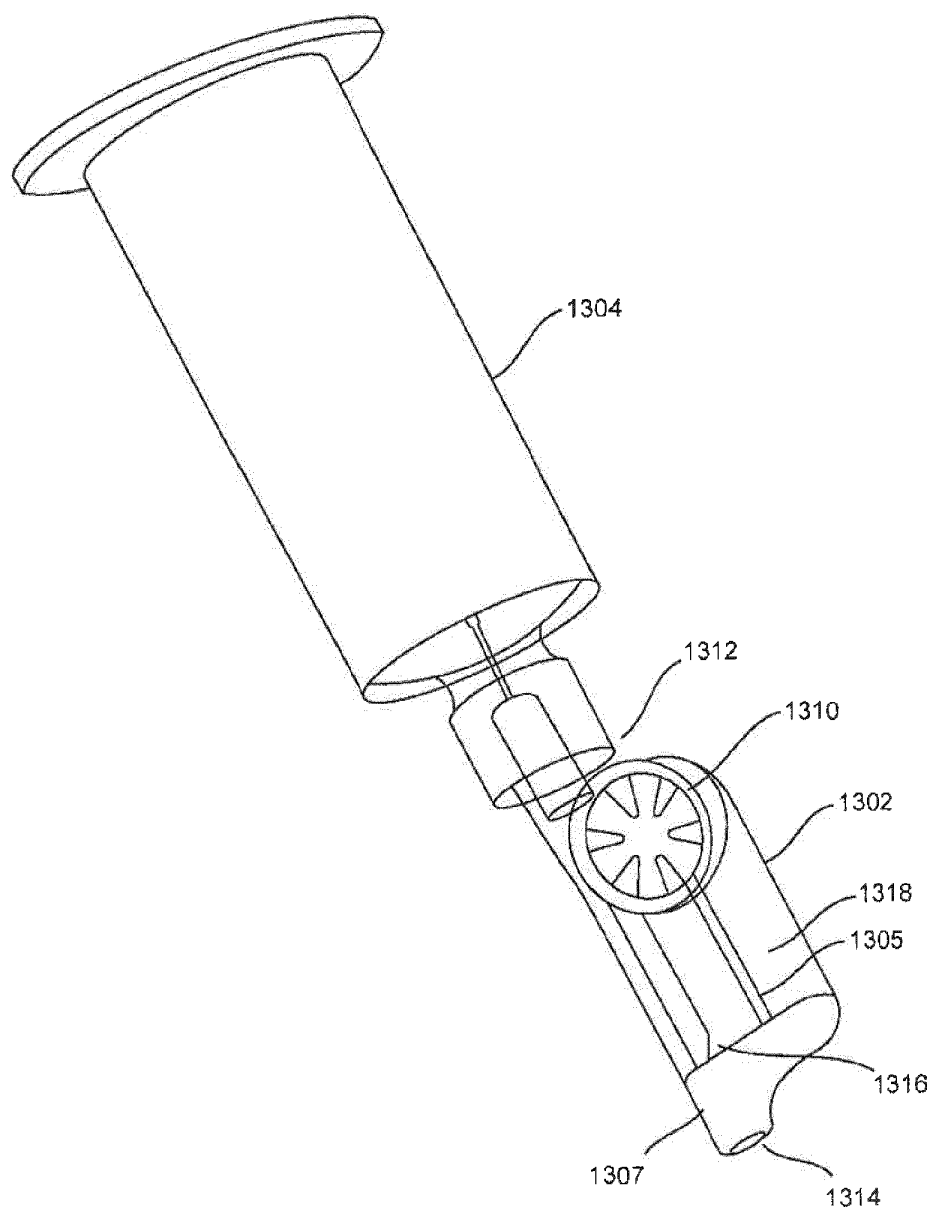


FIG. 13B

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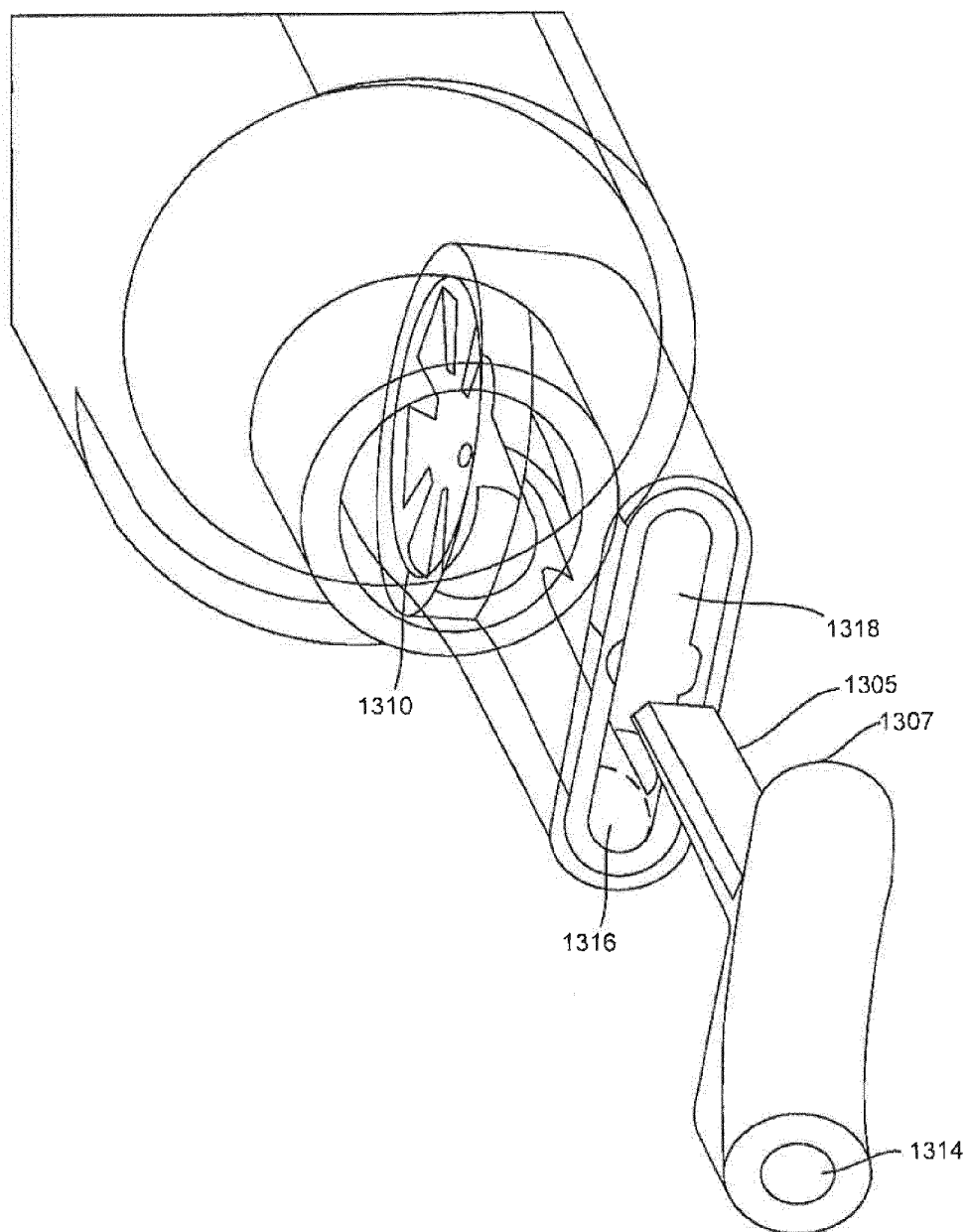


FIG. 13C

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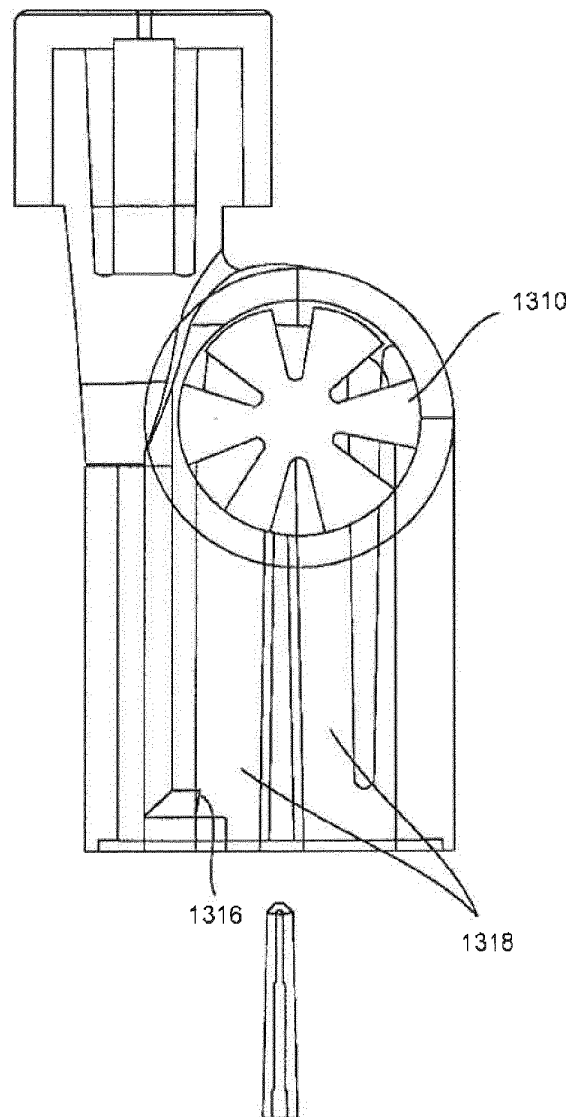


FIG. 13D

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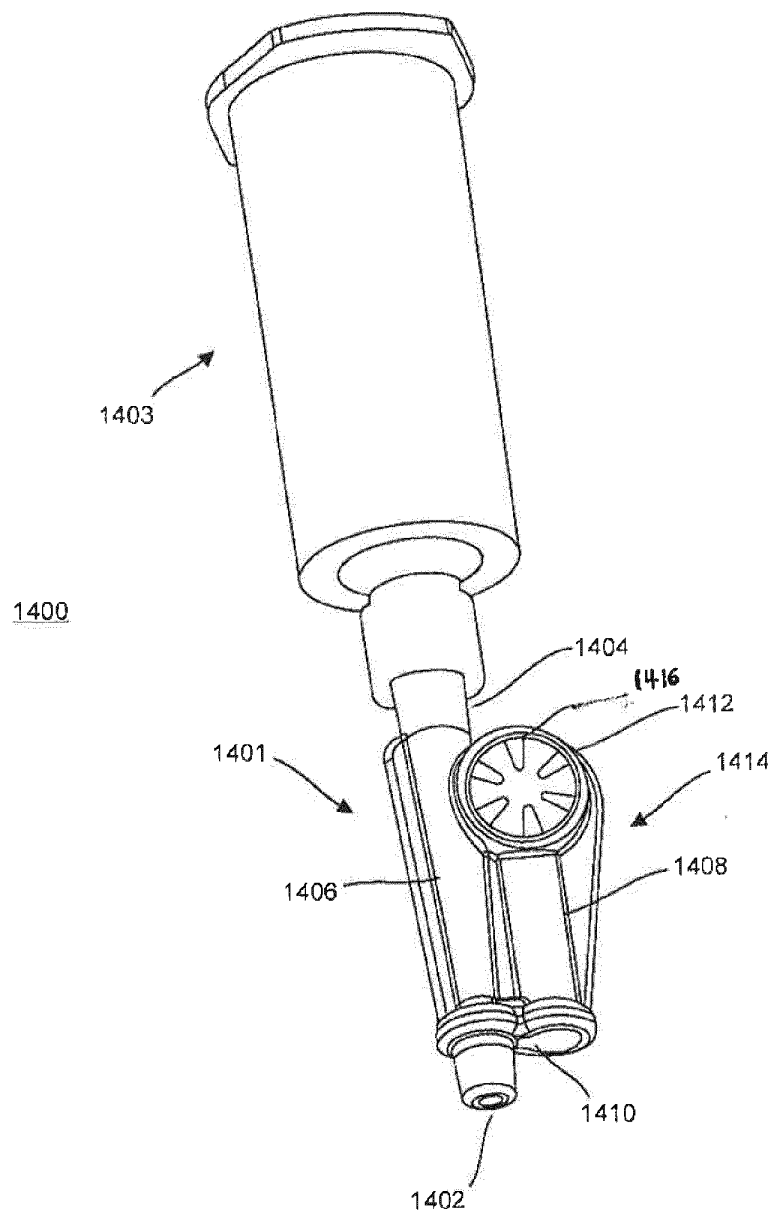


FIG. 14A

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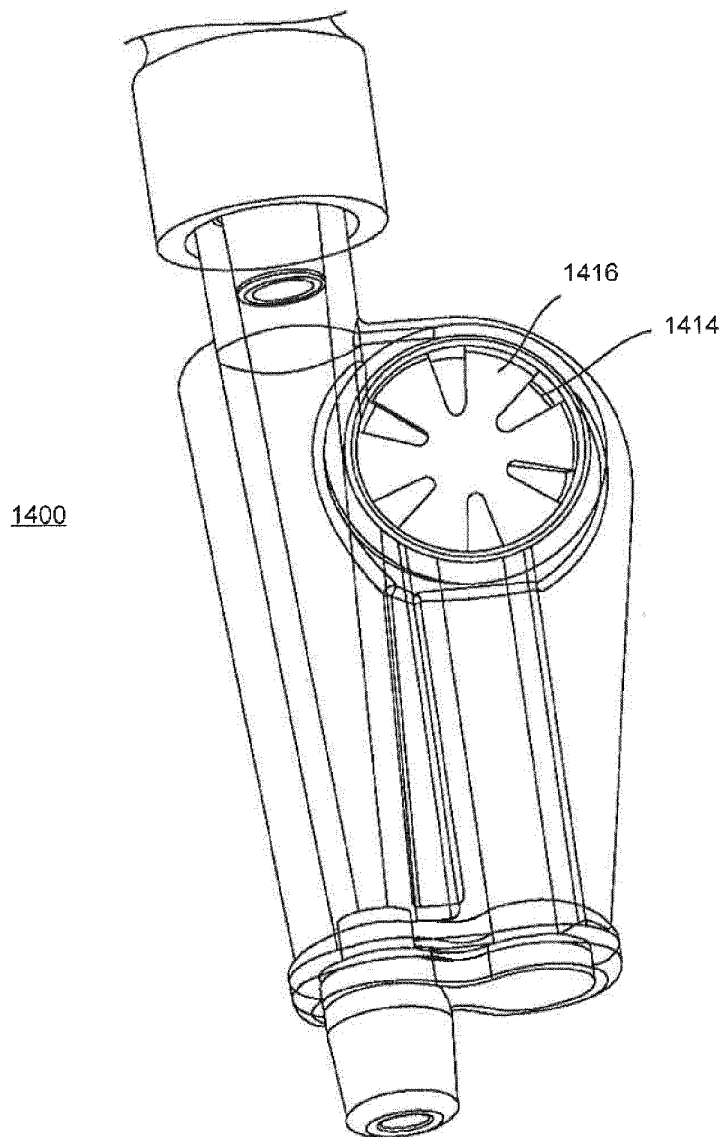


FIG. 14B

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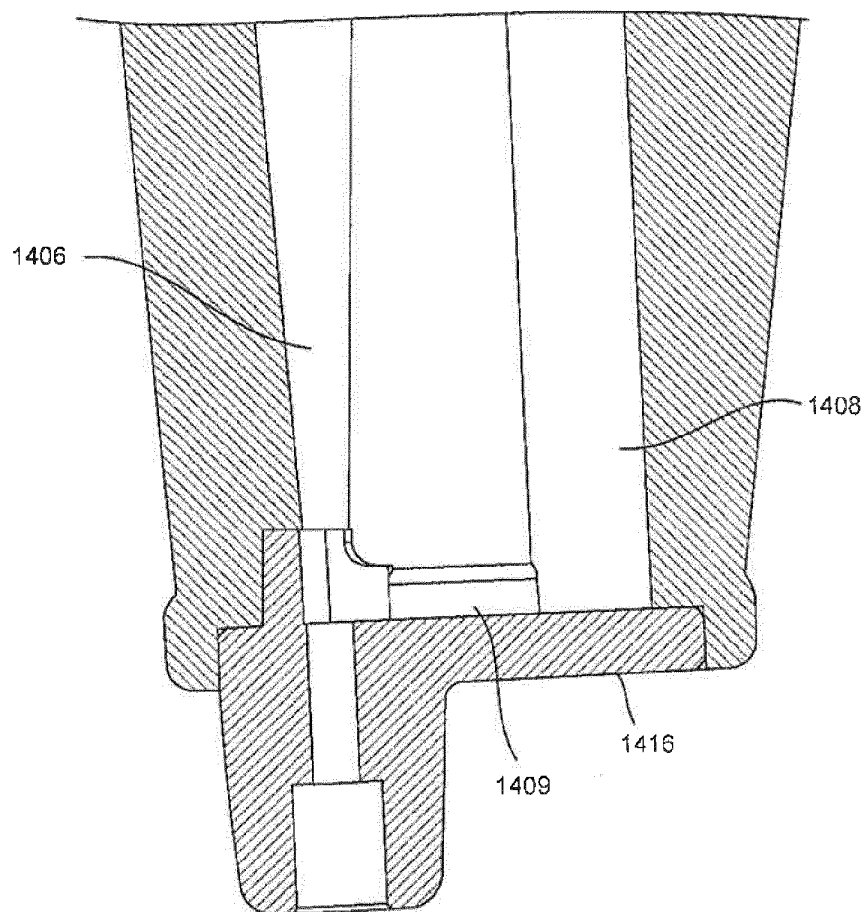


FIG. 14C

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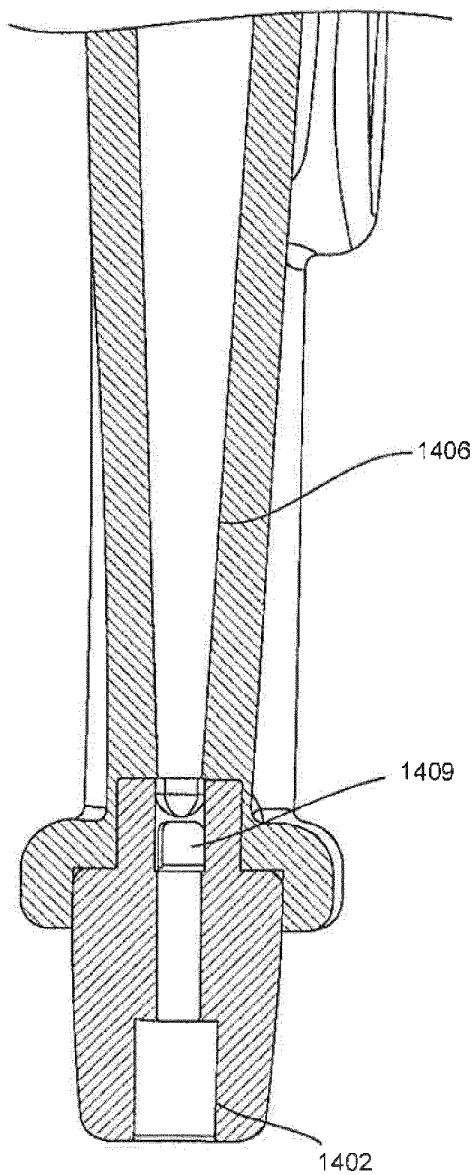
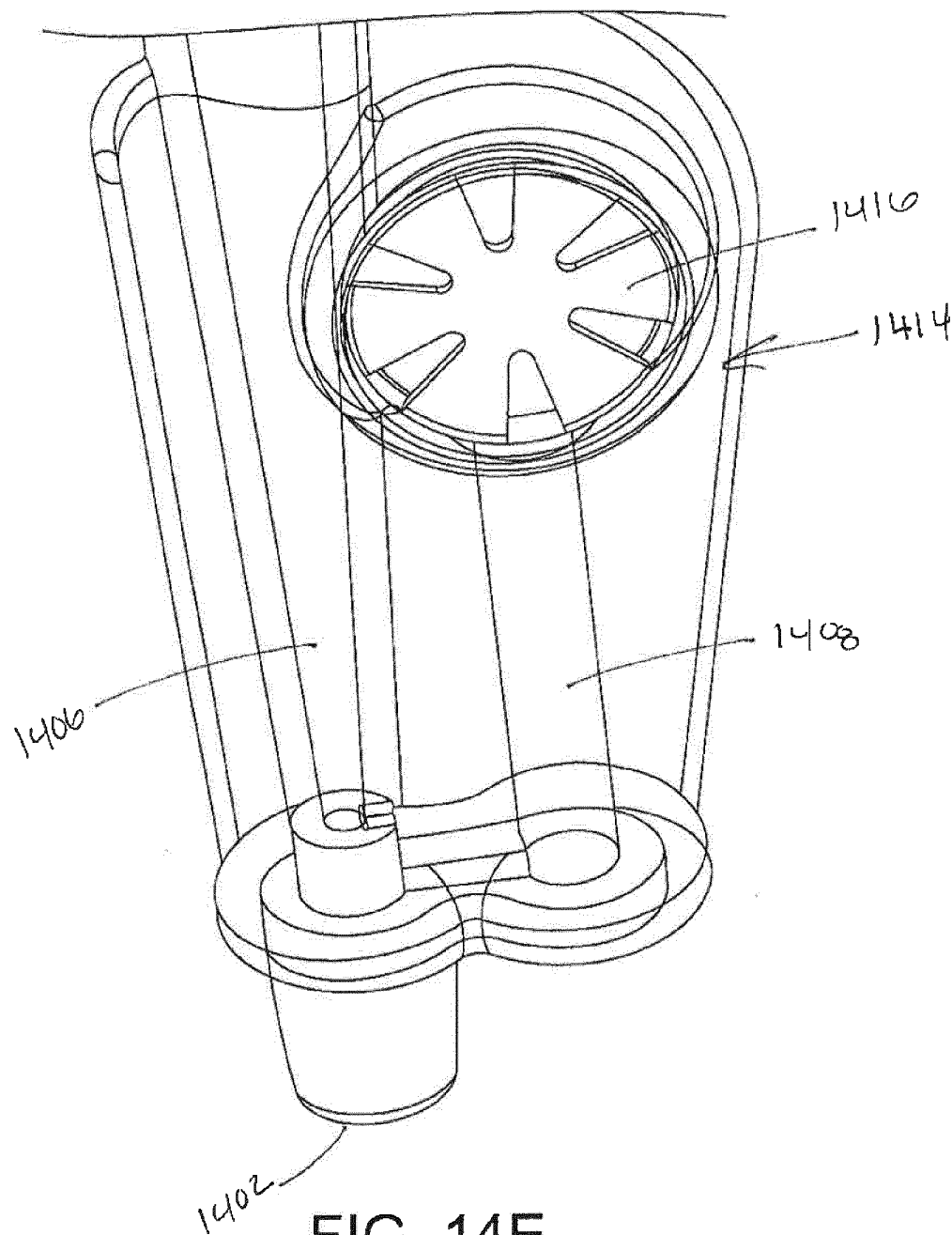


FIG. 14D

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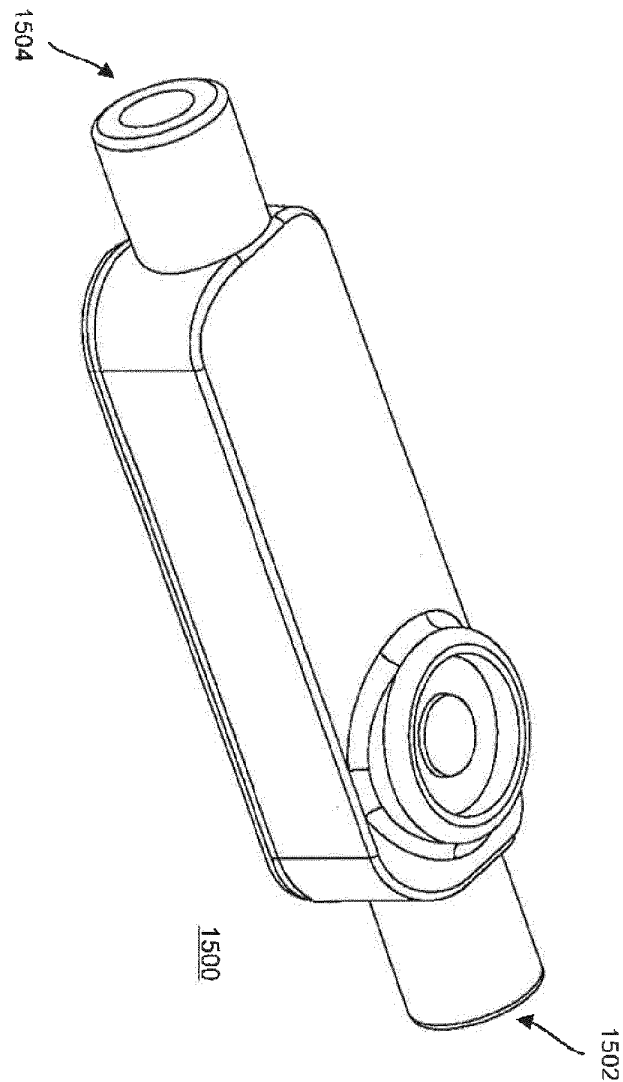


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FIG. 15A

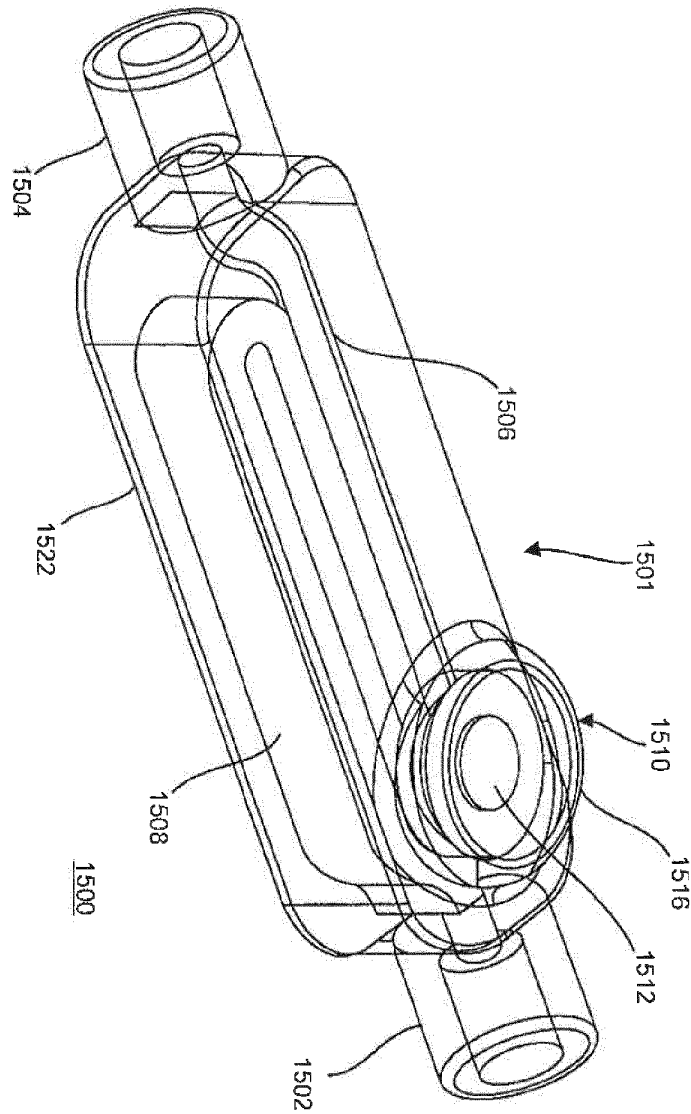


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FIG. 15B

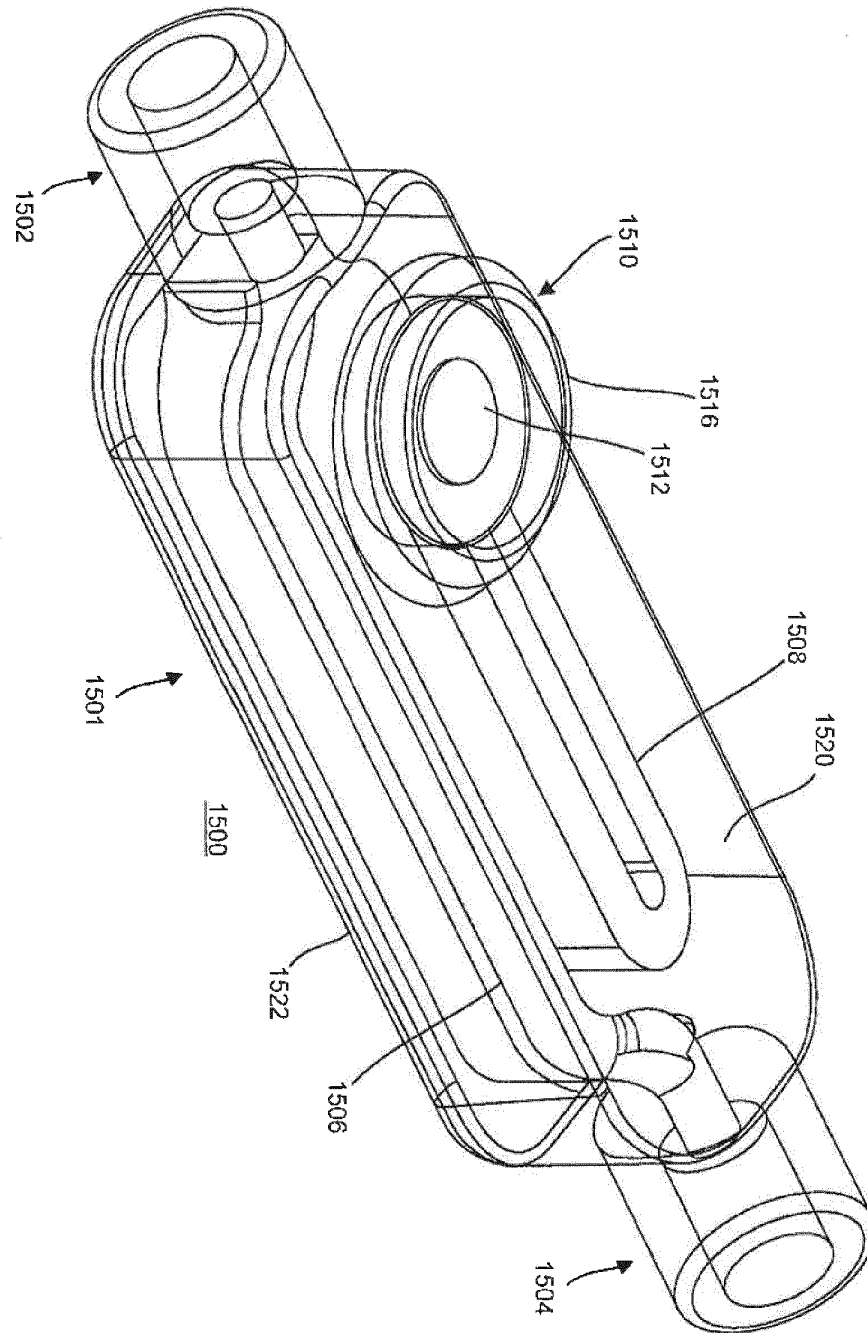


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FIG. 15C

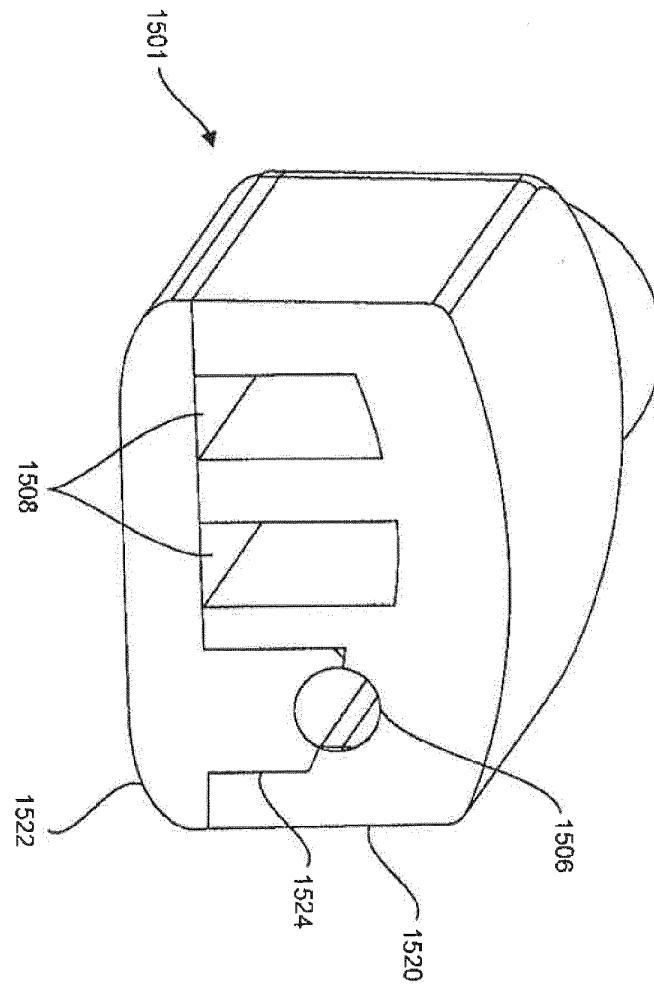


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FIG. 15D



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FIG. 15E

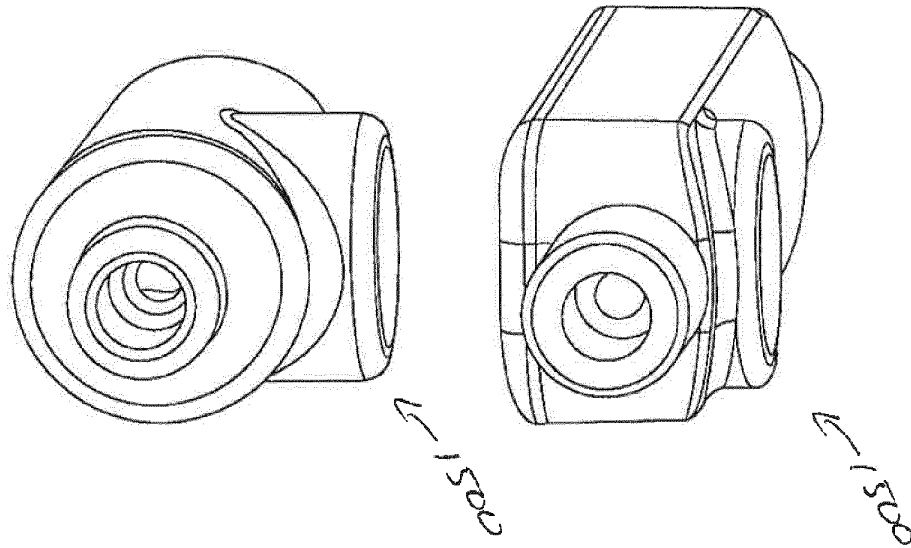
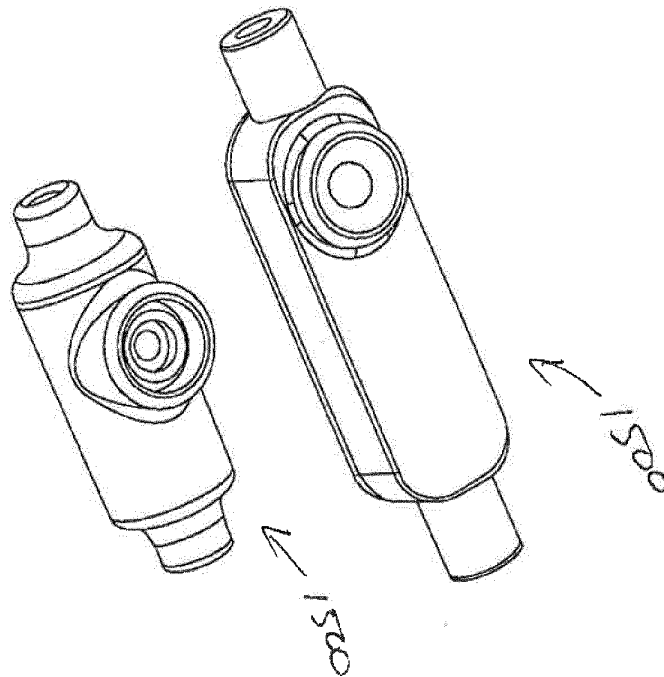


FIG. 15F

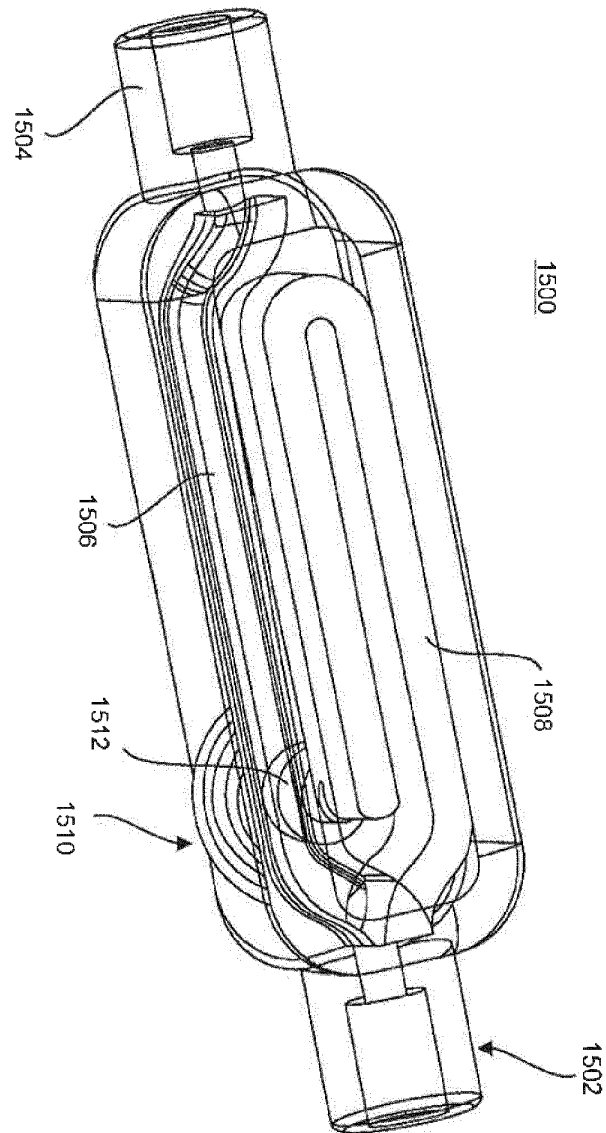


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FIG. 15G



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FIG. 16A

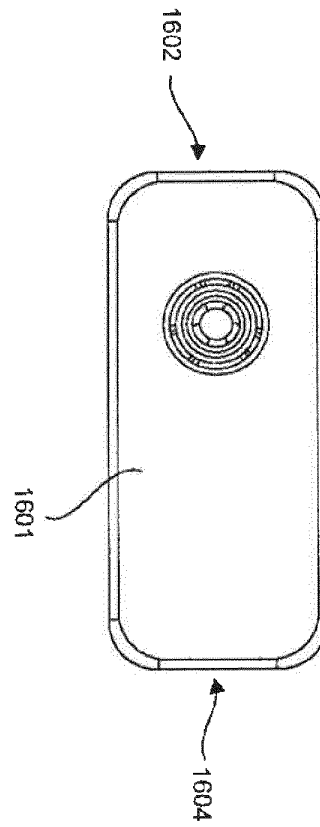


FIG. 16B

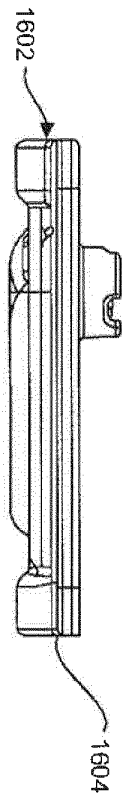
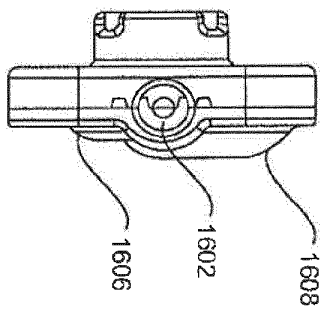


FIG. 16C

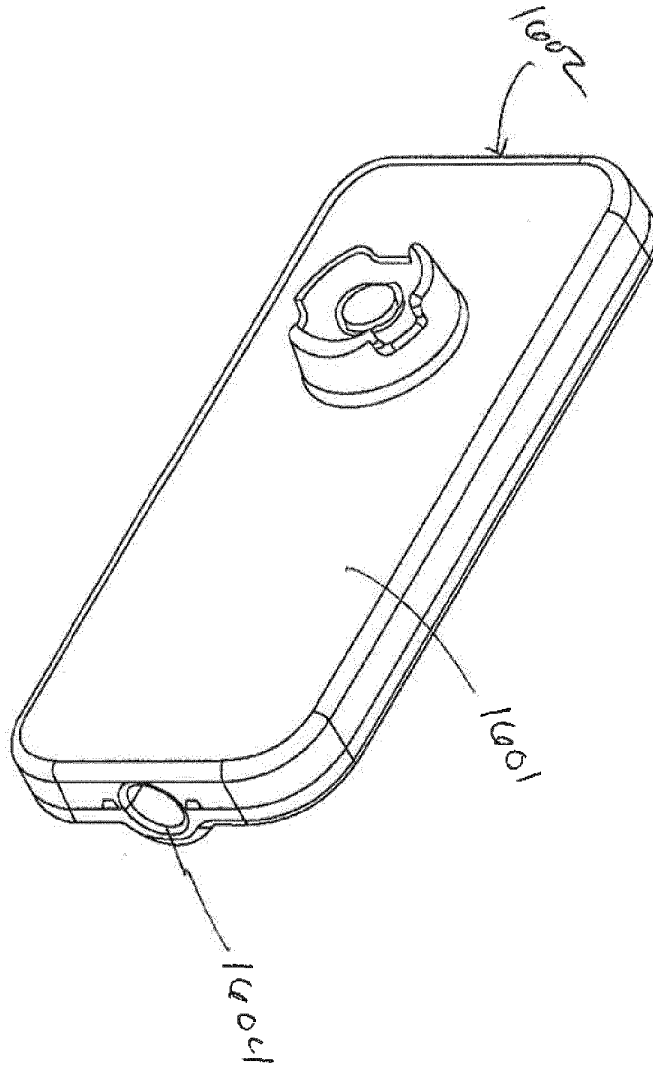


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FIG. 16D



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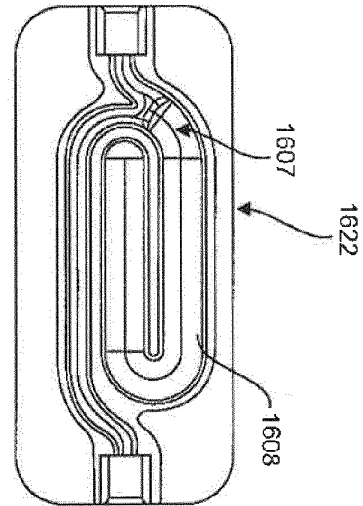


FIG. 17A

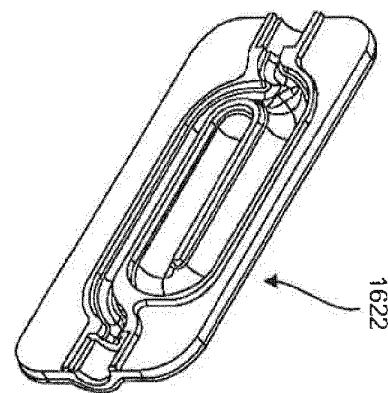


FIG. 17B

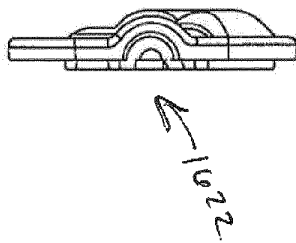


FIG. 17C

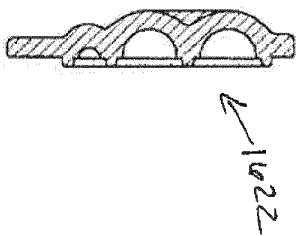


FIG. 17D

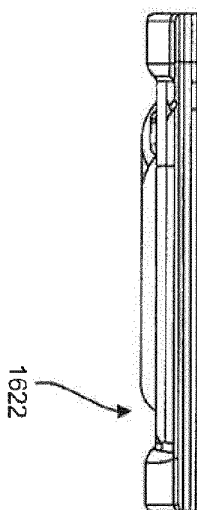


FIG. 17E

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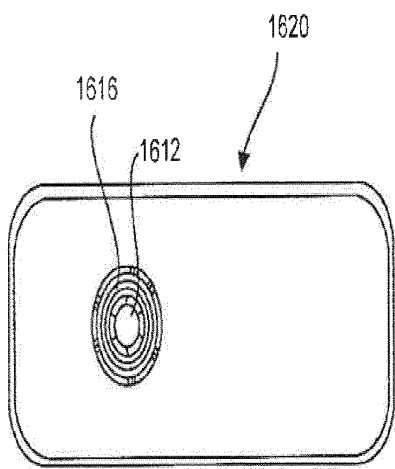


FIG. 18A

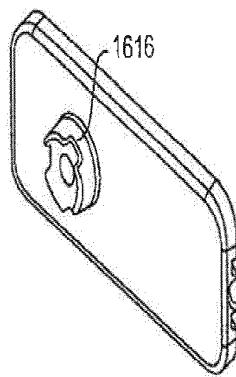


FIG. 18B

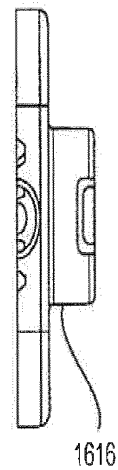


FIG. 18C

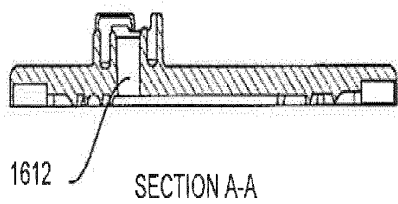


FIG. 18D

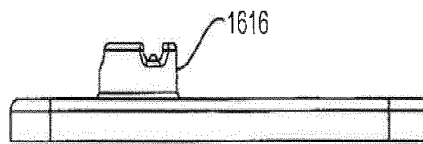


FIG. 18E

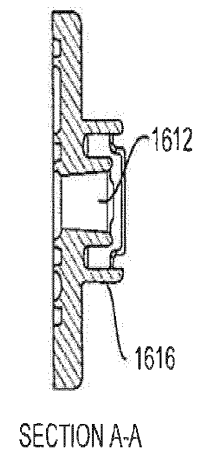


FIG. 18F

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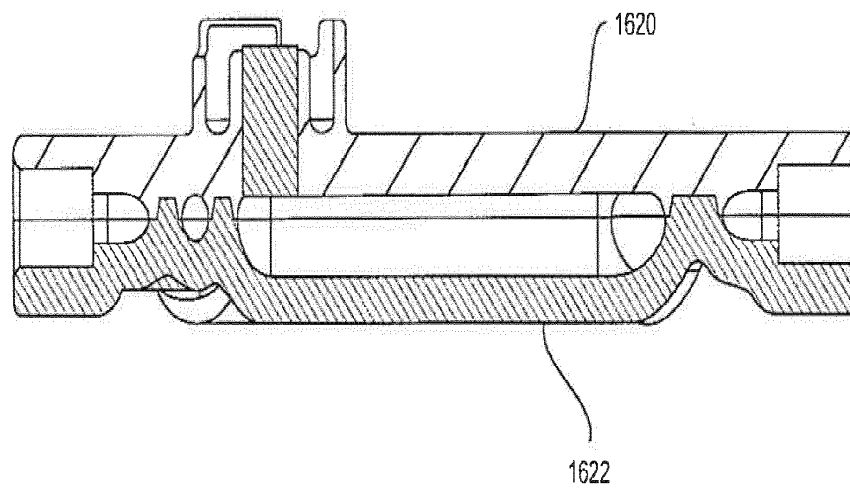


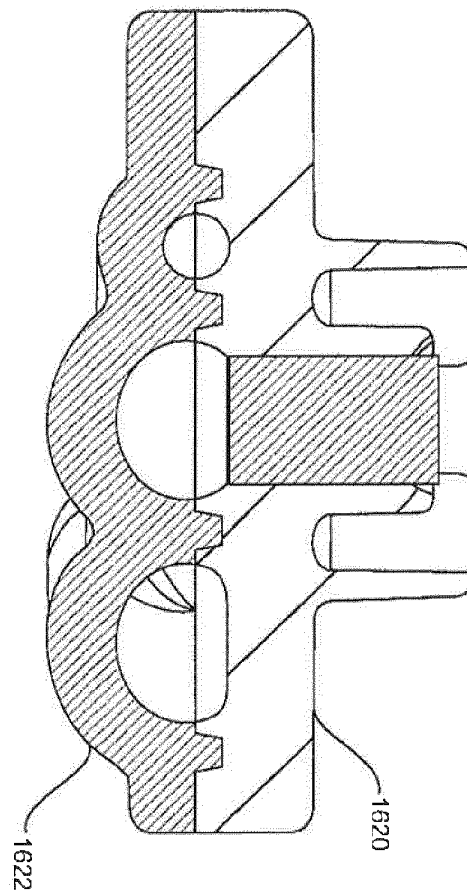
FIG. 19A

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FIG. 19B

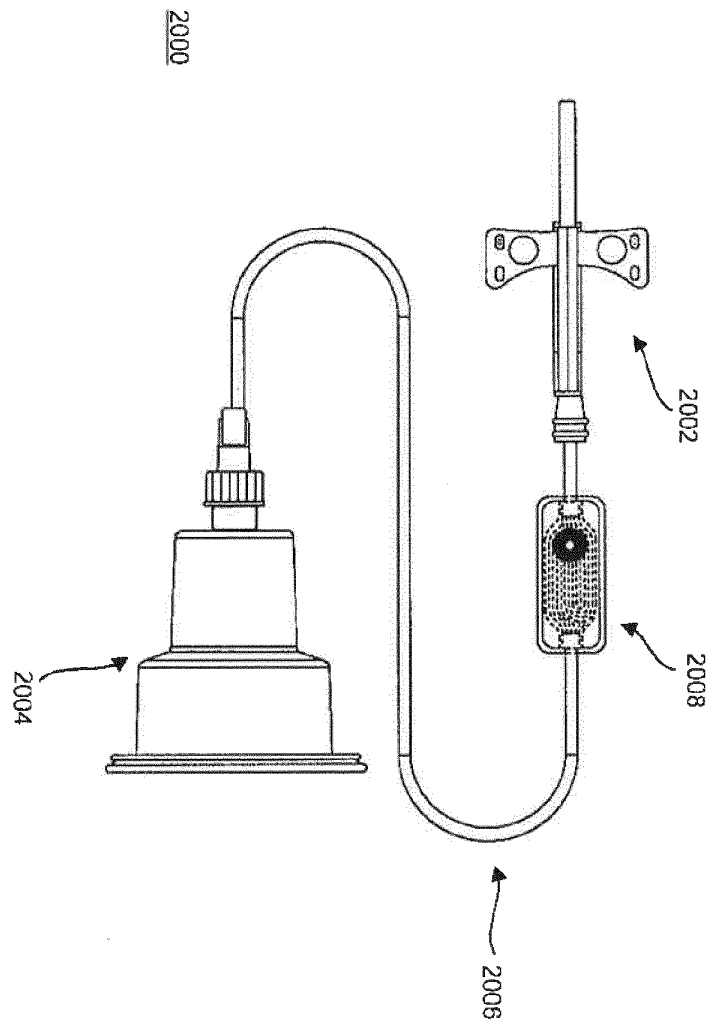


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FIG. 20



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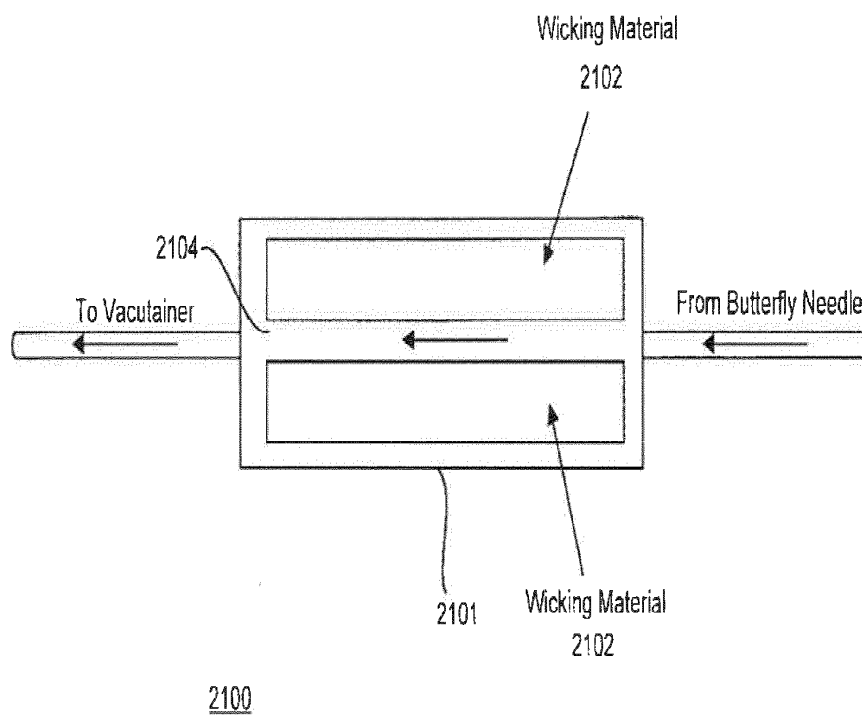


FIG. 21

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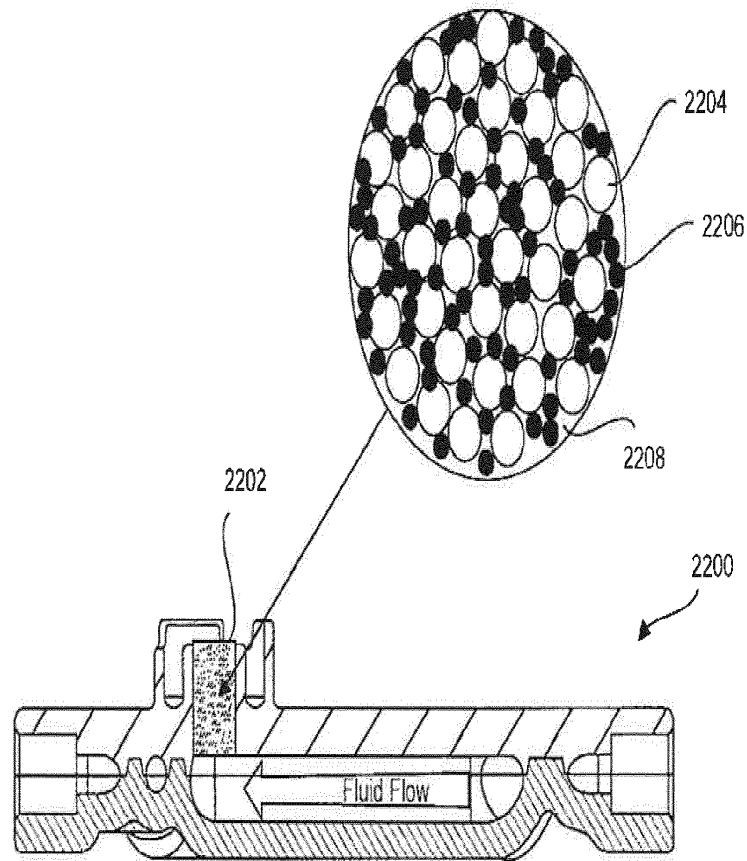


FIG. 22A

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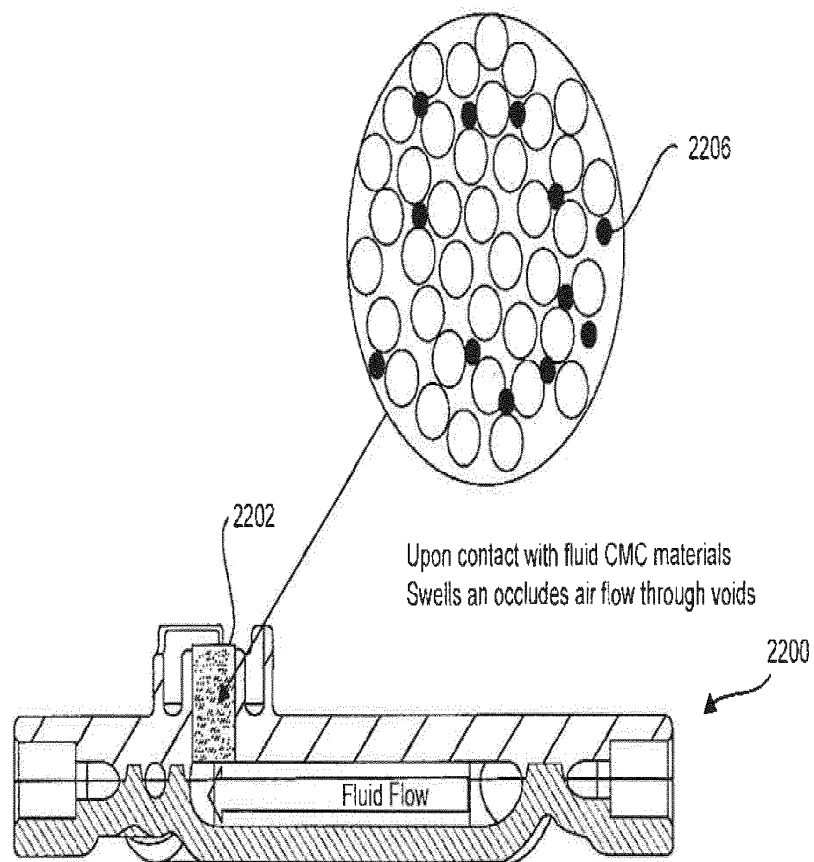


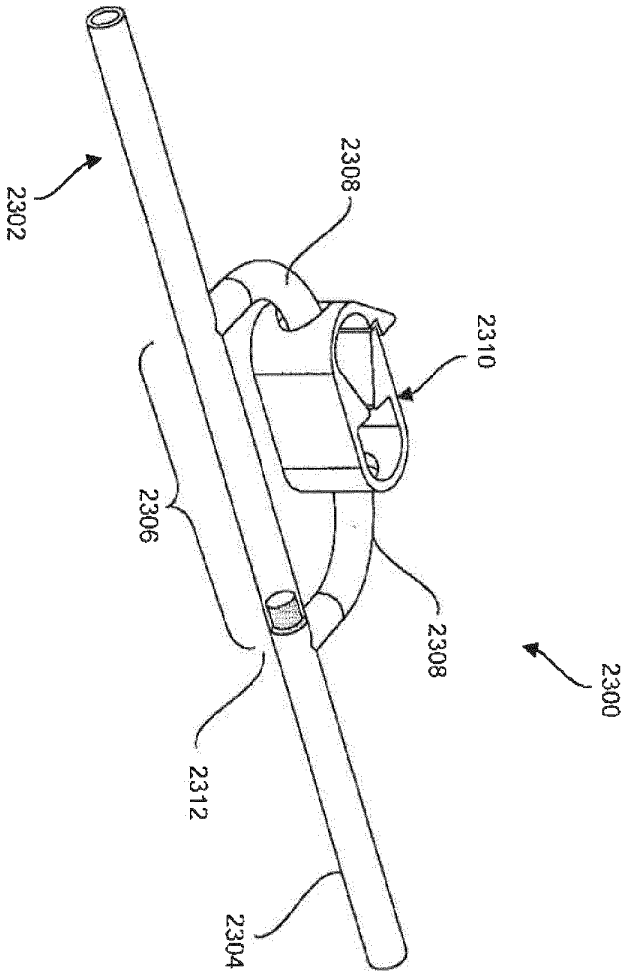
FIG. 22B

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FIG. 23A



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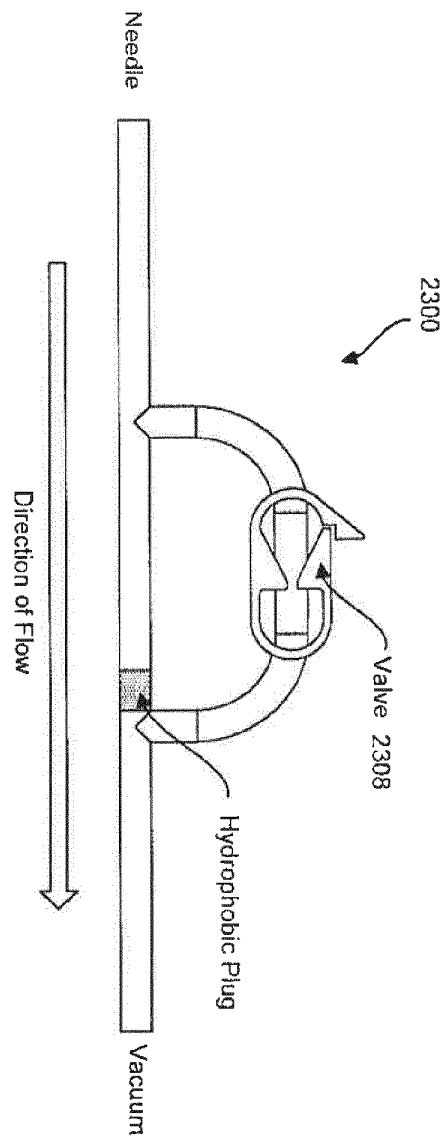


FIG. 23B

RELATED APPLICATIONS

5 [0001] This application claims the benefit of priority of U.S. Non-Provisional Application Serial No. 15/140,443, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD" and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD
10 CONTAMINANT SEQUESTRATION DEVICE AND METHOD", both of which claim priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015 and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S. Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled "BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING";
15 and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD".

BACKGROUND

[0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on
20 the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with

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catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles.

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Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination,

20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

5 [0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

10 [0012a] WO 96/05875 A1 discloses a blood sampling device comprising a bifurcated capillary tube which has a first branch having a cannula shaped end for withdrawing and conveying blood to a blood collection zone for storing a quantity of withdrawn blood and feeding an initial fraction of withdrawn blood to a blood disposal chamber having an air permeable liquid sealed end; and a second branch
15 connected to the blood collection zone which terminates in an opening adapted to receive a blood withdrawal device.

SUMMARY

[0013] This document presents systems and methods (a method is not claimed) for reducing blood

20 culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

25 [0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to

accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is provided, comprising; an inlet port; a junction connected with the inlet port; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with an outlet port; and a housing that houses and defines the inlet port, the junction, the sequestration chamber, the sampling channel, and the outlet port, wherein the sequestration chamber is connected with the inlet port via the junction which is configured to direct a first portion of blood to the sequestration chamber, wherein the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood.

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[0016] In another aspect, a system of a blood sequestration device, a blood sampling pathway having a patient needle, and a sample collection device is provided, the blood sequestration device comprising; an inlet port connected with the patient needle; a junction connected with the inlet port opposite the blood sampling pathway; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port; and an outlet port connected with a distal end of the sampling channel and with the sample collection device; and a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel, wherein the sequestration chamber is connected with the inlet port and the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with blood.

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[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims. The invention is best illustrated by figures 16A to 19B.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

[0024] FIG. 1 illustrates a blood sample optimization system.

[0025] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0026] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0027] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0028] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0030] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

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- [0031]** FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.
- [0032]** FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.
- [0033]** FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.
- [0034]** FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.
- [0035]** FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.
- [0036]** FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.
- [0037]** FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminants of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.
- [0038]** FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.
- [0039]** FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.
- [0040]** FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.
- [0041]** FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

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[0042] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0043] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0044] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0045] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0046] FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0047] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0048] This document describes blood sample optimization systems and methods (a method is not claimed)

for reducing or eliminating contaminants in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient

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needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0049] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0050] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

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[0051] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0052] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

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[0053] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0054] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0055] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

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[0056] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminant, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0057] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0058] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable

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blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0059] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0060] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0061] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is

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added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0062] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0063] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0064] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone

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to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0065] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indicator or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0066] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

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[0067] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0068] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0069] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable

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blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0070] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0071] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a

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sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0072] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0073] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0074] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0075] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can

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be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0076] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0077] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0078] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with

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one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0079] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0080] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0081] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved,

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and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0082] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0083] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminants of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port

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1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0084] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.114 cm (0.045 inches),

but can have a diameter of between 0.0254 cm (0.01 inches) or less to 0.508 cm (0.2 inches) or more. The

blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403.

The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0085] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0086] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration

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chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0087] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0088] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion

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pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0089] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0090] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.114 cm (0.045 inches), but can have a diameter of between 0.0254 cm (0.01 inches) or less to 0.508 cm (0.2 inches) or more.

[0091] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some

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implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0092] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0093] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0094] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port

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1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0095] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel

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1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0097] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0098] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0099] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00100] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial

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groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00101] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00102] After a venipuncture by a patient needle of a patient (not shown, not claimed),

which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure

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overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00103] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00104] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS.

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16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00105] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.114 cm (0.045 inches), but can have a diameter of between 0.0254 cm (0.01 inches) or less to 0.508 cm (0.2 inches) or more.

[00106] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00107] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need

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for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00108] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00109] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00110] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

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[00111] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17D and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00112] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00113] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00114] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other

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pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00115] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00116] In use (neither use nor method is claimed), the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-

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filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00117] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00118] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00119] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

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[00120] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00121] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00122] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00123] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

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[00124] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00125] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

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Amended claims

1. A blood sequestration device (1500) comprising;
an inlet port (1502);
5 a junction (1607) connected with the inlet port (1502);
a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);
a sampling channel (1506) having a proximal end connected with the inlet port (1502) via the junction (1607), and a distal end connected with an outlet port (1504); and
10 a housing (1501) that houses and defines the inlet port (1502), the junction (1607), the sequestration chamber (1508), the sampling channel (1506), and the outlet port (1504),
wherein the sequestration chamber (1508) is connected with the inlet port (1502) via the junction (1607) which is configured to direct a first portion of blood to the sequestration chamber (1508),
15 characterized in that the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood.
20
2. The blood sequestration device (1500) in accordance with claim 1, wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).
- 25 3. The blood sequestration device (1500) in accordance with claim 1 or 2, further comprising a blood sampling pathway connected with the inlet port (1502) opposite the junction (1607), and
wherein the inlet port (1502) defined by the housing (1501) has a cross-sectional geometry consistent with the blood sampling pathway.
30
4. The blood sequestration device (1500) in accordance with one of the preceding claims, wherein the sampling channel (1506) defined by the housing (1501) has a cross-sectional geometry consistent with the inlet port (1502).
- 35 5. The blood sequestration device (1500) in accordance with one of claims 2 to 4, wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520)

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defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

6. A system of a blood sequestration device (1500), a blood sampling pathway
5 having a patient needle, and a sample collection device, the blood sequestration device (1500) comprising;
an inlet port (1502) connected with the patient needle;
a junction (1607) connected with the inlet port (1502) opposite the blood
sampling pathway;
10 a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);
a sampling channel (1506) having a proximal end connected with the inlet port (1502); and
an outlet port (1504) connected with a distal end of the sampling channel
15 (1506) and with the sample collection device; and a housing (1501) that houses and defines the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506),
characterized in that the sequestration chamber (1508) is connected with the inlet port (1502) and the air permeable blood barrier (1512) includes an air
20 permeable material that seals at least partially upon contact with blood.
7. The system in accordance with claim 6, wherein the inlet port (1502) is connected with the patient needle via a first portion of the blood sampling pathway.
- 25 8. The system in accordance with claim 6 or 7, wherein the outlet port (1504) is connected with the sample collection device via a second portion of the blood sampling pathway.
9. The system in accordance with one of claims 6 to 8, wherein the sequestration
30 chamber (1508) includes a sequestration channel defined in the housing (1501).
10. The system in accordance with claim 9, wherein the sequestration channel has a proximal end connected with the inlet port (1502), and a distal end having the vent (1510) comprising an air permeable blood barrier (1512).
35
11. The system in accordance with one of claims 6 to 10, wherein the sequestration chamber (1508) and the sampling channel (1506) are connected with

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the inlet port (1502) by the junction (1607) that is configured to direct a first portion of blood to the sequestration chamber (1508).

5 12. The system in accordance with one of claims 6 to 11, wherein the sampling channel (1506) has a substantially uniform cross-sectional geometry that is consistent with the blood sampling pathway.

10 13. The system in accordance with claim 12, wherein the sequestration chamber (1506) includes a sequestration chamber that has a cross-sectional area that is larger than the cross-sectional geometry of the sampling channel (1506).

15 14. The system in accordance with claim 7, member (1520), wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520) defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

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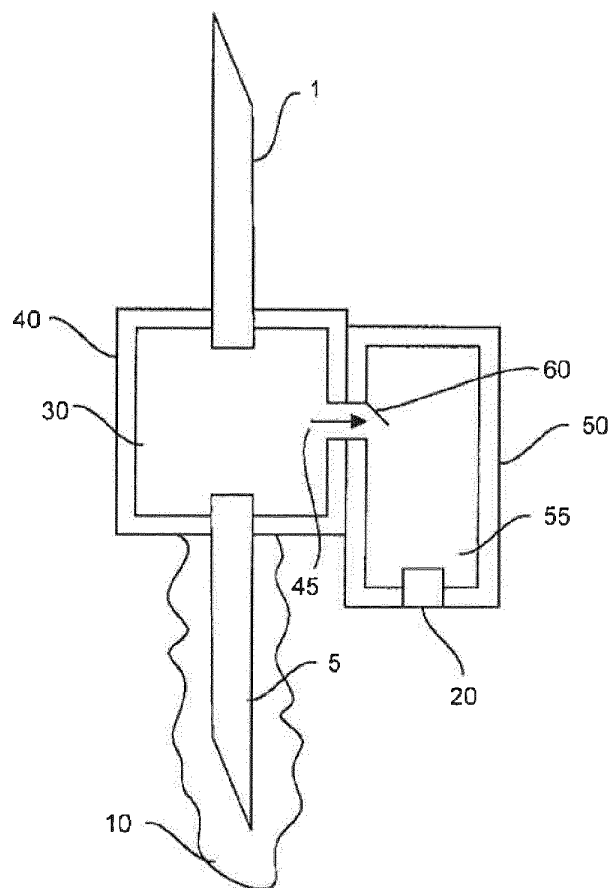


FIG. 1

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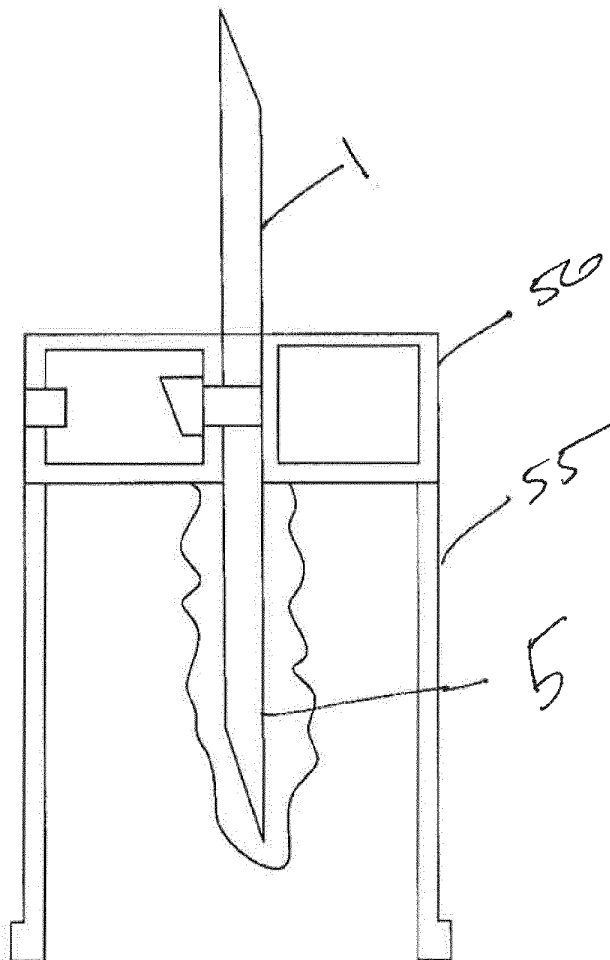
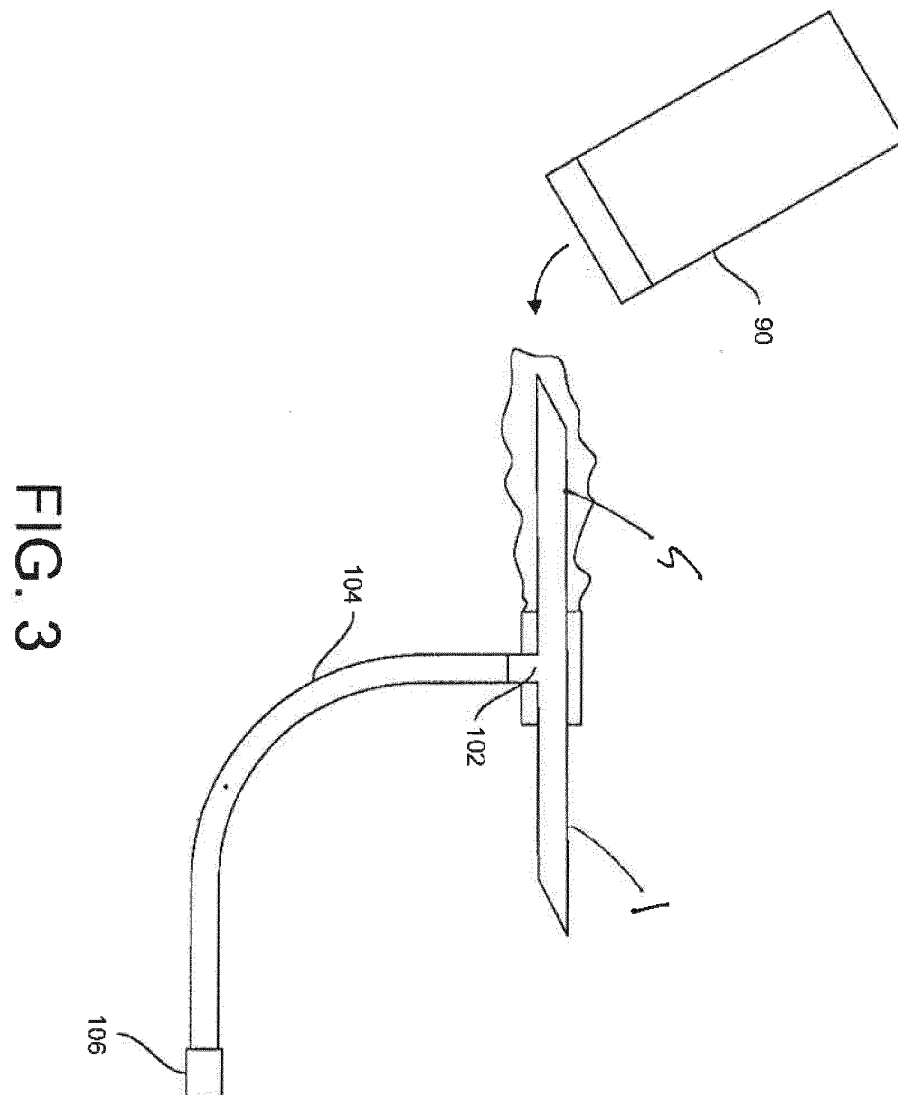


FIG. 2

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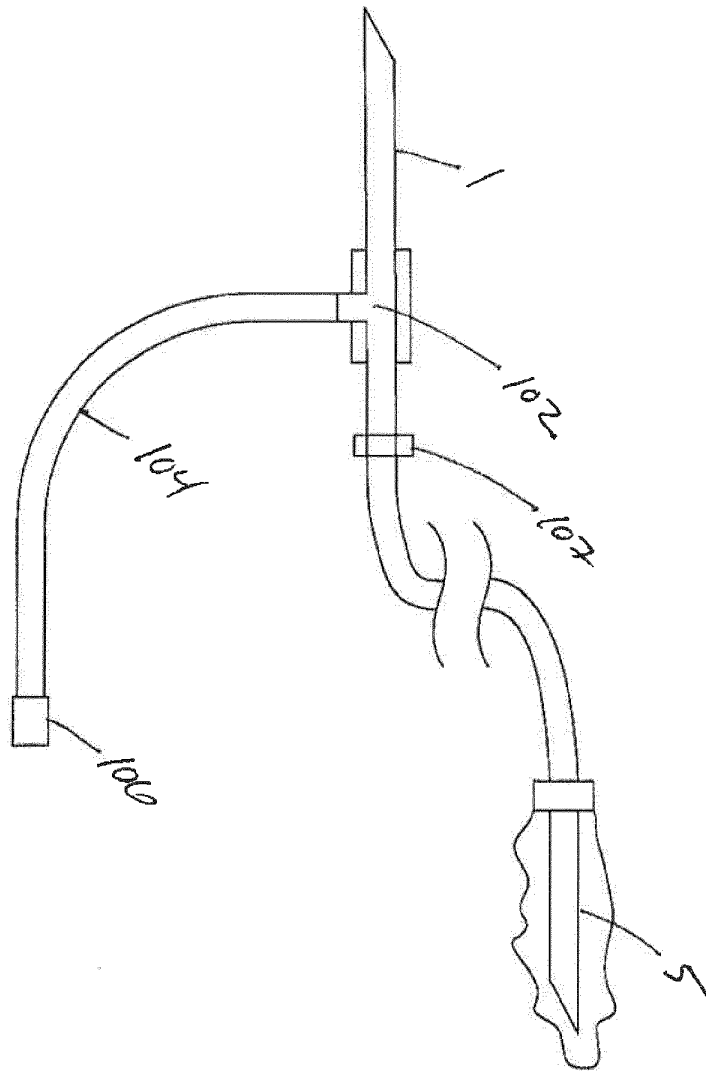


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FIG. 4



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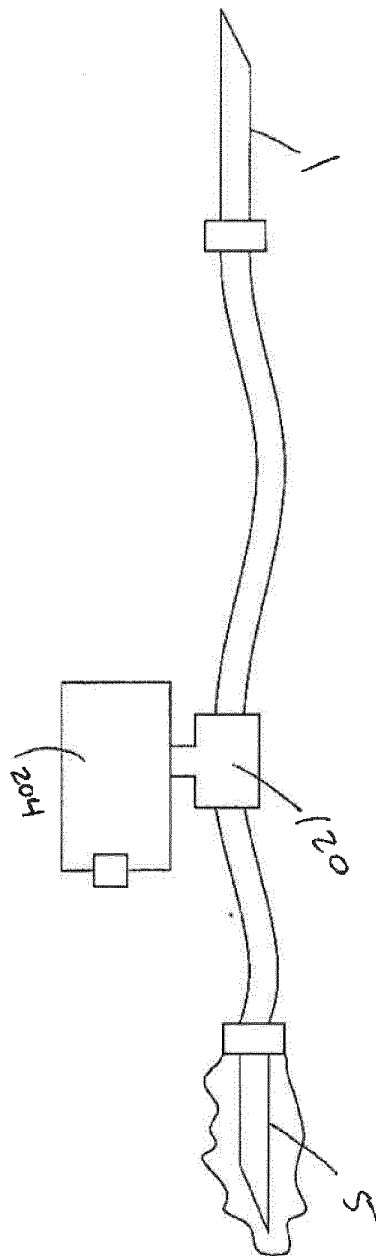


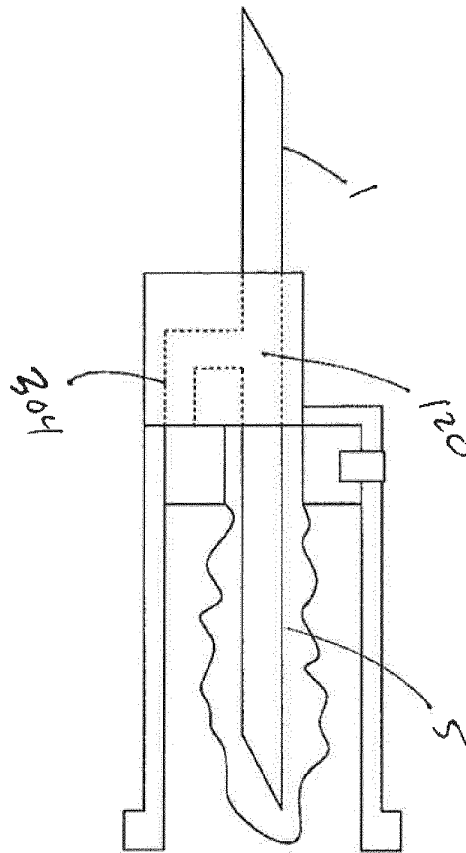
FIG. 5

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FIG. 6



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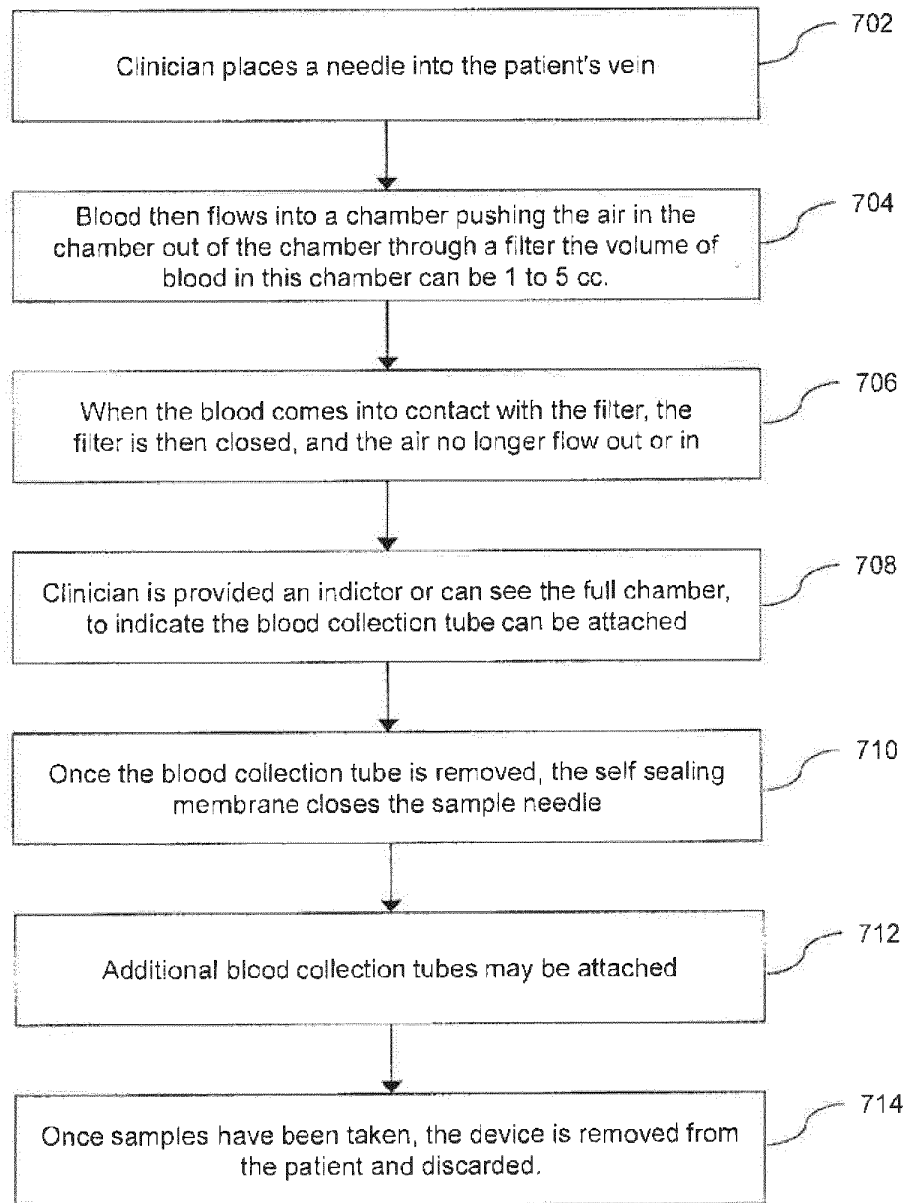


FIG. 7

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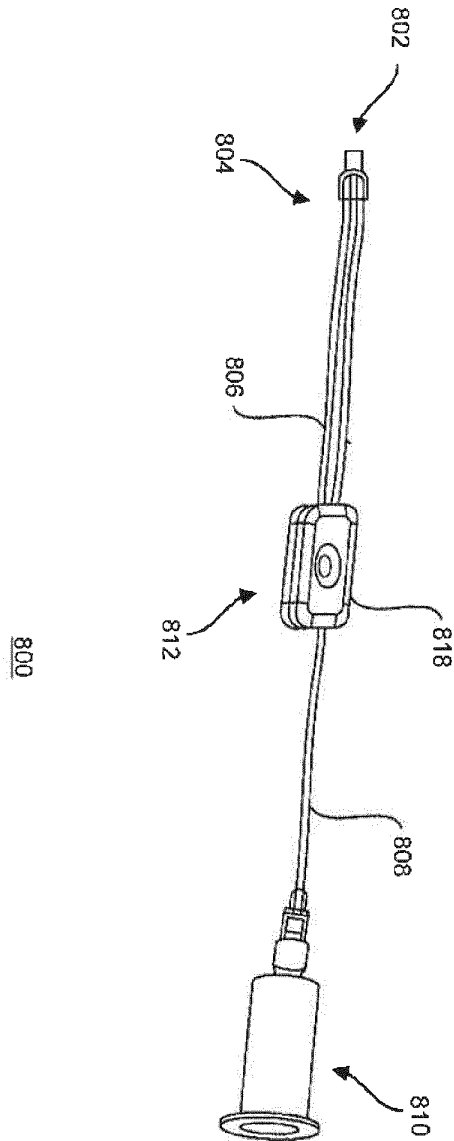


FIG. 8A

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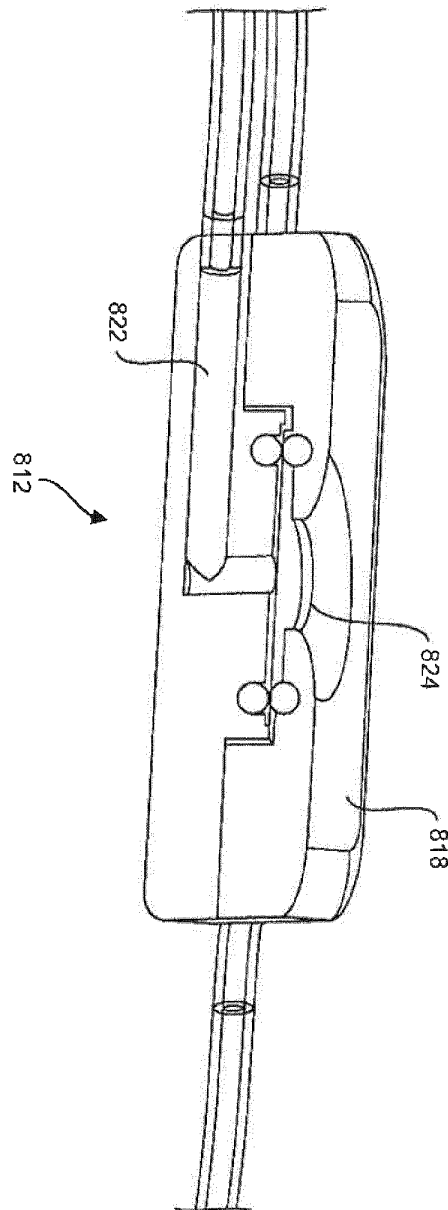


FIG. 8B

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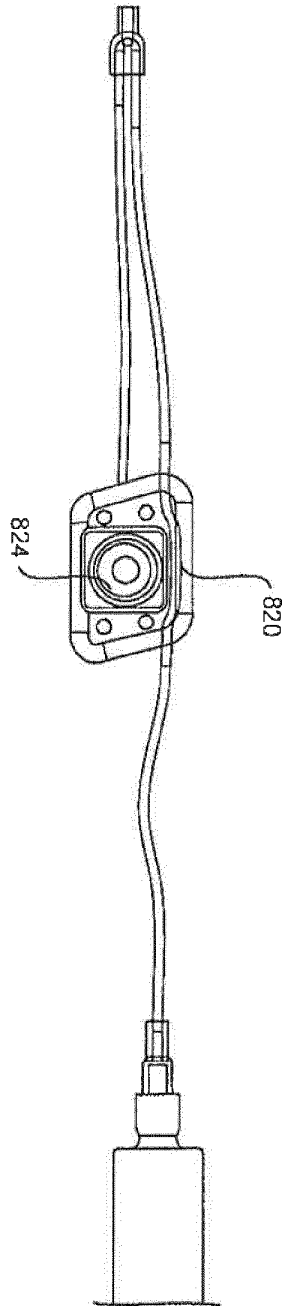


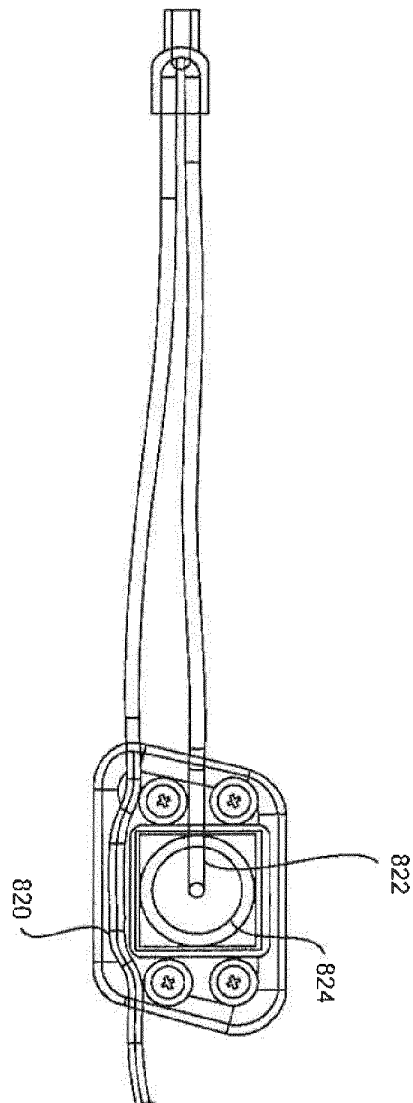
FIG. 8C

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FIG. 8D

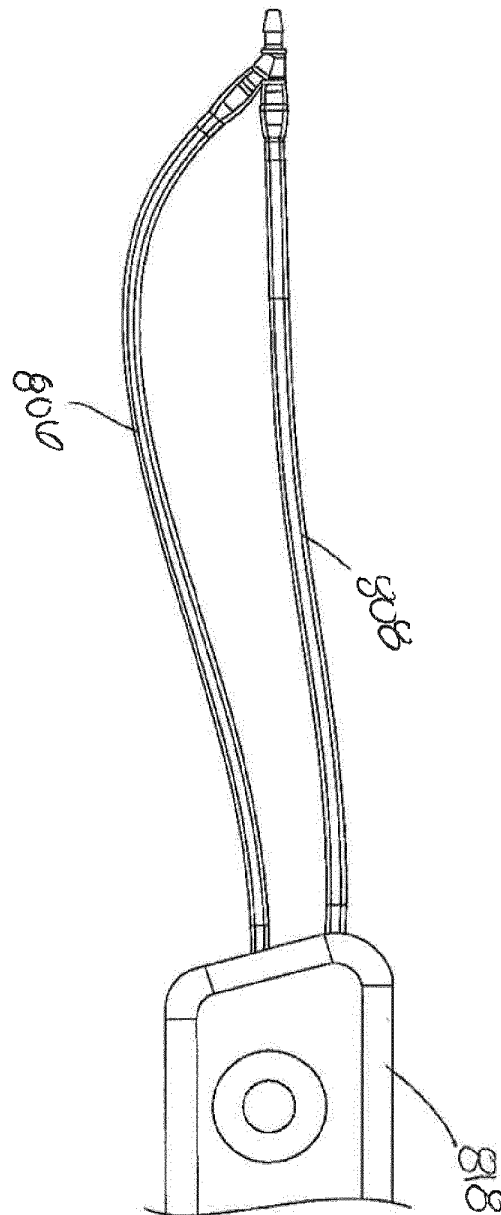


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FIG. 8E

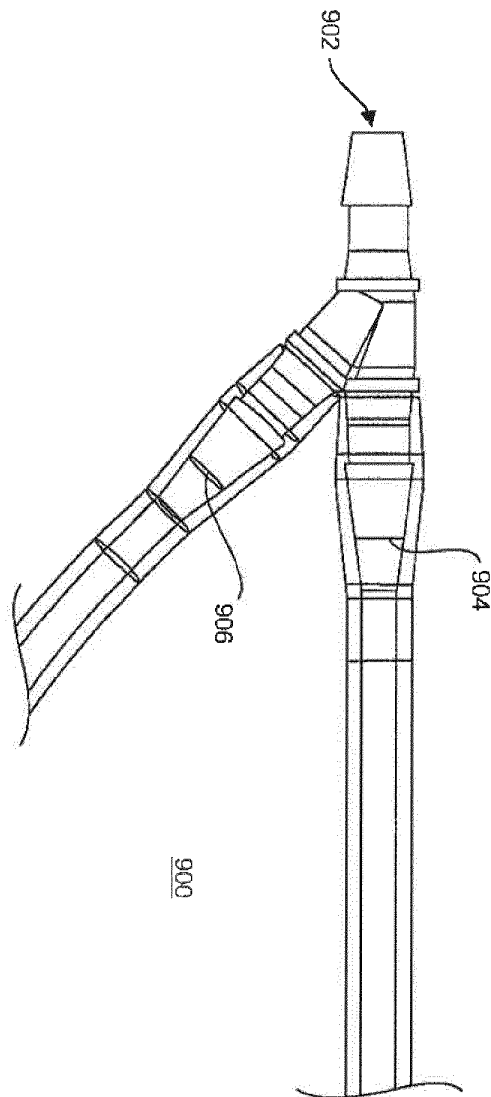


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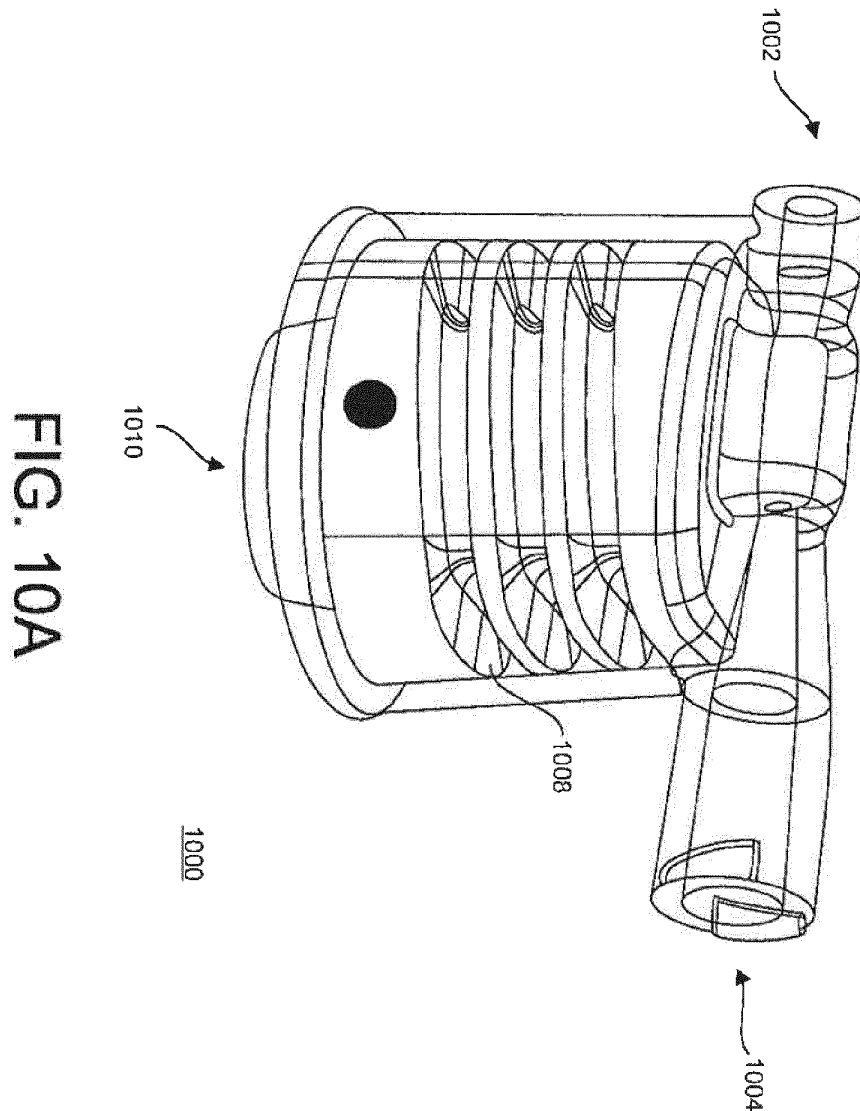
FIG. 9



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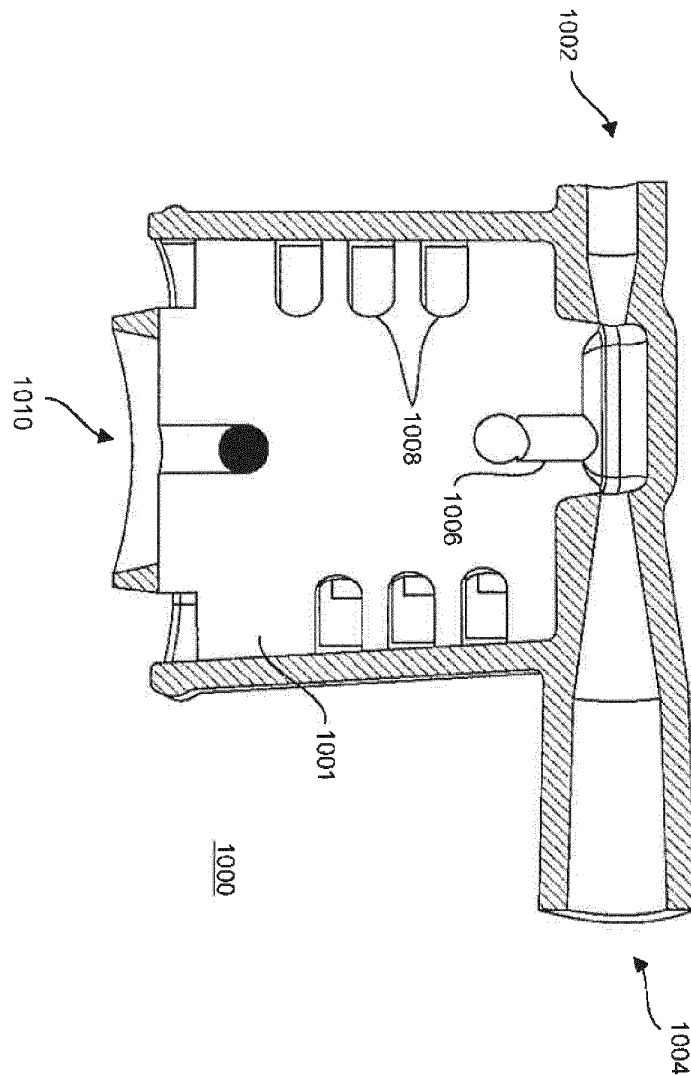


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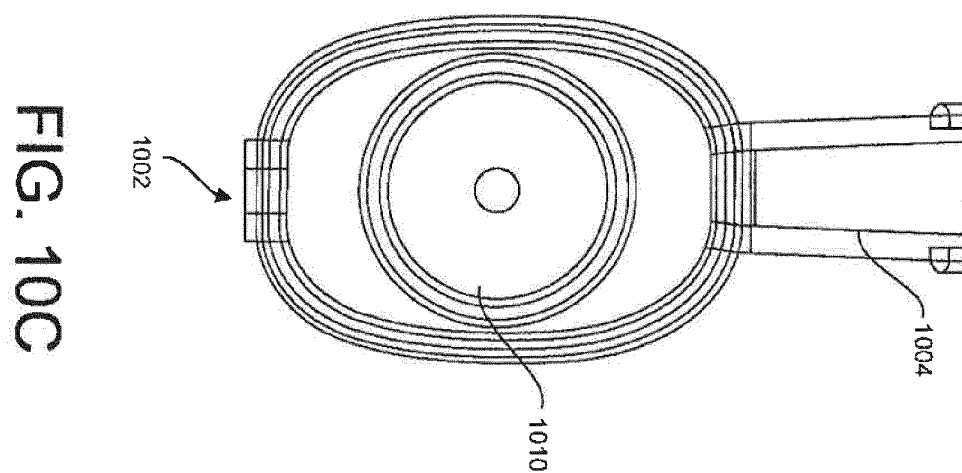
FIG. 10B



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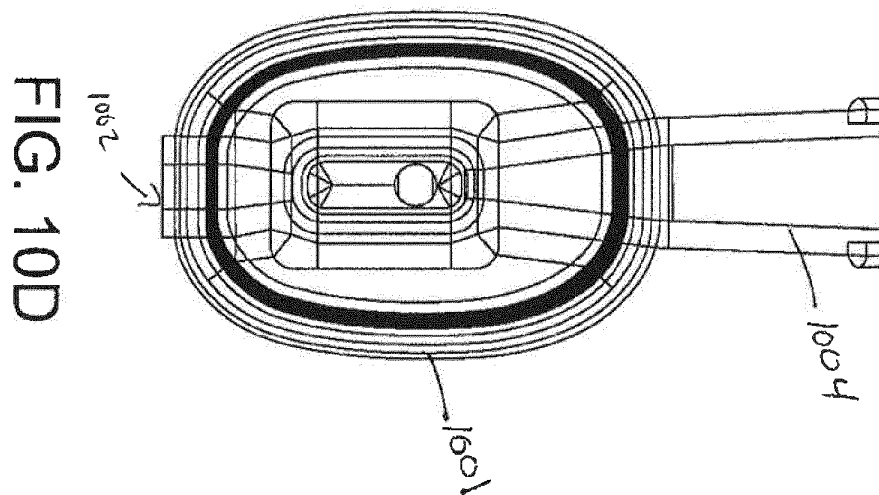
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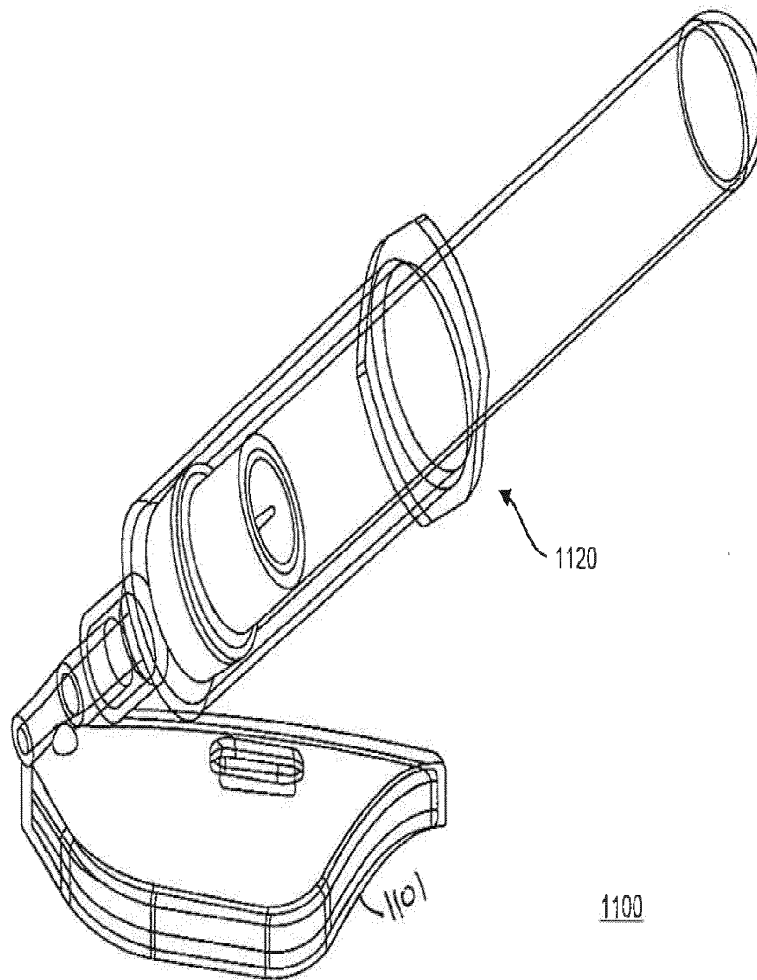


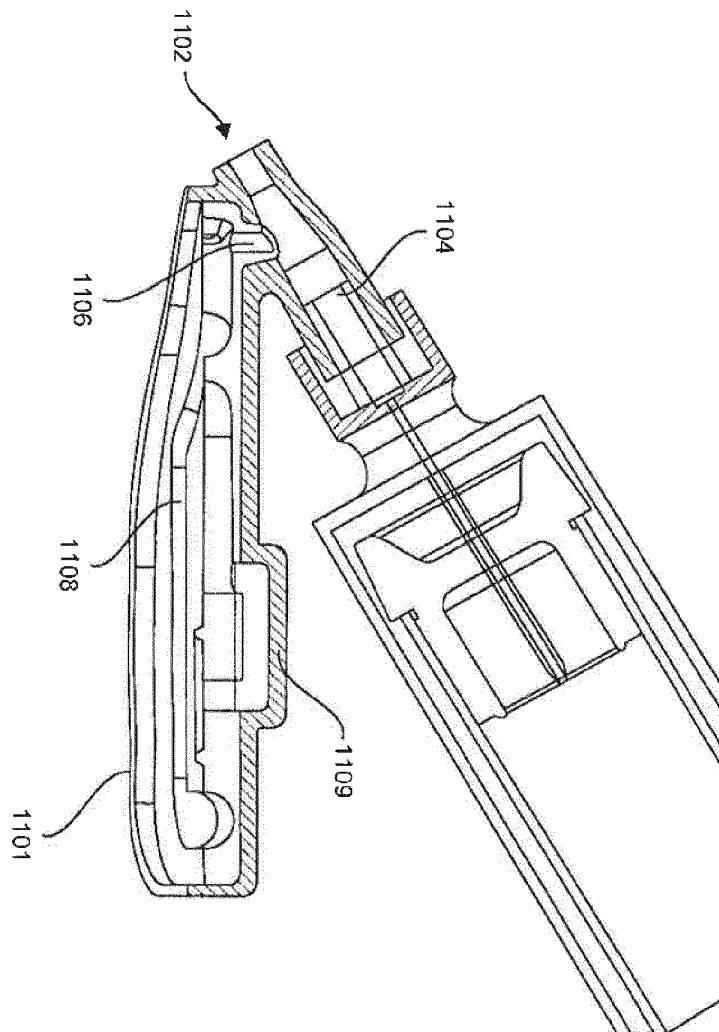
FIG. 11A

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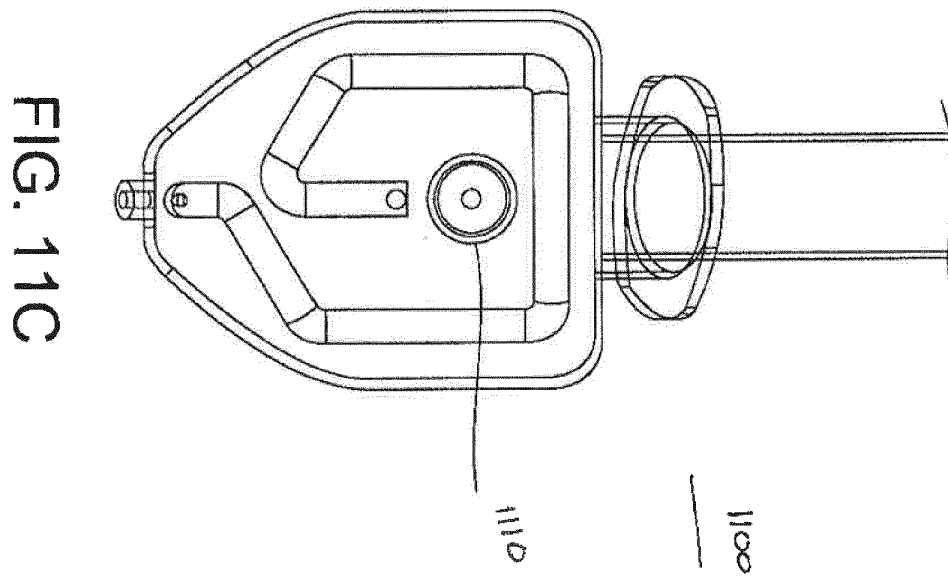
FIG. 11B



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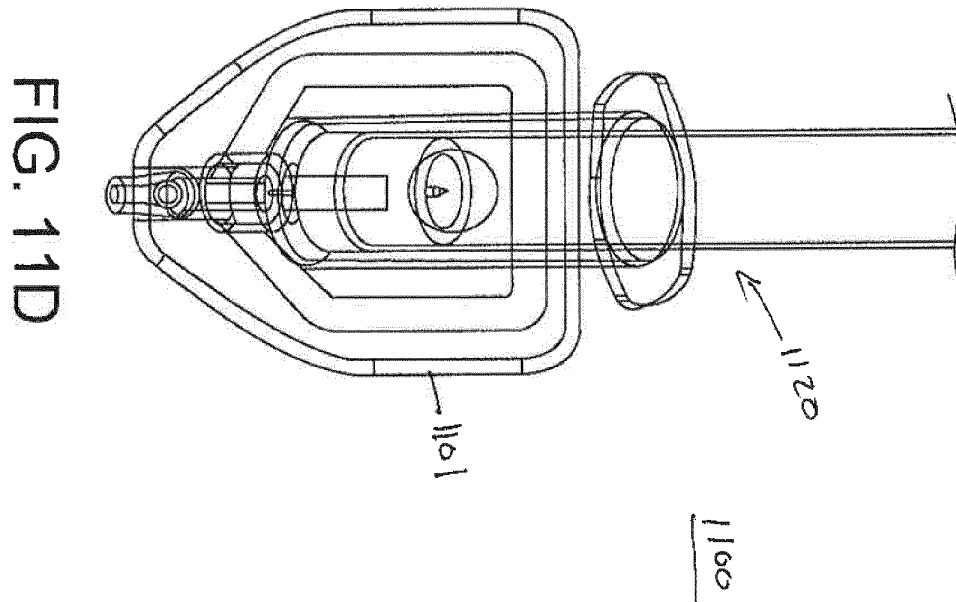
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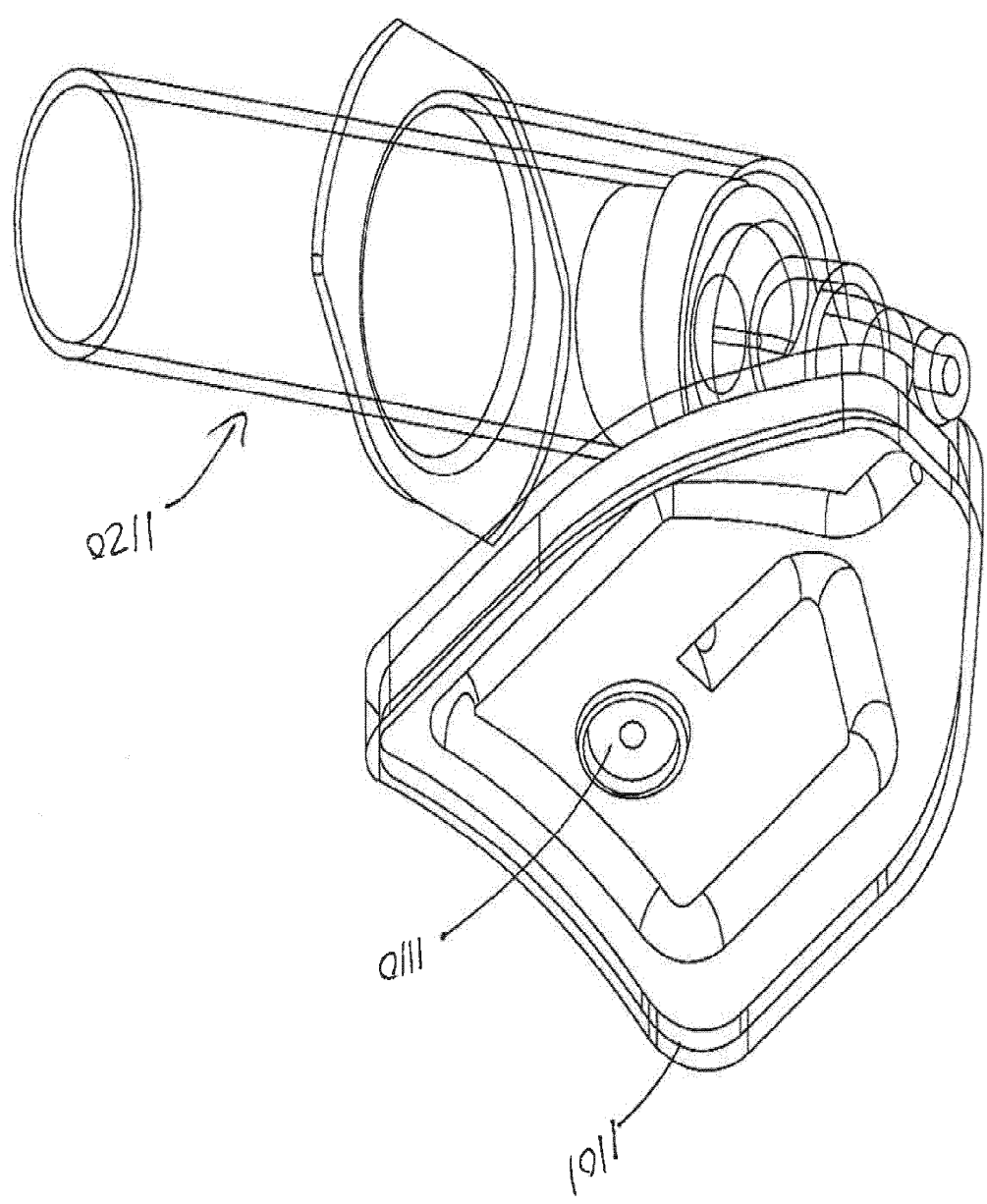
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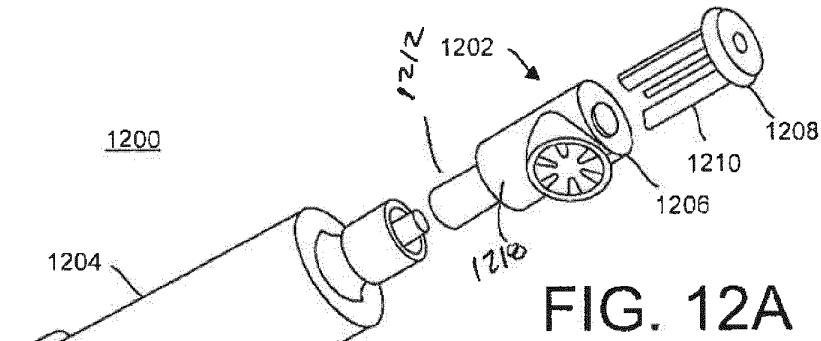
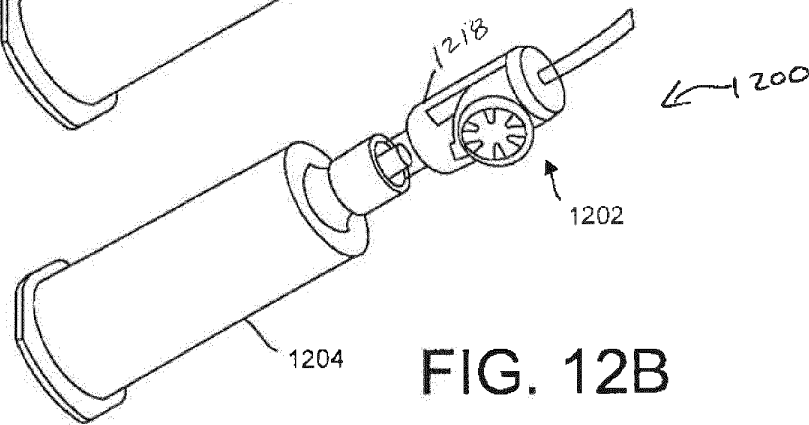
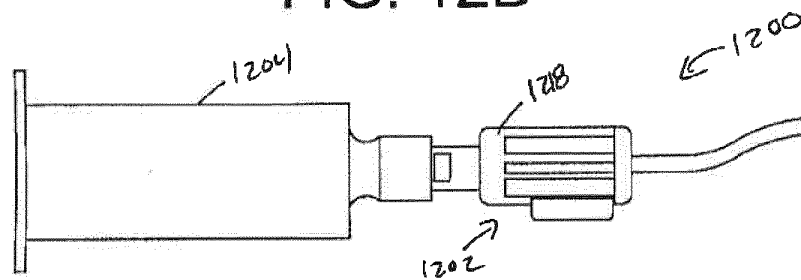
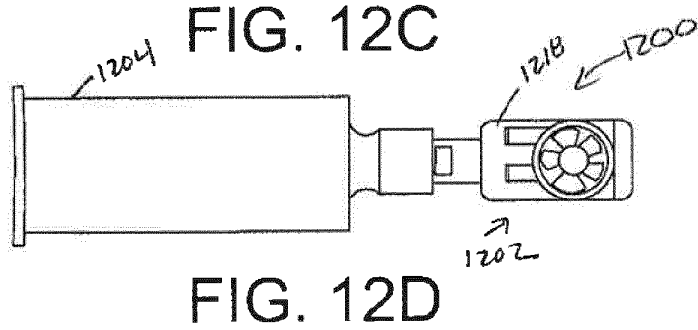
FIG. 11E



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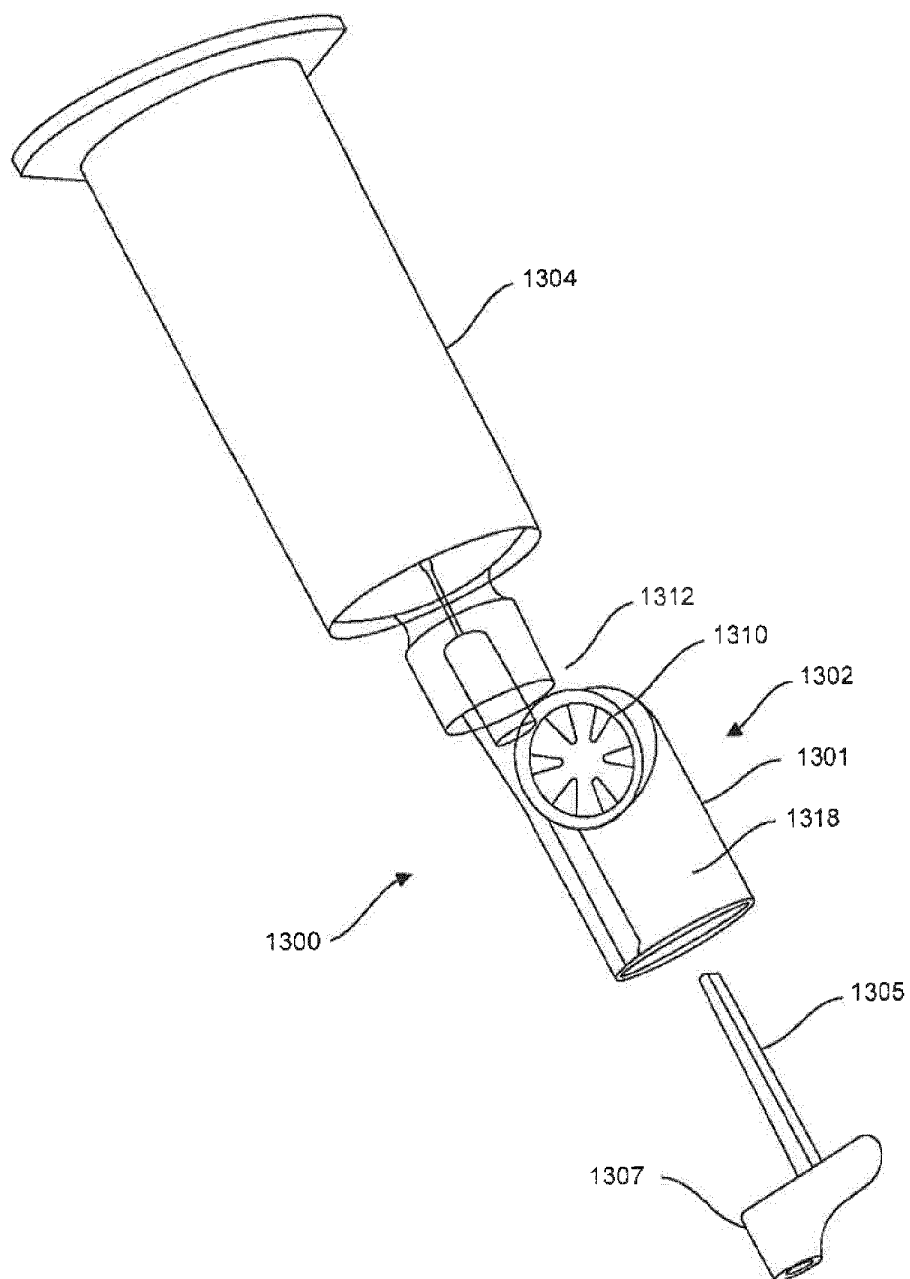


FIG. 13A

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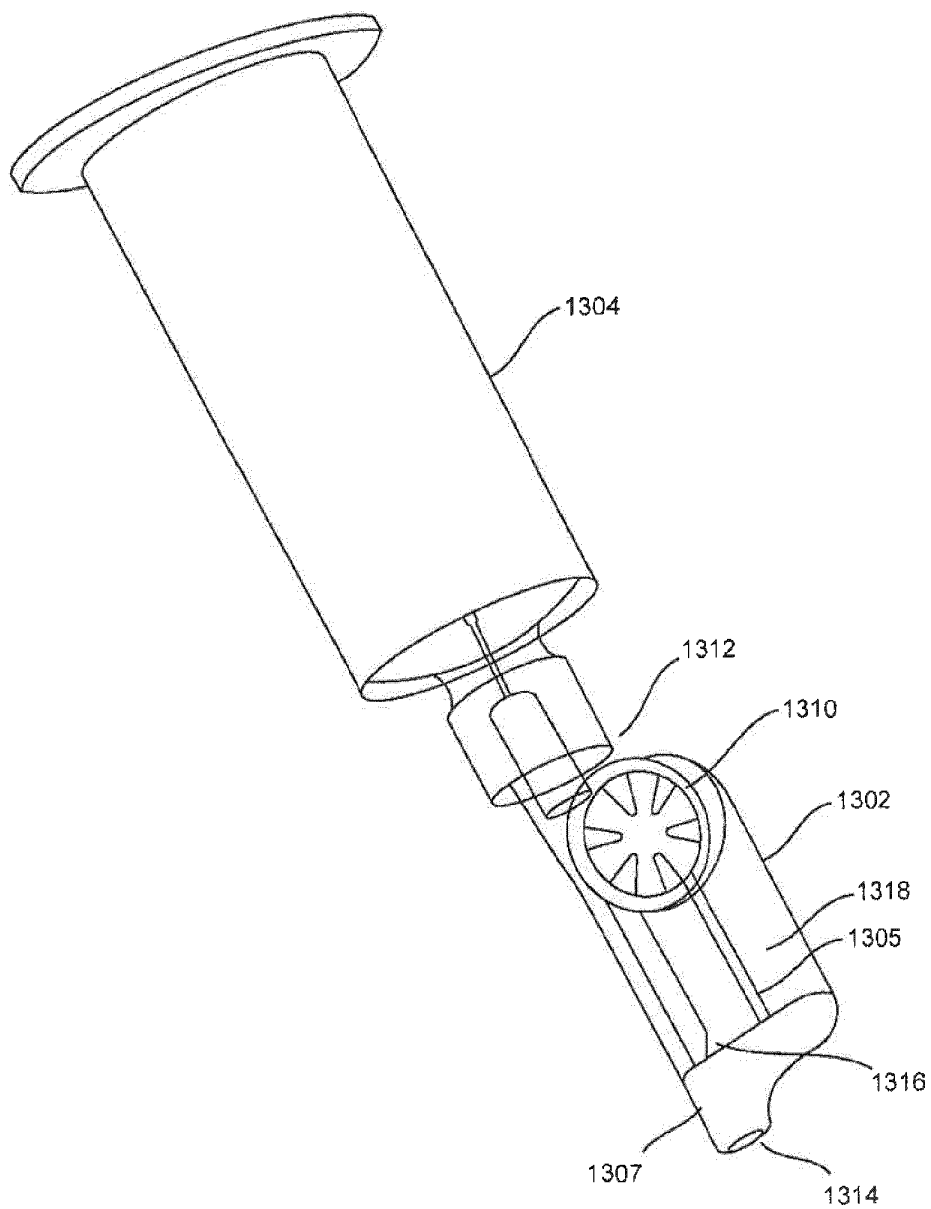


FIG. 13B

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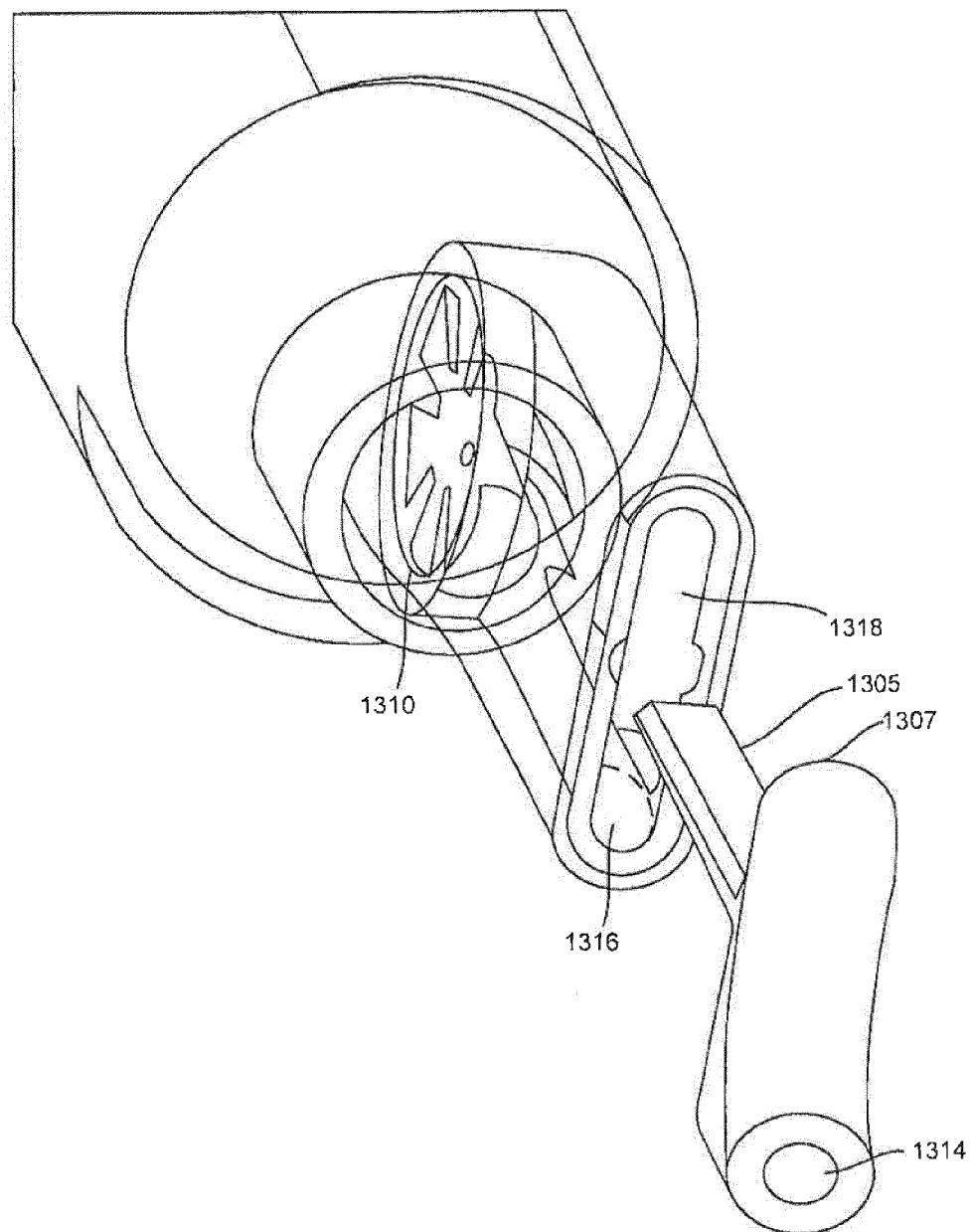


FIG. 13C

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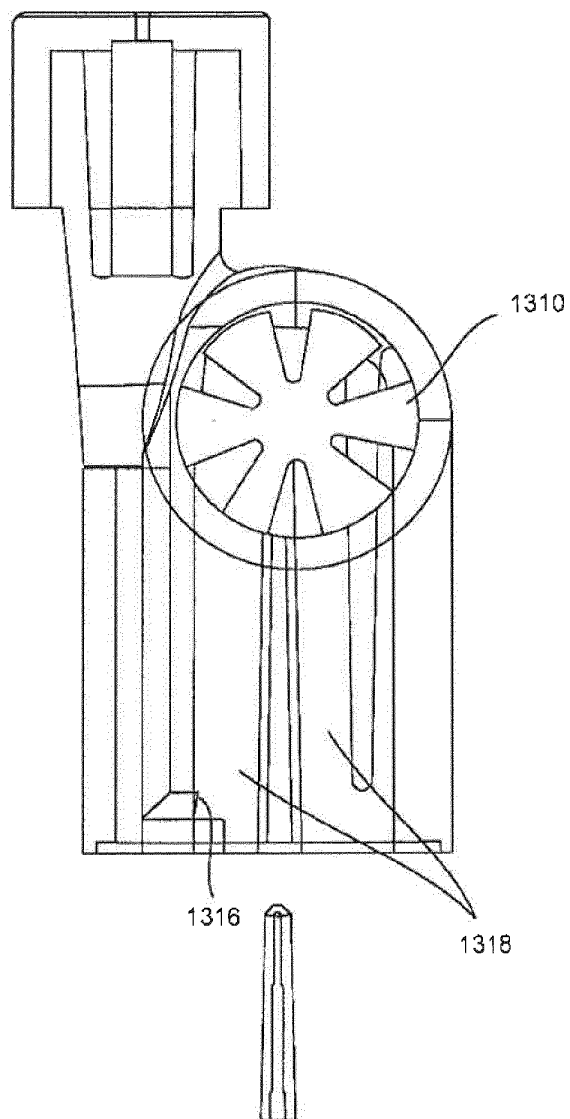


FIG. 13D

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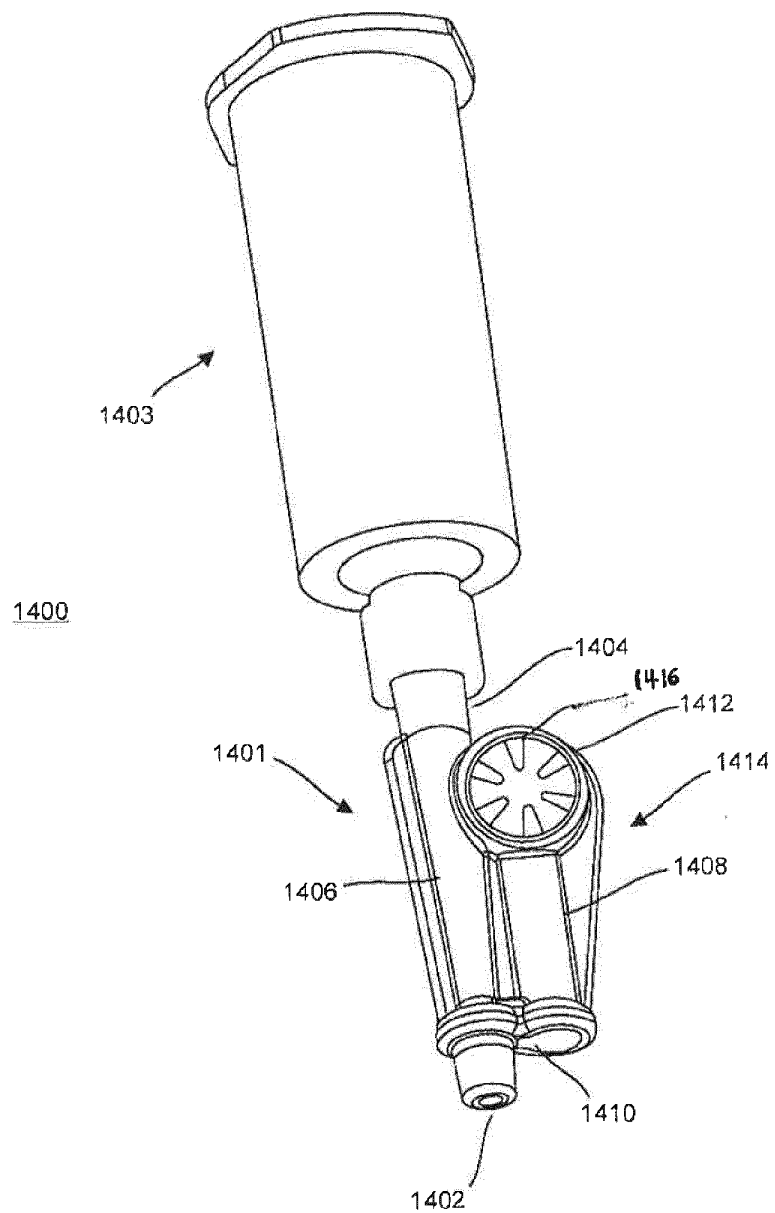


FIG. 14A

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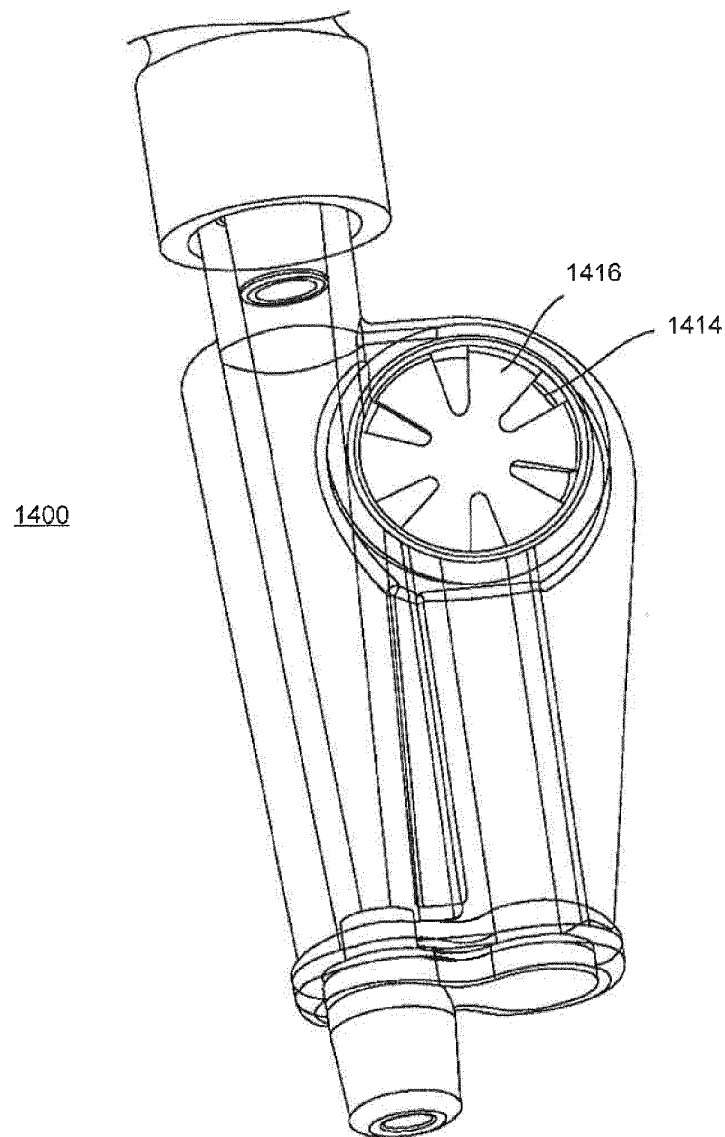


FIG. 14B

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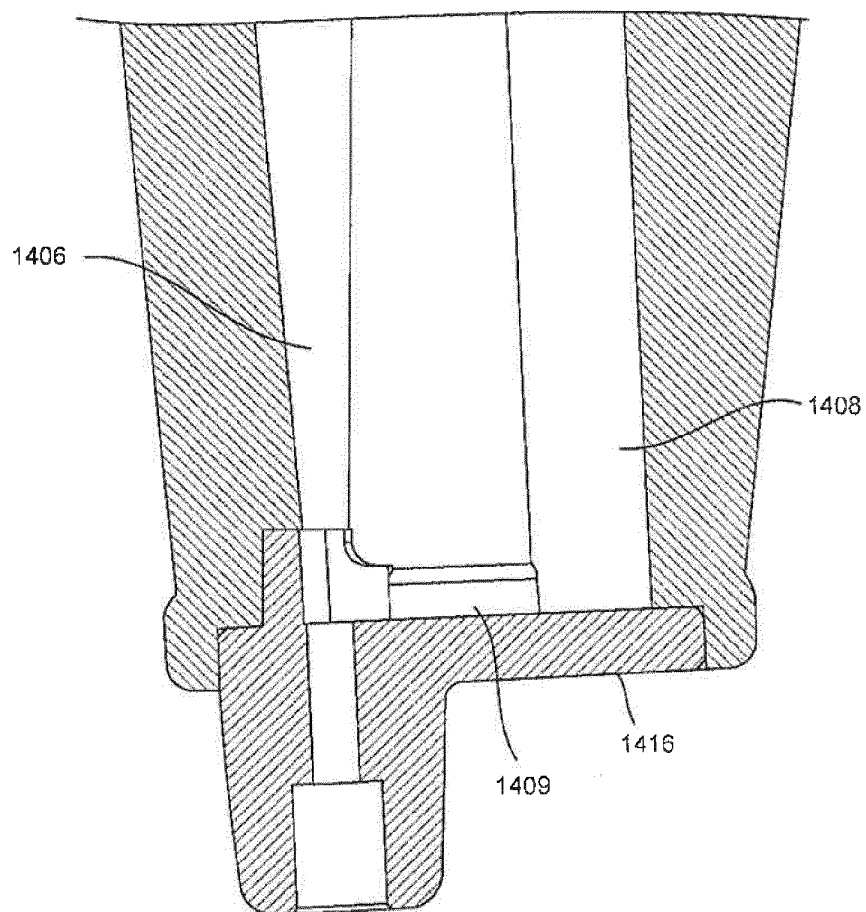


FIG. 14C

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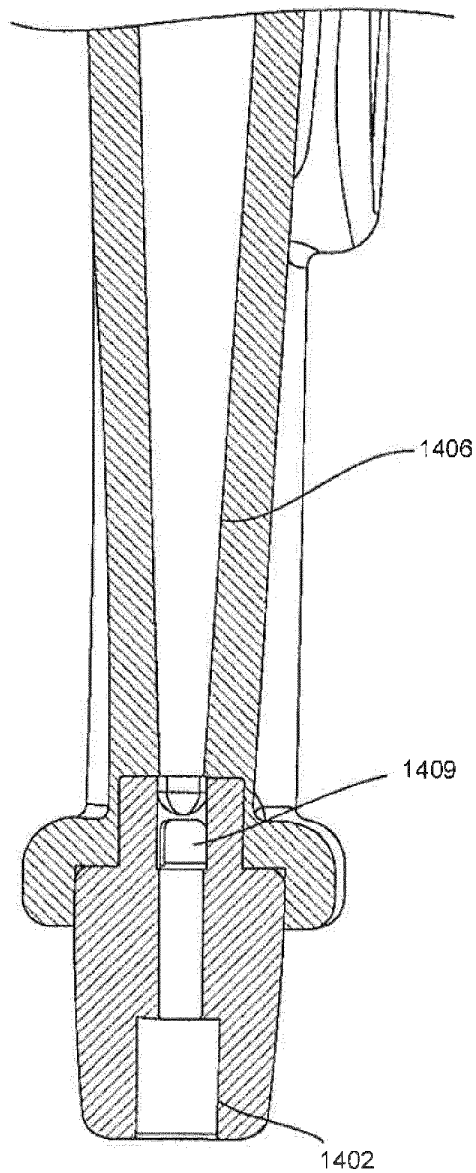


FIG. 14D

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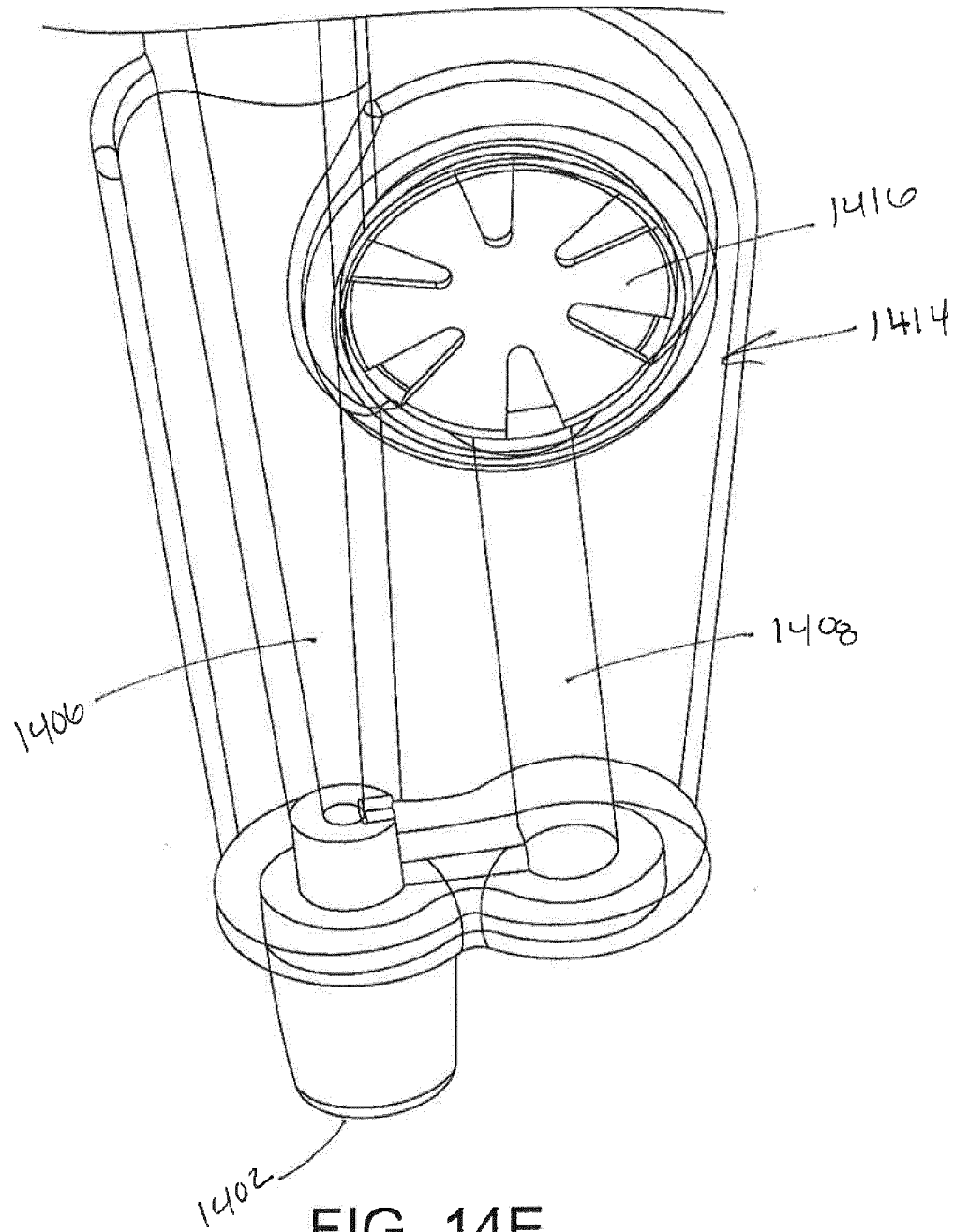


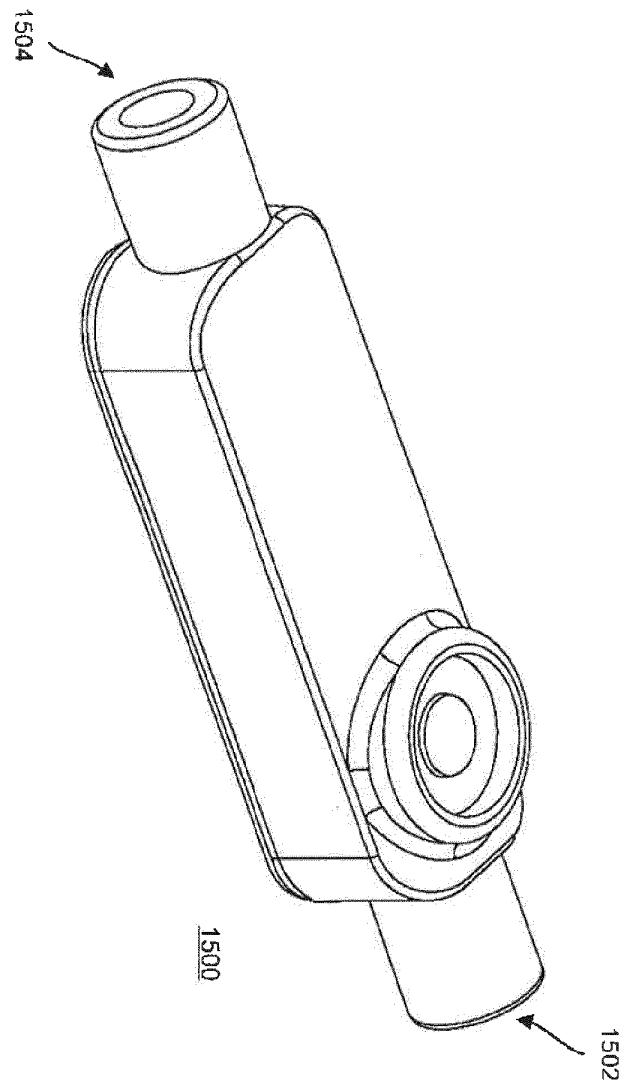
FIG. 14E

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FIG. 15A

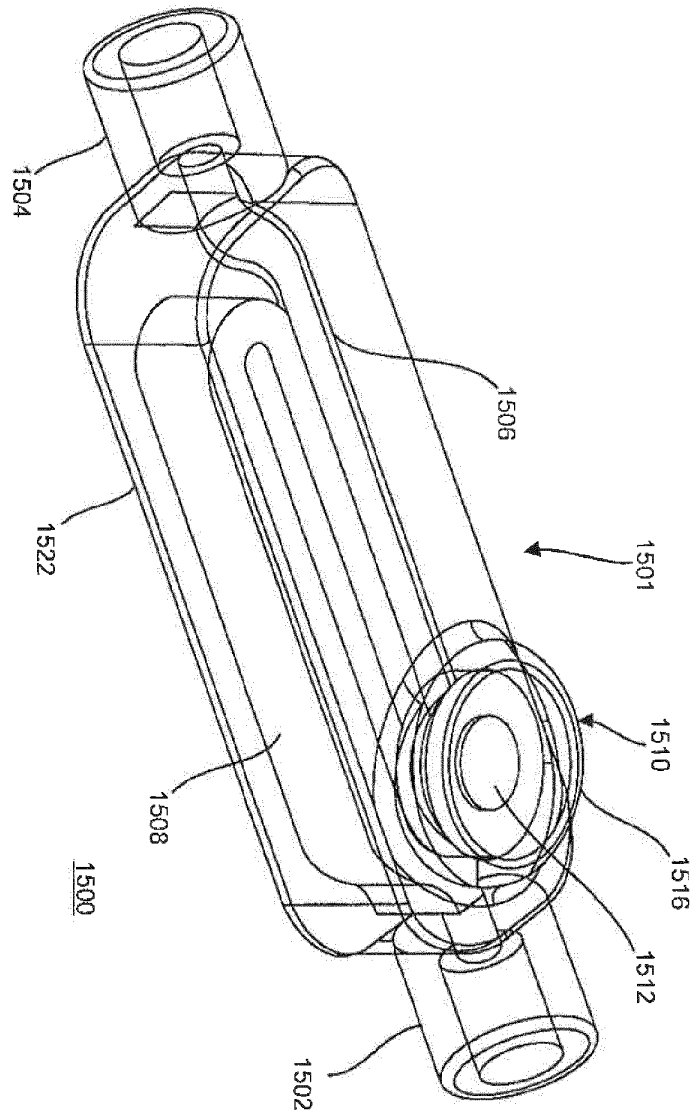


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FIG. 15B



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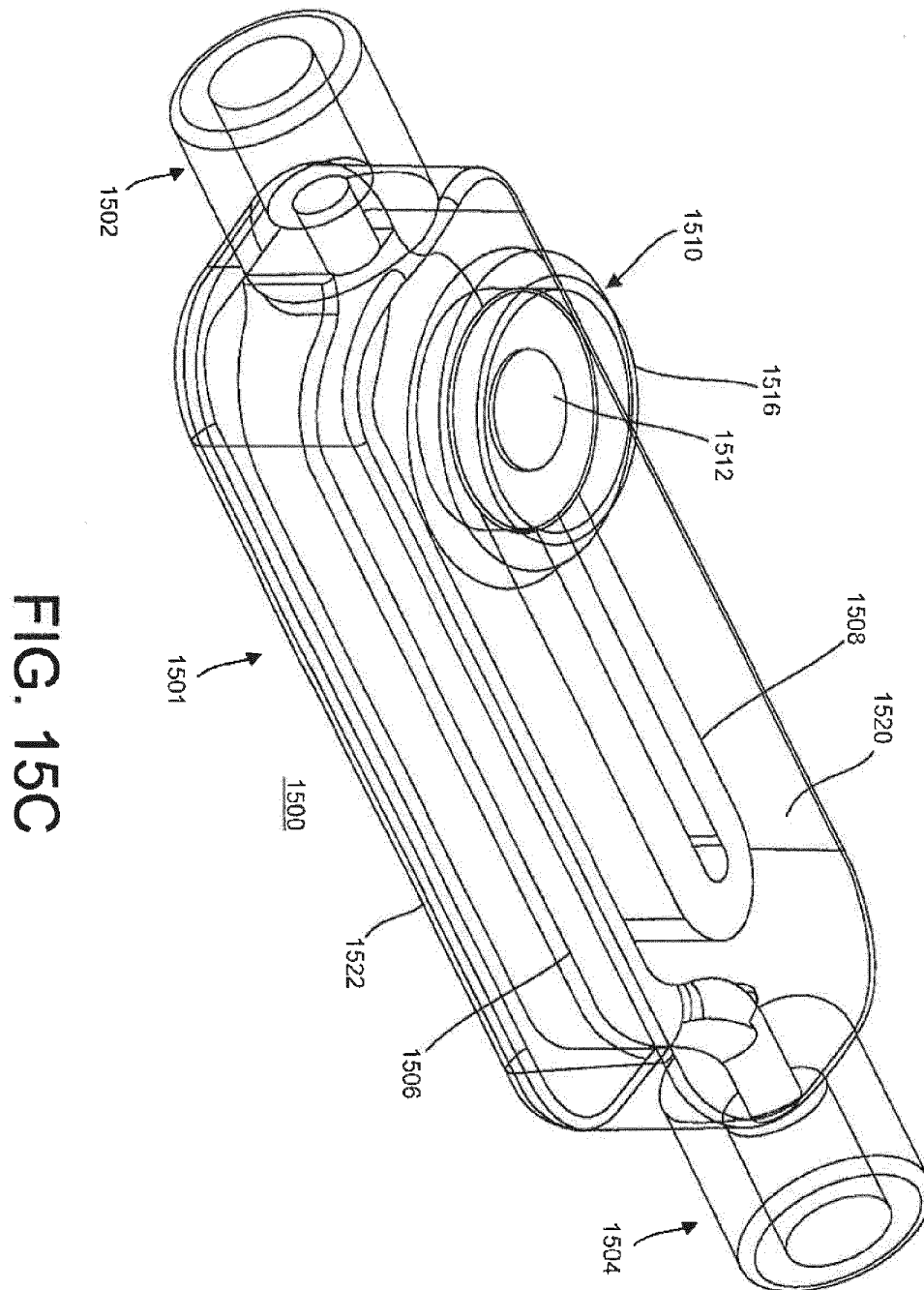


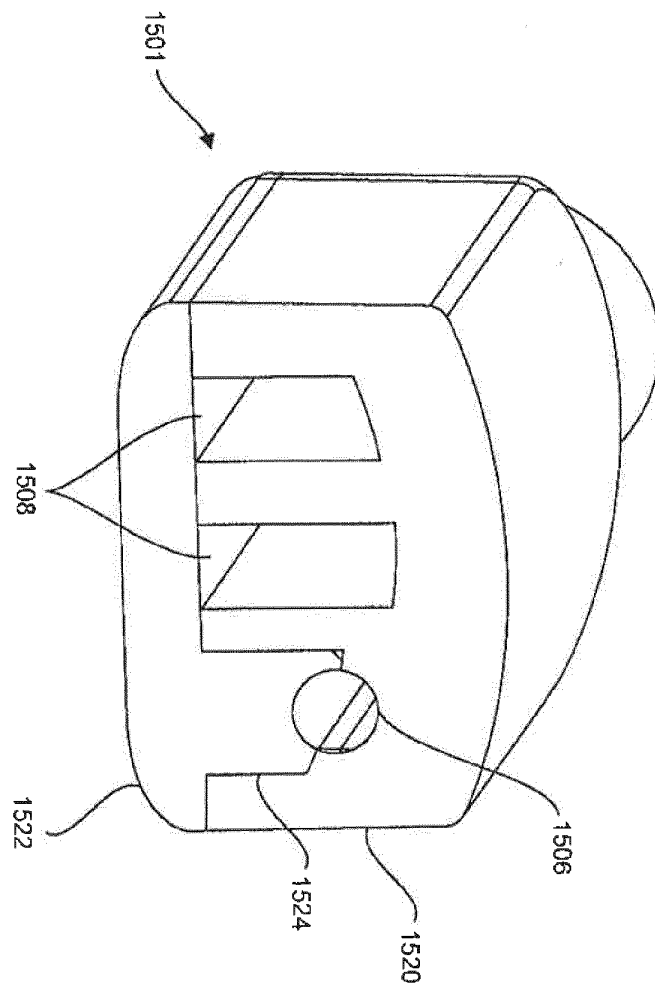
FIG. 15C

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FIG. 15D



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FIG. 15E

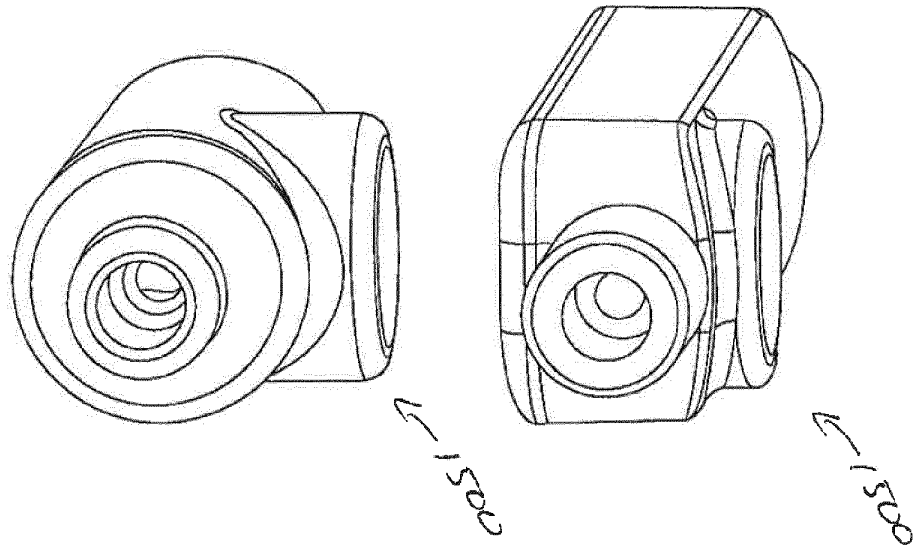
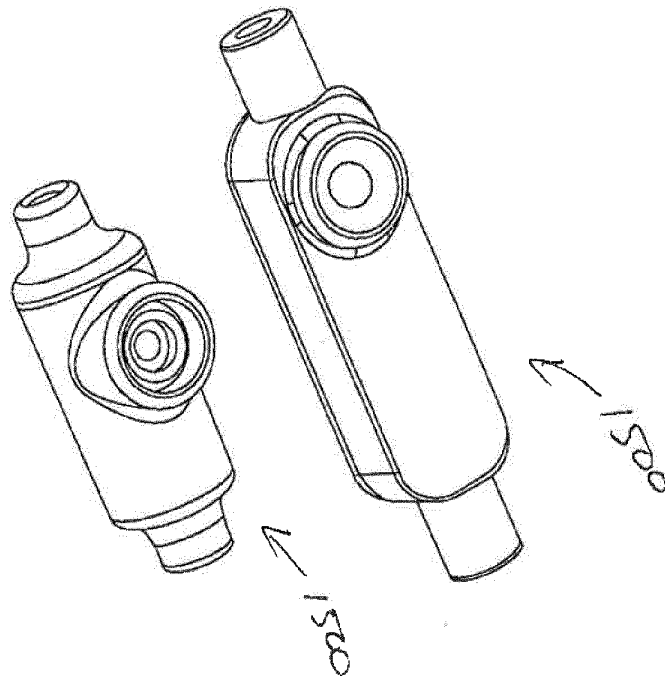


FIG. 15F

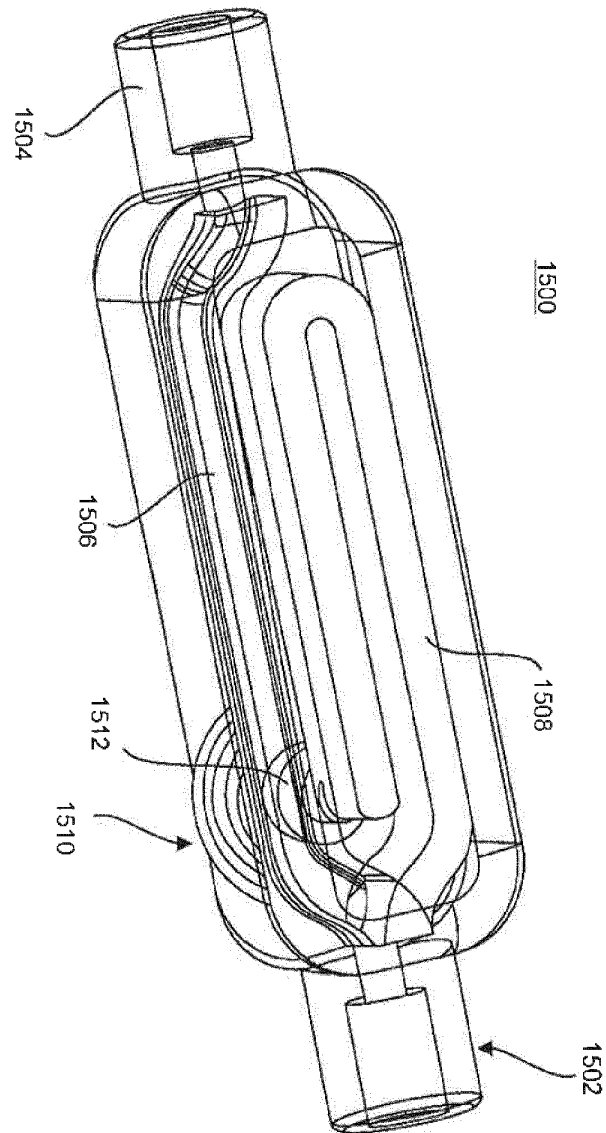


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FIG. 15G



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FIG. 16A

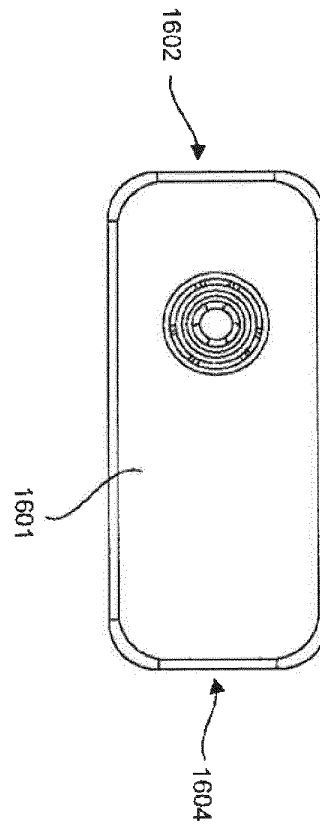


FIG. 16B

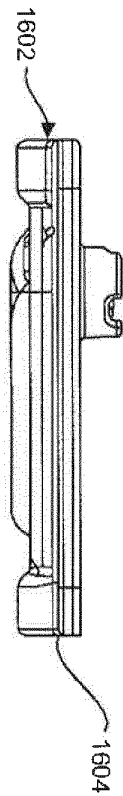
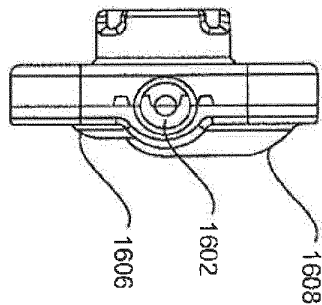


FIG. 16C

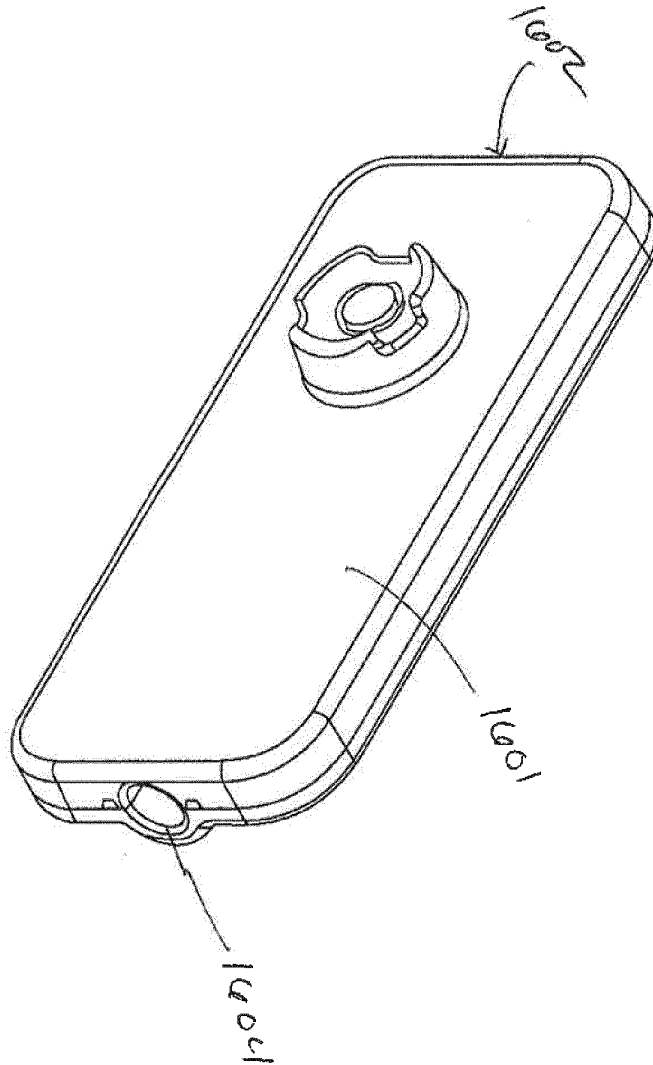


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FIG. 16D



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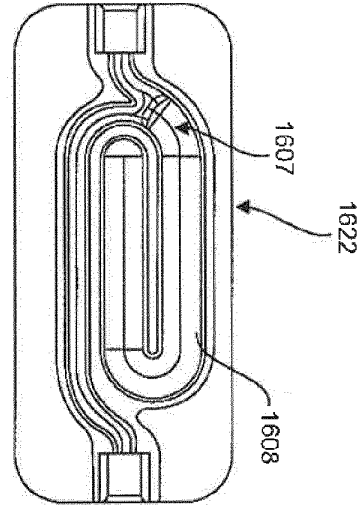


FIG. 17A

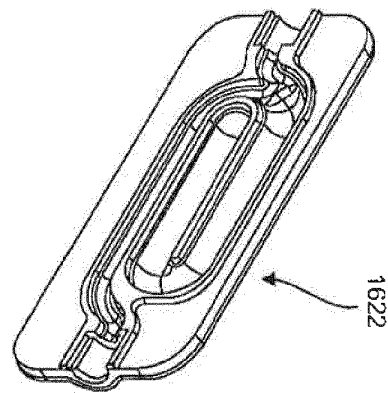


FIG. 17B

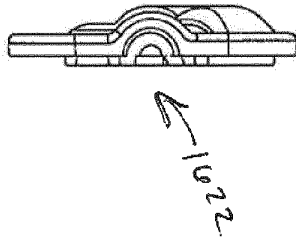


FIG. 17C

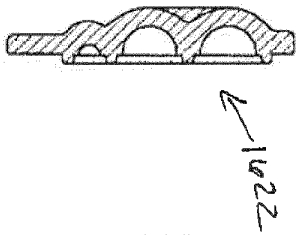


FIG. 17D

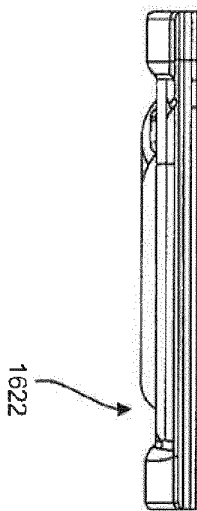


FIG. 17E

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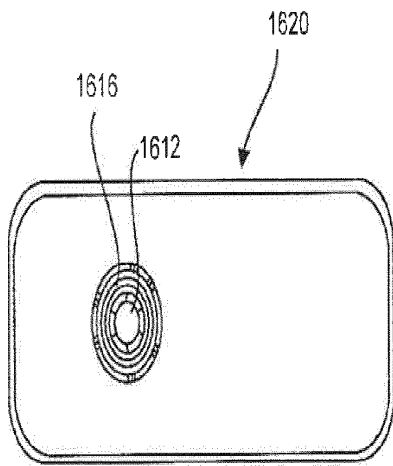


FIG. 18A

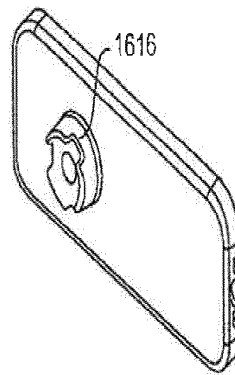


FIG. 18B

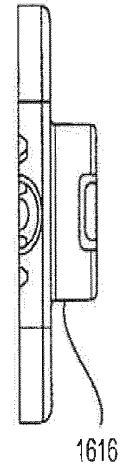


FIG. 18C

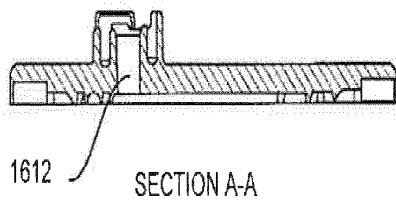


FIG. 18D

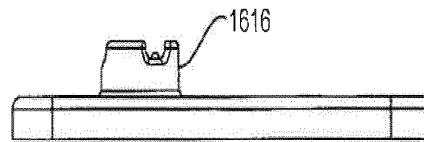


FIG. 18E

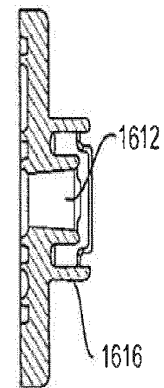


FIG. 18F

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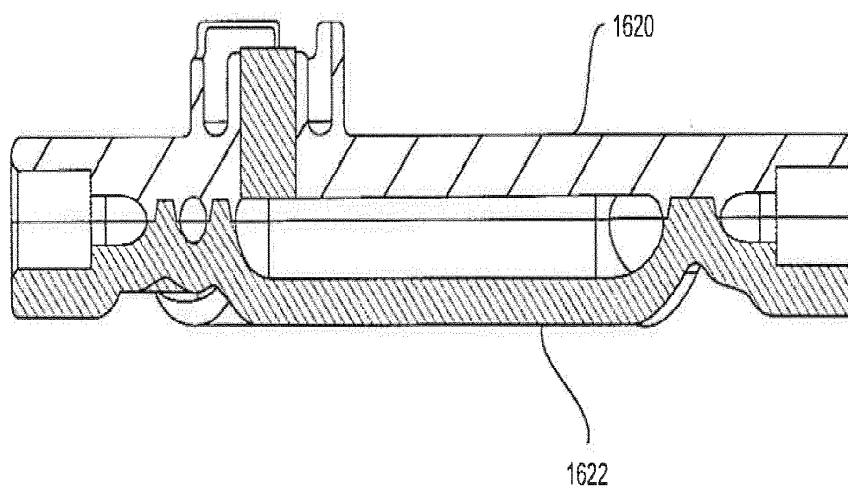


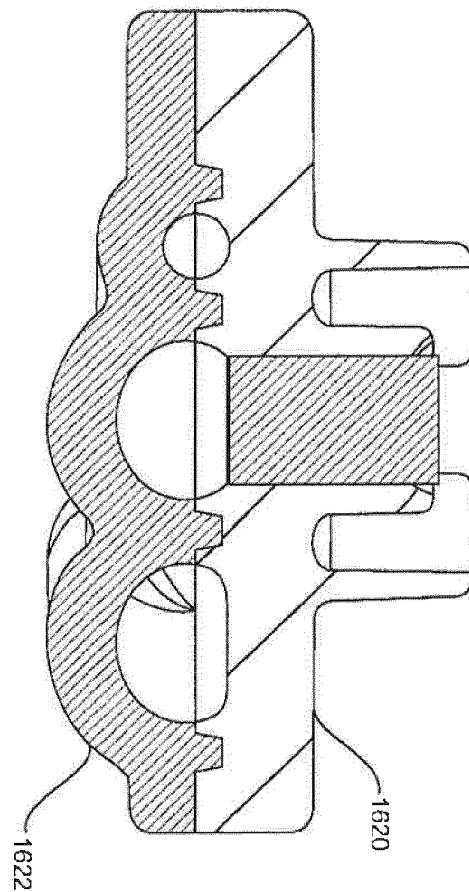
FIG. 19A

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FIG. 19B

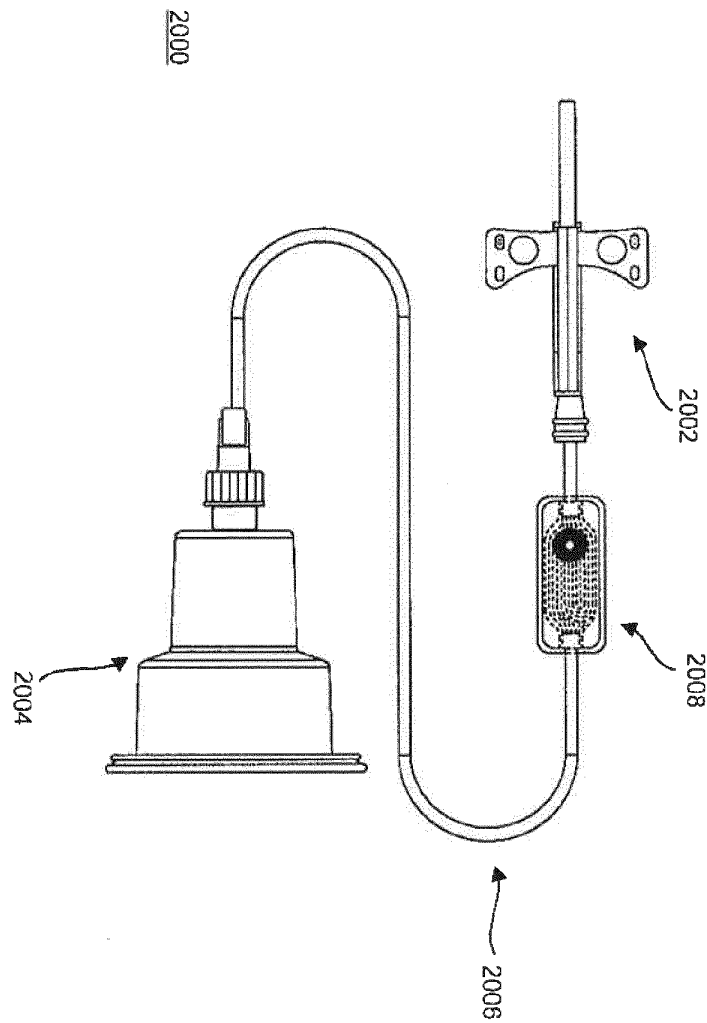


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FIG. 20



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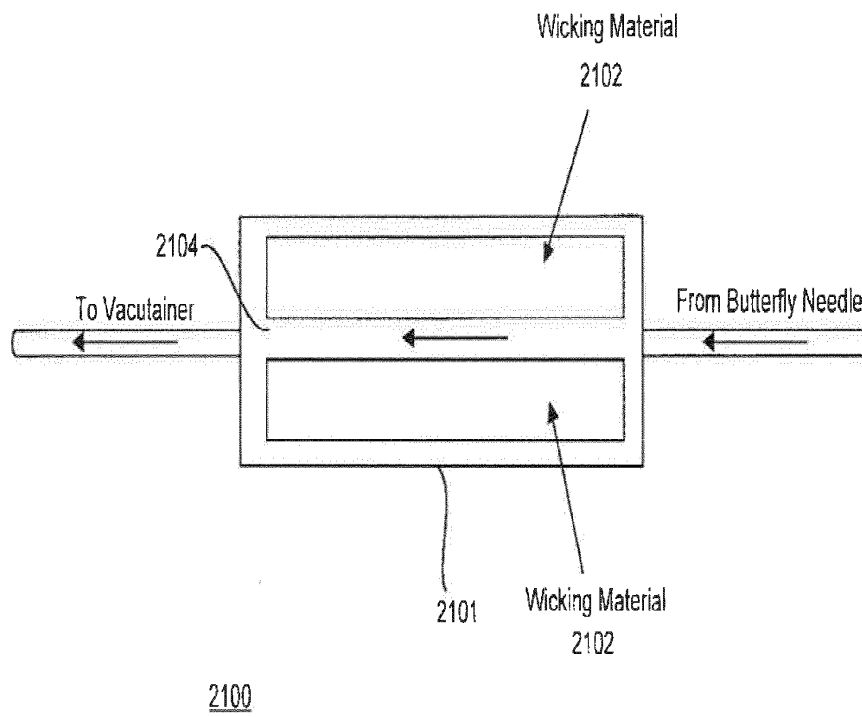


FIG. 21

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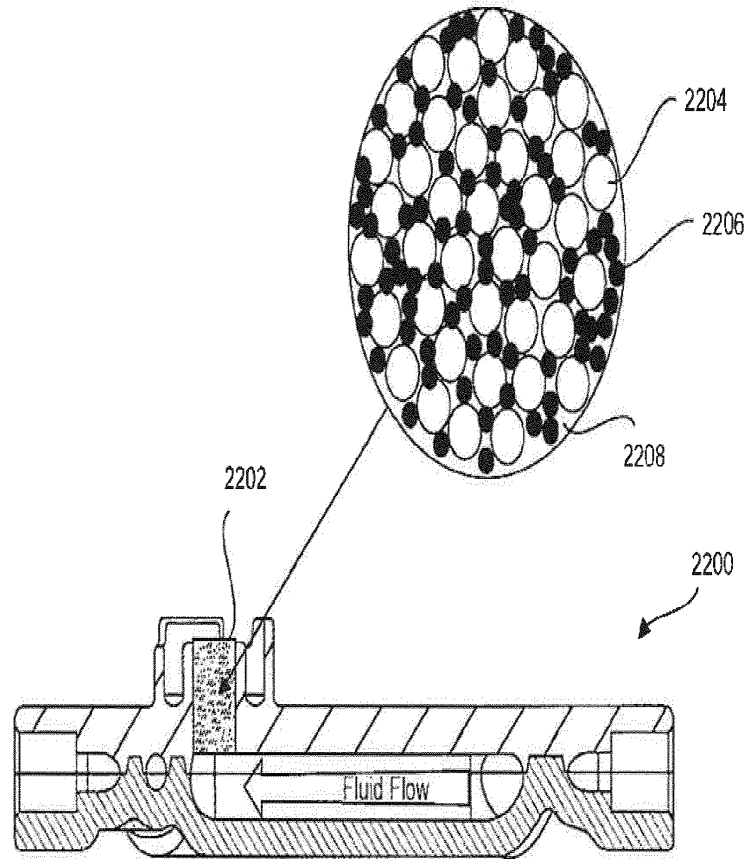


FIG. 22A

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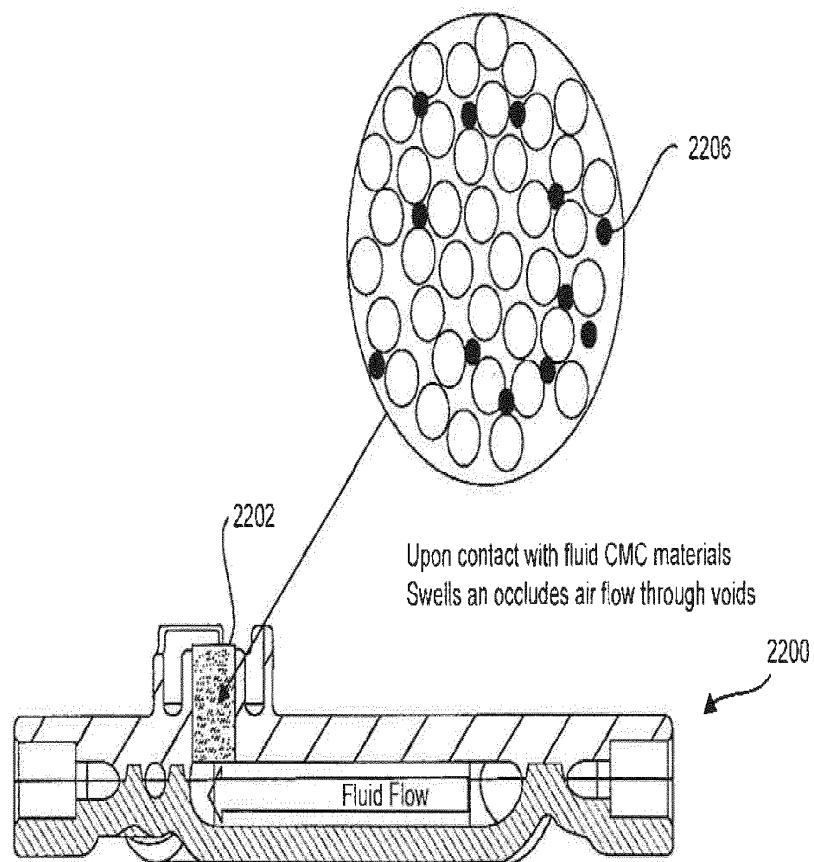


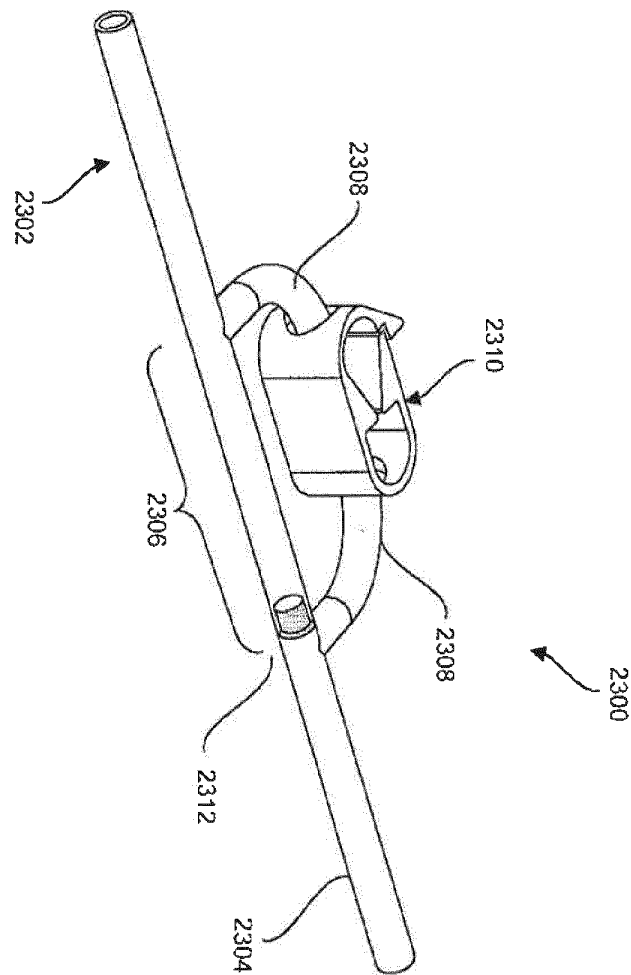
FIG. 22B

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FIG. 23A



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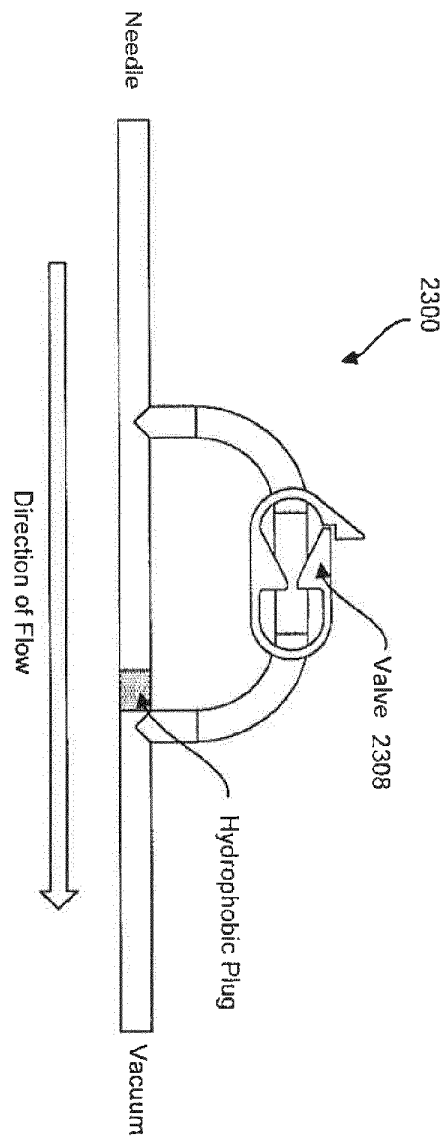
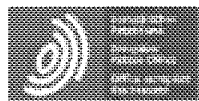


FIG. 23B



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Apparatus for processing a fluid sample

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This invention relates to an apparatus for an apparatus for processing a fluid sample comprising: (i) a sample processing chamber comprising a fluid inlet and a fluid outlet; (ii) a waste chamber downstream from the sample processing chamber and in fluid communication with the sample processing chamber fluid outlet and wherein the fluid communication between the sample processing chamber outlet and the waste chamber comprises a divergent analyte flow path; (iii) at least two further chambers up stream from the sample processing chamber both of which are in fluid communication with the sample processing chamber fluid inlet; (iv) a means for moving fluid from each of the at least two further chambers through the sample processing chamber and into the waste chamber or into the divergent analyte flow path as desired by applying positive or negative pressure to the desired flow path; and (v) a passive means for restricting the flow of fluid. This invention also relates to a method and use of the same.

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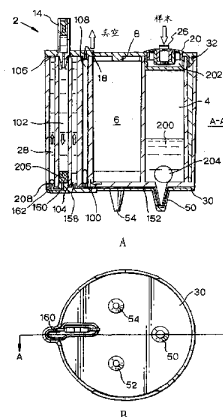
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[54] 发明名称

用于处理流体样本的设备

[57] 摘要

本发明涉及一种用于处理流体样本的设备，其包括：(i)样本处理腔室，其包括流体入口和流体出口；(ii)废物腔室，其位于样本处理腔室的下游并与样本处理腔室的流体出口流体连通，并且其中在样本处理腔室出口和废物腔室之间的流体连通包括分叉的分析物流动通道；(iii)至少两个附加腔室，其位于样本处理腔室的上游并与样本处理腔室的流体入口流体连通；(iv)用于通过向所需的流动通道施加正压或负压，从而按照需要使流体从所述至少两个附加腔室中的各个腔室运动通过样本处理腔室并进入废物腔室或者分叉的分析物流动通道中的装置；以及(v)用于限制流体的流动的被动装置。本发明还涉及一种方法及其用途。



1、一种用于处理流体样本的设备，该设备包括：

(i) 样本处理腔室，其包括流体入口和流体出口；

5 (ii) 废物腔室，其位于样本处理腔室的下游并与样本处理腔室的流体出口流体连通，并且其中在样本处理腔室出口和废物腔室之间的流体连通包括分叉的分析物流动通道；

(iii) 至少两个附加腔室，其位于样本处理腔室的上游并与样本处理腔室的流体入口流体连通；

10 (iv) 用于通过向所需的流动通道施加正压或负压，从而按照需要使流体从所述至少两个附加腔室中的各个腔室运动通过样本处理腔室并进入废物腔室或者分叉的分析物流动通道中的装置；以及

(v) 用于限制流体的流动的被动装置。

2、根据权利要求1所述的设备，其特征在于，所述用于使流体从所述至少两个附加腔室中的至少一个腔室运动通过样本处理腔室的装置包括用于产生真空的装置。

3、根据权利要求2所述的设备，其特征在于，所述废物腔室包括一出口部，该出口部与所述用于产生真空的装置相连。

4、根据权利要求2所述的设备，其特征在于，所述分析物流动通道
20 包括一出口部，该出口部与所述用于产生真空的装置相连。

5、根据权利要求1所述的设备，其特征在于，所述用于使流体从所述至少两个附加腔室中的至少一个腔室运动通过样本处理腔室的装置包括活塞，该活塞能够压下以从至少一个附加腔室中排出流体。

6、根据权利要求5所述的设备，其特征在于，所述用于使流体从所述至少两个附加腔室中的至少一个腔室运动通过样本处理腔室的装置还
25 包括用于产生真空的装置。

7、根据权利要求1至6中任一项所述的设备，其特征在于，所述用于使流体从所述两个附加腔室中的每一个运动通过样本处理腔室的装置，使流体顺序地从所述至少两个附加腔室中的第一腔室运动通过样本

处理腔室，并进入废物腔室中，然后从所述至少两个附加腔室中的第二腔室运动通过样本处理腔室，并进入废物腔室或者分叉的分析物流动通道中。

8、根据权利要求1至7中任一项所述的设备，其特征在于，所述用于限制流体流动的被动装置包括阀，该阀位于在所述样本处理腔室和废物腔室之间的流体连通中。

9、根据权利要求8所述的设备，其特征在于，所述阀位于分叉的分析物流动通道的下游。

10、根据权利要求8所述的设备，其特征在于，所述阀包括小珠，该小珠通过施加正压或负压而打开。

11、根据权利要求1至10中任一项所述的设备，其特征在于，所述用于限制流体流动的被动装置包括容器，该容器位于在所述至少两个附加腔室中的至少一个腔室和样本处理腔室之间的流体连通中。

12、根据权利要求1至11中任一项所述的设备，其特征在于，所述用于限制流体流动的被动装置包括小直径的流体通道，从而流体不会在没有施加正压或负压的情况下而流过该通道，该流体通道位于在所述至少两个附加腔室中的至少一个腔室和样本处理腔室之间的流体连通中。

13、根据权利要求1至12中任一项所述的设备，其特征在于，该设备包括收集腔室，该收集腔室位于所述分析物流动通道的下游并与分析物流动通道出口流体连通。

14、根据权利要求13所述的设备，其特征在于，所述收集腔室包括试剂，该试剂优选地为包括一种或多种核酸扩增试剂的试剂，更优选地为从下组中选择的试剂，该组包括核酸引物、核酸探针、荧光染料、酶缓冲剂、核苷酸、镁盐、牛血清白蛋白和变性剂。

15、根据权利要求13所述的设备，其特征在于，所述收集腔室包括出口部，该出口部可选择地与用于产生真空的装置相连。

16、根据权利要求15所述的设备，其特征在于，该设备包括后处理腔室，所述后处理腔室位于所述收集腔室的下游并与收集腔室出口流体连通，并且其自身可选择地包括出口，该出口可以与用于产生真空的装

置相连。

17、根据权利要求 1 至 16 中任一项所述的设备，其特征在于，所述样本处理腔室包括活动元件，所述活动元件优选地为从下组中选择的捕获元件，该组包括微流体芯片、固相材料、过滤器、过滤器组、亲和性
5 基质、磁分离基质、体积排阻柱、毛细管及它们的混合物。

18、根据权利要求 17 所述的设备，其特征在于，所述样本处理腔室包括玻璃纤维过滤膜。

19、根据权利要求 1 至 18 中任一项所述的设备，其特征在于，所述至少两个附加腔室中的至少一个腔室预填充有缓冲剂溶液，优选地为从
10 下组中选择的缓冲剂溶液，该组包括乙酸钾和三羟甲基氨基甲烷盐酸盐的水溶液，或者乙酸钾和三羟甲基氨基甲烷盐酸盐的乙醇水溶液。

20、根据权利要求 1 至 19 中任一项所述的设备，其特征在于，所述至少两个附加腔室中的至少一个腔室用作样本腔室，所述样本腔室包括入口部，通过该入口部将样本引入设备中。

15 21、根据权利要求 20 所述的设备，其特征在于，所述样本腔室入口部包括过滤膜。

22、根据权利要求 20 或 21 所述的设备，其特征在于，所述样本腔室包括试剂，所述试剂优选地为包括溶解试剂的试剂，更优选地为离液序列高的盐。

20 23、根据权利要求 1 至 22 中任一项所述的设备，其特征在于，该设备包括至少一个位于设备主体外部的腔室。

24、根据权利要求 23 所述的设备，其特征在于，所述位于设备主体外部的腔室为所述收集腔室。

25 25、根据权利要求 23 所述的设备，其特征在于，所述位于设备主体外部的腔室为所述至少两个附加腔室中的至少一个腔室。

26、根据权利要求 23 所述的设备，其特征在于，位于外部的至少一个腔室具有涂覆有导电聚合物的壁。

27、一种处理流体样本的方法，包括：

(i) 将样本放置在根据权利要求 1 的设备的样本处理腔室中；

- (ii) 施加正压或负压以使流体运动通过该设备;
- (iii) 对该样本进行一个或多个处理步骤; 以及
- (iv) 从所述分叉的分析物流动通道收集处理过的样本。

28、根据权利要求 1 所述设备的用途，用于从流体样本中纯化并浓缩核酸材料。

29、根据权利要求 28 所述的用途，其特征在于，然后对所述核酸材料进行聚合酶链反应扩增。

用于处理流体样本的设备

5 技术领域

本发明涉及一种用于处理流体样本的设备以及相关方法。

背景技术

可以由于种种原因而对流体样本（例如，临床或者环境样本）进行分析。目前所关注的领域是在流体样本（例如，临床或者环境样本）中正确识别生物材料的方法的发展。其之所以重要是因为其将有助于病状的早期诊断，这样就能进行快速治疗和感染控制，或者有助于识别环境污染物等。尽管对于生物材料的正确识别，核酸扩增（例如，聚合酶链反应（PCR））是非常有用且常用的方法，但是当试图将其成功地开发为在日常非实验室环境中用于在多种个别的流体样本中快速识别生物材料时，例如在所关心的疾病诊断的病人或地点附近时，会出现一些问题。

其中一个关键问题在于，在对典型的临床或环境样本进行核酸扩增之前，需要用试剂进行一系列处理步骤（其中一些是危险的）来纯化并浓缩生物材料。然而，核酸扩增只是这样一种技术的多种不同的可行示例中的一种，在所述技术中需要处理样本（尤其是样本样本），其中涉及大量同时或者连续的处理步骤。这些处理步骤本身可以很多且可以变化，并且除了可能的稀释和浓缩步骤外还可包括例如化学、光学、电、热、机械、声学、加工、传感或者监测。迄今为止，这种复杂的处理是在实验室中进行，其中可依次手动处理样本，或者通过使用专家机器人设备并行加工许多不同样本。然而，存在一些与这些方法相关的问题。这些问题包括速度慢、资源密集、昂贵、易出错和易交叉样本污染。此外，传统的流体处理系统需要流体样本顺序流过一系列不同的腔室，其中各个腔室依次用于单个步骤，这会导致样本的损失，并且这些过程的自动化需要使用复杂的流体组件和处理算法。

这样，仍需要开发一种改进的设备，从而可以使用一系列的预定的连续步骤来处理流体样本，以获得期望的最终产物。这种设备应该易适用于非实验室环境并且由具有很少或没有实验室训练的操作者使用，从而其可以在例如通过核酸扩增进行分析之前，用于操纵流体样本，例如
5 临床或环境样本。这种设备将确保可以快速获得分析结果、使熟练的工作人员免于重复任务并降低成本。另外，这种设备应具有足够的一致性和准确度以防止后面试验的失败，这种设备应能便宜地生产并且是一次性的，从而使交叉污染的可能性最小化并不必对大量装置进行消毒。

现有技术的检索发现了 US 6,374,684，其中公开了一种流体控制和处理系统，该系统包括多个腔室和可运动的阀体，该阀体可以用于根据给定的规程（protocol）来促进对流体样本的处理。尽管这为用于处理流体样本的设备领域中提供了进展，但是仍存在一些问题。一个问题是，为了使流体样本顺序地暴露于不同的溶液，有必要使阀体旋转以通过一些外部端口将样本处理腔室与各溶液的容器依次相连。这种设备并不十分适于由非熟练的实验室工作人员在非实验室环境中使用，这是因为需要将外部端口与各所需溶液的容器相连，而这是不切实际的并且当为危险化学药品时可能有安全隐患，以及其他原因。此外，这种设备由于其复杂性而具有较高的相关成本，并且不可能作为一次性设备节省成本，这导致潜在的交叉样本污染。另外，该设备采用单独的流体移动腔室来
15 依次将各处理溶液传递到样本，并除去任何废料，这可导致在流体移动腔室中剩余材料的混合以及可能破坏灵敏的处理顺序。仍需要开发一种能克服上述问题的用于处理流体样本的设备。

WO 00/62931 公开了一种微流体设备，其具有样本入口，该入口通过一微通道与检测模块相连。在该设备中的流体运动由接通或断开施加
25 电场的芯片泵来控制。该设备可选择地包括存储模块、废物模块、反应模块等，并且该申请以示例的方式公开了将该设备用于核酸扩增反应。该设备可用于对微量体积样本进行核酸扩增反应，但是仍存在关于如何开发这样一种设备的问题，该设备可用于这样的领域中，其中如在临床或环境样本的情况下样本容积为几毫升。

另外, US 6,391,541 公开了一种用于从流体样本分离所需分析物的药筒 (cartridge), 该药筒包括样本流动通道、样本溶解腔室、废物腔室、分析物流动通道以及用于引导流体流动的流动控制器。该专利还以示例的方式公开了将该设备用于从流体样本中分离核酸样本。该设备还展示了处理流体样本领域中的进展, 但是仍存在一些问题。这些问题包括, 5 为了可以以期望的方式 (包括所期望的化学和物理处理步骤) 来处理样本, 该设备包括复杂的流体通道。这需要使用多个贯穿设备的阀, 这些阀需要机械打开/关闭, 以确保流体以期望的方式行进。另外, 该复杂的结构可使得一些样本留在流体药筒内, 从而减少了最终处理的样本量。10 这在大容量的、保留有低浓度的期望分析物的样本的情况下会导致不准确的结果。最后, 该药筒的复杂性使得该设备更难于由该领域中不熟练使用者操作。

已经开发了一种克服上述问题的设备以及相关方法。该设备包括: 样本处理腔室, 其包括流体入口和流体出口; 废物腔室, 其位于样本处15 理腔室的下游并与样本处理腔室的流体出口流体连通, 并且其中在样本处理腔室出口和废物腔室之间的流体连通包括分叉的分析物流动通道; 至少两个附加腔室, 其位于样本处理腔室的上游并均与样本处理腔室的流体入口流体连通; 用于通过向所需的流动通道施加正压或负压, 从而按照需要使流体从所述至少两个附加腔室中的各个腔室运动通过样本处20 理腔室, 并进入废物腔室或者分叉的分析物流动通道中的装置; 以及用于限制流体的流动的被动装置。

将流体样本可选择地通过样本腔室而引入样本处理腔室中, 其中该样本腔室可选择地与功能性试剂相互作用。然后, 使一种或多种流体处理溶液同时或顺序地从所述附加腔室中的至少一个腔室运动通过样本处25 理腔室 (在那里它们与流体样本相互作用), 然后进入废物腔室中。通过确保两个附加腔室都与样本处理腔室连通, 可在不必依次形成各个流体连通路的情况下使流体运动通过该设备。通过控制用于使流体运动通过流体连通路径的装置, 可确保各个流体通过预定的规程流动进入样本处理腔室中, 并且如果必要可使各流体在到达样本处理腔室之前与另一

流体的相互作用最小化。通过采用用于施加正压或负压以使流体运动通过该设备的装置，可以以最小的复杂性形成正确的流体流动通道，并且通过使用用于限制流体流动的被动装置，可以简单地控制流体通道。可以以多种方式来改进该设备。这些方式可选择地包括：采用施加正压和
5 负压（即真空）的组合，以使流体以受控的方式运动通过该设备；在生产期间使腔室预先加载任何试剂或流体，因此使得该设备的使用者不必处理这些材料；使用多个被动阀，以防止流体通过该设备回流；以及将收集腔室集成入该设备中，从而可以直接收集处理过的样本用于进一步使用，例如用于核酸扩增。另外，可以选择性地使用一个或者多个腔室，
10 使得可以对一种或多种流体（包括流体样本）进行物理处理，例如热、声学、光学、电处理、传感或者监测技术。

本发明的设备具有一些优点。这些优点包括：其可被容易地设计成适应多种预定的处理顺序，包括化学和物理步骤，从而能够简单地使用流体处理装置；该设备采用单个处理腔室，因此使样本损失最小；该设
15 备、包括所有的化学试剂和任何生成的废物可完全集成在单个单元中，因此使样本污染最小化并且减少了使使用者暴露于潜在危险材料的可能性；由于减少了所使用的运动部件的数量，因此可能提高可靠性和使用简单性，即使对于具有很少或者没有实验室训练的使用者来说也是如此；以及制造廉价，这意味着该设备可设计为一次性的，从而进一步减少样
20 本交叉污染的危险。

本发明的一个目的是开发一种用于处理流体样本的设备以及相关方法。本发明的另一目的是设计这样一种设备，其能够对流体样本以预定的顺序进行一系列的顺序的化学或物理处理步骤，优选在核酸扩增反应之前醇化并浓缩流体样本。本发明的另一目的是设计这样一种设备，其
25 易于由具有很少或者没有实验室训练的使用者在非实验室环境下使用。本发明的又一目的是设计这样一种设备，使得任何所需的化学药品或废弃产物都保持集成在设备中，以使得使用者暴露于样本、化学品或者废物的可能性最小化。本发明的又一目的是设计这样一种设备，其制造廉价，从而在一次使用后可被处理掉，因此减少了样本交叉污染的可能性

并不必对大量设备进行消毒。从如下公开中将明白本发明的这些和其它目的。

发明内容

5 根据第一方面，本发明涉及一种用于处理流体样本的设备，其包括：

(i) 样本处理腔室，其包括流体入口和流体出口；

(ii) 废物腔室，其位于样本处理腔室的下游并与样本处理腔室的流体出口流体连通，并且其中在样本处理腔室出口和废物腔室之间的流体连通包括分叉的分析物流动通道；

10 (iii) 至少两个附加腔室，其位于样本处理腔室的上游并均与样本处理腔室的流体入口流体连通；

(iv) 用于通过向所需的流动通道施加正压或负压，从而按照需要使流体从所述至少两个附加腔室中的各个腔室运动通过样本处理腔室并进入废物腔室或者分叉的分析物流动通道中的装置；以及

15 (v) 用于限制流体的流动的被动装置。

根据第二方面，本发明涉及一种处理流体样本的方法，包括：

(i) 将样本放置在根据本发明的设备的样本处理腔室中；

(ii) 施加正压或负压以使流体运动通过该设备；

(iii) 对该样本进行一个或多个处理步骤；以及

20 (iv) 从所述分叉的分析物流动通道收集处理过的样本。

根据第三方面，本发明涉及将根据本发明的设备用于从流体样本提纯并浓缩核酸材料的用途。

在这里引用的所有出版物除非另有说明，其全部内容均已参考的方式在此引用。

25 这里使用的术语“流体连通”是指存在于所关心腔室之间的通道，尽管流体流受到用于限制流体流动的一个或多个被动装置的限制，但流体可原则上可以流过该通道。

这里使用的术语“连续的流体连通”是指始终存在于所关心腔室之间的通道，流体可流过该通道。

这里使用的术语“用于限制流体流动的被动装置”是指限制流体流过给定通道的装置，但是其中可通过被动地，即纯粹地向装置或者流动通道自身施加正压或负压来克服该限制，从而允许流体沿着给定的通道流动。可选地，这些装置可由被动动作打开或由被动动作关闭。另外，
5 根据施加压力的位置，该装置可允许流体沿着任一方向流过该装置所处的流体流动通道，或者该装置仅允许流体沿着单一方向流过流体流动通道。

这里使用的术语“流体样本”是指任何以气体、液体、包括由溶剂溶解的样本的溶液、或者包括一个或多个相的流体体系（例如，乳剂）
10 存在的样本。“流体样本”还可指这样的样本，其最初以固态或者粘性液体被引入该设备中，但是然后通过添加一定量的溶剂被稀释或者溶解。

这里使用的术语“功能性试剂”是指用于本发明的设备或方法中的固态化学或物理试剂。其可包括以固态粉末、小珠、胶囊、压片等定量的一种或多种化学试剂，包括与流体样本相互作用的试剂。这种试剂的
15 适当示例包括但并不限于溶解试剂，例如离液序列高的盐、核酸靶、核酸合成对照物、噬菌体、冻干的酶、染料、清洁剂等。然而，功能性试剂还应该理解为包括用于与流体样本相互作用的物理工具。这些物理工具可包括但并不限于磁力搅拌珠、加热装置、包被有抗体的磁性珠等。

下面将更详细地描述所述设备的元件。

20 本发明涉及一种用于处理流体样本的设备，包括样本处理腔室、废物腔室、至少两个附加腔室、和用于通过向所需的流动通道施加正压或负压，从而按照需要使流体从所述至少两个附加腔室中的各个腔室运动通过样本处理腔室，并进入废物腔室或者分叉的分析物流动通道中的装置；其特征在于，所述至少两个附加腔室中的各个腔室均与样本处理腔
25 室流体连通，并且样本处理腔室与废物腔室流体连通。本发明的实施方式便于根据预定的规程来处理流体样本。

样本处理腔室是在其中对流体样本自身进行一个或多个处理步骤的设备区域。这些处理步骤可包括化学处理步骤，例如稀释样本、使用一种或多种缓冲剂溶液来顺序清洗样本、使样本与一种或多种化学试剂反

应，但是也可包括物理步骤，例如用一种或多种热辐射来照射流体样本、对流体样本进行声学处理等。样本处理腔室可选择地包括活动部件，优选地为从下组中选择的捕获元件，该组包括微流体芯片、固相材料、过滤器、过滤器组、亲和性基质、磁分离基质、体积排阻柱、毛细管以及它们的混合物。优选地，样本处理腔室包括能够捕获流体样本中的生物材料的捕获元件，例如能够捕获细胞、孢子、病毒、大分子或小分子、蛋白质等。所选择的正确的捕获元件将取决于待捕获材料的性质。这里使用的优选捕获元件为玻璃纤维过滤器，其横跨样本处理腔室的部分或整个内表面区域延伸。

10 样本处理腔室包括流体入口和流体出口，并且一方面与至少两个附加腔室流体连通，另一方面与废物腔室流体连通。废物腔室位于样本处理腔室的下游并与样本处理腔室的流体出口流体连通，并且至少两个附加腔室位于样本处理腔室的上游并均与样本处理腔室的流体入口流体连通。这些流体连通中的至少一个可以为连续的流体连通。在样本处理腔室出口和废物腔室之间的流体连通包括分叉的分析物流动通道。该流体连通也可以是连续的流体连通。该设备还包括这样的装置，其用于通过向所需的流动通道施加正压或负压，从而按照需要使流体从所述至少两个附加腔室中的各个腔室运动通过样本处理腔室，并进入废物腔室或者分叉的分析物流动通道中。优选地，用于使流体从所述两个附加腔室中的每一个腔室运动通过样本处理腔室并进入废物腔室或者分叉的分析物流动通道中的装置，使流体顺序地从至少两个附加腔室中的第一腔室运动通过样本处理腔室并进入废物腔室中，然后从另一附加腔室运动通过样本处理腔室并进入废物腔室或者分叉的分析物流动通道中。

25 用于使流体运动的多种不同装置都是可接受的。这些装置通过向期望的流动通道施加正压或负压而使流体运动。用于施加负压的装置的一个示例为用于产生真空的装置，该真空通过出口部（例如废物腔室上的出口部或者分叉的分析物流动通道上的出口部）与该设备相连，并且能够按需要吸引流体通过该设备。该真空可以使用本领域普通技术人员已知的几种不同的装置中的一种与出口部件相连。将真空与出口部相连的

一种有效的方法是使用风箱，这是因为这些风箱可以容易地与甚至较小的出口部相连，可以提供高容忍度并降低了对于非常准确地处理的需求。如果该设备将以机械的方式或者由非熟练的工作人员操作，则这种布置尤其有用。优选地，设备的废物腔室包括一出口部，用于产生真空的装置可与该出口部相连。这样的结果是，真空能够将流体从附加腔室中的至少一个腔室引导通过样本处理腔室并进入废物腔室中。还优选的是，分叉的分析物流动通道包括出口部，从而可以在这里容易地安装用于产生真空的装置。也可以多种方式来采用用于产生真空的装置。例如，其可以适于以预定顺序将流体引导通过该设备。可选择地，该设备可设计成包括用于限制流体流过该设备的被动装置，从而需要增加的真空力从各个腔室顺序释放流体，由此通过在使用期间增加真空度，可以例如通过控制流体流动通道的尺寸或者通过加入膜或闸门（其需要被动地打开以允许流体流动），来顺序地引导来自第一腔室的流体然后引导来自另一腔室的流体。使用真空也可适于将空气引导通过该设备作为在各流体运动之间的中间步骤，从而清理流体连通路程，并且不同的流体在进入样本处理腔室之前不会彼此相互作用。这对于非常灵敏的样本处理规程是重要，例如其中在进入样本处理腔室之前第一缓冲剂与第二缓冲剂的相互作用会中和其效果，或者其中非常少量的材料整体到达样本是很重要的。如果使用真空，则还优选的是考虑可通过真空使设备内的任何材料雾化并从该设备排出至大气中。如果该设备适于与这样的试剂一起使用，该试剂如果释放就会造成安全危害，则采用该设备最小化或者消除雾化材料的释放是很重要的。这样一种可行的变化是将过滤膜加入至该设备中，或者加入至用于施加真空的装置中，从而使得雾化材料被捕获并且不会释放到大气中。

用于使流体运动通过该设备的另一合适装置的示例为这样的装置，其用于在流体后面施加正压或者力。同样可以通过本领域普通技术人员已知的多种装置来施加这种力。一个示例为在多个附加腔室中的一个使用活塞，该活塞的压下使得腔室中的任何流体通过流体连通路程排进样本处理腔室中，并然后进入废物腔室中。另外，使用用于在流体后面施

加力的装置，例如使用活塞可适于使得流体从至少两个附加腔室同时或者顺序运动，优选从附加腔室顺序地通过样本处理腔室并进入废物腔室或者分叉的分析物流动通道中。例如，可使一系列活塞中的一个或多个顺序地压下，以使流体顺序地从第一附加腔室运动通过样本处理腔室进入废物腔室，并且然后从另一附加腔室运动等等。在所述的两种情况下，5 可通过使用注射器、活塞、泵等手动地提供用于使流体运动的装置，或者通过将本发明的设备集成至能够提供动力和装置的另一设备中而机械地提供用于使流体运动的装置。另外，这种用于施加正压的装置可以与用于限制流体流过该设备的被动装置结合使用。

10 优选地，在本发明的设备中，采用用于产生真空的装置以及用于在流体后面施加力的装置的组合，来使流体从附加腔室中的至少一个腔室运动通过样本处理腔室并进入废物腔室中。一起使用这两个装置的优点在于，在流体后面的初始力促使流体从任何给定腔室释放，真空可引导流体流动通过该设备，因此防止其从期望通道转向。这使得所述设备容易设计成使得流体可根据预定的规程从附加腔室顺序地流过样本处理腔室。15

通过贯穿所述设备的、以期望的方式连接腔室的一个或多个通道，来提供本发明的流体连通路程。该设备设计成使得至少两个附加腔室在流体中通过样本处理腔室并进入废物腔室或分叉的分析物流动通道中。20 例如，可使一系列活塞中的一个或多个顺序地压下，以使流体顺序地从第一附加腔室运动通过样本处理腔室进入废物腔室，并且然后从另一附加腔室运动等等。在所述两种情况下，可通过使用注射器、活塞、泵等手动地提供用于使流体运动的装置，或者通过将本发明的设备集成至能够提供动力和装置的另一设备中而机械地提供用于使流体运动的装置。另外，这种用于施加正压的装置可以与用于限制流体流过该设备的25 被动装置结合使用。

优选地，在本发明的设备中，采用用于产生真空的装置以及用于在流体后面施加力的装置的组合，来使流体从附加腔室中的至少一个腔室运动通过样本处理腔室并进入废物腔室中。一起使用这两个装置的优点

在于，在流体后面的初始力促使流体从任何给定腔室释放，真空可引导流体流动通过该设备，因此防止其从期望通道转向。这使得所述设备容易设计成使得流体可根据预定的规程从附加腔室顺序地流过样本处理腔室。

- 5 通过贯穿所述设备的、以期望的方式连接腔室的一个或多个通道，来提供本发明的流体连通路程。该设备设计成使得至少两个附加腔室与样本处理腔室流体连通。这些腔室可选择地设计成各自具有单独的流出通道，它们在进入样本处理腔室之前在同一点处相连。优选地，只有一个用于使溶液进入样本处理腔室中的进入点，即样本处理腔室入口，以
- 10 降低设计的复杂性。这样，优选地，来自各个附加腔室的流出通道在进入样本处理腔室之前汇合然后流入共同的样本处理通道中。这些流体连通中的一个或多个可以为连续的流体连通。

- 为了使以不适当的方式流过腔室的流动最小化，优选地该设备包括用于限制流体流动通过该设备的被动装置，该设备设计成具有这样的特
- 15 征：其限制任何特定流体流动路径直到需要该流动路径之时。否则，将导致流体从多个腔室同时流动，并因此会破坏样本处理顺序或者可导致流体从废物腔室回流通过该设备。控制这种流动的合适方法的示例包括：使用一个或多个覆盖通道的膜，当在它们后面或前面施加压力时所述膜将破裂；使用极小直径的通道，在不施加力的情况下流体由于其表面张
- 20 力而不能流过所述通道；使用抽吸力预先填充任何包括缓冲剂溶液的腔室，该抽吸力可用于将这种流体保持在适当的位置直到施加释放它的力；使用贯穿该设备的阀，其通过真空、压力、磁体等操作；将流体连通路程设计成包括需要完全填充以形成流体连通的较小的容器，该流体连通允许在没有溢出的情况下容纳较小的泄漏，等等。优选地，该设备包括
- 25 这些特征中的一个或多个，以确保适当的流体流动。在本发明的设备中，优选地，用于限制流体流动的被动装置包括一容器，该容器位于在至少两个附加腔室中的至少一个腔室与样本处理腔室之间的流体连通中。还优选地，用于限制流体流动的被动装置包括较小直径的流体通道，从而流体不会在没有施加正压或负压的情况下流过该通道，该流体通道位于

在至少两个附加腔室中的至少一个腔室与样本处理腔室之间的流体连通中。更优选地，在至少两个附加腔室中的至少一个腔室与样本处理腔室之间的连续流体连通包括这两个特征。用于限制流体流动的被动装置的该示例允许在设备内形成连续流体连通通道，同时控制设备内的流体流动。这还进一步降低了设备的复杂性。

样本处理腔室同样通过废物通道与废物腔室流体连通。还重要的是，在废物腔室中的材料不能流回到样本腔室中。因此，优选地将该设备设计成在样本处理腔室和废物腔室之间加入用于限制流体流动的被动装置。优选包括被动阀（优选为单向阀），其位于样本处理腔室和废物腔室之间的流体连通中，以防止这种回流。优选地，该被动阀位于分叉的分析物流动通道的下游。一种简单的方案为采用小珠，例如玻璃珠，其位于流体通道中将其与样本处理腔室相连的点处的废物腔室的开口中。当该设备处于使用中且流体从样本处理腔室运动到废物腔室时，流体的流动或者使用真空将会从开口释放小珠，因此允许流体流动。当没有流体流动时，小珠将返回座在废物腔室的开口中，因此防止了液体回流通过该设备。优选地，采用通过废物腔室的真空来操作该阀。

用于限制流体流动的被动装置的另一示例为使用重力来控制流体的流动。优选地，在进入样本处理腔室之前，优选用真空引导流体向上通过预处理通道。然后，流体从上方（在那里其可通过重力而落下经过该腔室）进入样本处理腔室。还优选地，当流体通过废物通道离开样本处理腔室时，其再次向上流动并从顶部进入废物腔室。这种结构也可以防止流体回流通过该设备，例如从废物腔室进入样本处理腔室以及从样本处理腔室进入附加腔室。根据所关心的特定用途，本领域中普通技术人员能够将该设备设计成包括任何从那些所述的以及其它机构中选择的必需的流体流动控制机构。

来自样本处理的废料被收集在废物腔室中。优选地，将该废物腔室完全集成至本发明的设备中，从而不需要额外的瓶子来收集并然后处理掉这种废物。如果所关心材料是危险的或者有传染性的，那么这是尤为优选的，因为这使得对于使用者处理的需要最小化。废物腔室应具有足

够的容积，以能够容易地保持在样本处理过程中使用的所有流体。优选地，废物腔室容纳在该设备内的任何多余空间中，所述空间位于样本处理腔室和至少两个附加腔室之间和周围。这使得能够最有效地利用空间，因此将设备的整体尺寸保持为最小。如前所述，优选地，废物腔室包括一出口，该出口可与用于产生真空的装置相连，从而可以向该设备施加真空以将流体流直接引导通过该设备并进入废物腔室中。

该设备还包括至少两个附加腔室。根据该设备的用途，这些附加腔室可以起到多种作用。这种腔室的可能示例可包括缓冲剂腔室或者样本腔室，该缓冲剂腔室包括在样本处理规程中所需要的缓冲剂溶液或者水，流体或者固体样本可以最初引入该设备的样本腔室中并且该样本腔室可选择地包括与样本相互作用的第一试剂，或者在该样本腔室中固体样本最初溶解在溶剂中，或者可选地将样本在其中进行物理处理。在制造期间，这些腔室可预先填充有所需溶液或试剂。这具有一些优点，包括使用者不必关心从大量化学溶液中准确地测量等分试样，腔室自身不必安装在溶液的容器上，并且腔室可以预载填充有气泡，当吸引流体通过该设备时，该气泡可跟随流体流动，以确保在使用随后的流体之前清理流体通道。这些腔室可选择地包括内部局部障碍物，例如延伸通过内部腔室的一部分的塑料心轴，如果施加真空或者力，则该心轴可用于使腔室内的固体试剂的运动最小化。同样，这些腔室可包括膜，以防止在在样本处理步骤期间所包含物被过早释放，或者例如通过污染或汽化而破坏了包含物。在本发明的一个实施例中，优选地，至少两个附加腔室中的至少一个腔室预填充有从下组中选择的缓冲剂溶液，该组包括乙酸钾和三羟甲基氨基甲烷盐酸盐的水溶液，或者乙酸钾和三羟甲基氨基甲烷盐酸盐的乙醇水溶液。还优选地，至少两个附加腔室中的至少一个腔室用作样本腔室，其包括一入口部，样本可通过该入口部被引入该设备中。另外，优选地，该样本腔室包括一试剂，优选地为包括溶解试剂的试剂，更优选地为离液序列高的盐。其可以为固体珠的形式或者被冻干到腔室内的一个或多个表面上。

如果需要可以将该设备的腔室（包括一个或多个附加腔室和/或样本

处理腔室)自身设计成,使得在处理顺序中可以对腔室的包含物实施物理步骤。例如,腔室壁可包括加热元件,用于加热其包含物,它们可以为柔性的以允许声学处理,它们可以透过一种或多种波长的光以允许光学处理、传感或者监测等。优选地,该设备腔室中的至少一个腔室涂覆有例如在 WO 98/24548 中披露的导电聚合物。如果需要这种物理处理,则该设备应设计成将腔室定位成易于并有效地接近物理处理源。例如,该腔室可定位成朝向设备的外表面,或者可在设备主体的外侧局部或完全延伸从而该腔室的一部分能够与物理处理源(例如,光源或者热源)相互作用。优选地,该设备的至少一个腔室位于设备主体的外部,且保持与样本处理腔室流体连通,并且还优选地该腔室具有壁,这些壁至少部分涂覆有导电聚合物。可优选地位于设备主体外部的腔室的示例包括其中需要加热分析物或任何缓冲剂的任何腔室。

另外,该设备也可设计成包括一个或多个过滤膜。如前所述,优选地,样本处理包括捕获元件。同样如前所述,如果该设备包括与用于产生真空的装置相连的出口,则优选地将一过滤器加入至该设备中或者用于产生真空的装置中,从而防止雾化材料被释放进大气中。另外,该设备可包括例如在连通路程中的其它过滤器,以防止固体颗粒导致阻塞。过滤器的另一可选用途是,在进入设备前在样本腔室的入口部过滤样本。或者,如果该设备包括一入口部,通过该入口部将空气从大气引入该设备中,则有必要使用过滤膜,以确保来自大气的任何污染不会进入设备中并潜在地污染所处理的样本。优选地,该样本腔室入口部包括过滤膜,该滤膜可以在将样本引入样本处理腔室之前或之后安置。

本发明的设备可选择地包括收集腔室,处理过的样本可直接收集在该收集腔室中。该腔室可以集成至在该设备中,或者如果需要该设备可设计成使得该腔室简单且可靠地夹在适当的位置。当适当时,该腔室可位于分析物流动通道的下游并与分叉的分析物流动通道出口连通并因此与样本处理腔室流体连通。可这样操作该设备,使得可使用用于使流体在设备内运动的装置来将样本引入该腔室中。例如,该设备还可设有用于使处理过的样本从样本处理腔室运动进入收集腔室中的装置。因此,

可通过与用于使流体运动进入废物腔室中的装置断开连接并连接用于使流体运动进入收集腔室中的装置，而将流体从样本处理腔室引入收集腔室中。优选地，这种装置包括用于产生真空的装置，该装置通过第二出口与收集腔室相连，在这种情况下真空路径从样本处理腔室流过收集腔室，因此将来自废物腔室的任何流体转向而进入收集腔室中。如前所述，如果使用真空，则有利地将过滤膜装配在该设备中真空的上游，以防止来自样本的雾化材料进入大气。与其它腔室一样，收集腔室可设计成可以对其进行物理处理、传感或监测，并且可在设备主体外侧完全或部分地延伸，从而便于收集腔室与物理处理源相互作用。高度优选收集腔室适用于核酸扩增。因此，优选地，收集腔室位于设备主体的外部，其包括至少部分涂覆有导电聚合物的壁以便于样本的热循环，并且还包括透明部分，通过该透明部分可以用光学的方式（优选地通过荧光）监测核酸扩增反应。或者，收集腔室是可拆卸的，从而一旦收集了处理过的样本，则可将其移除以用于别处。集成（如果可拆卸）的收集腔室的其中一个主要优点在于，可以在无需任何介入或额外设备的情况下收集处理过的样本。另外，这对于使用者简化了该设备，使交叉样本污染最小化并使使用者暴露于样本的可能性最小。然而，如果收集腔室预先定量有降解试剂，则有用的是单独存储收集腔室，并且如果需要则将其安装在设备上。这种试剂的示例包括本领域技术人员已知的、对于核酸扩增反应和检测体系所需的试剂，例如，核酸引物、核酸探针、荧光染料、酶缓冲剂、核苷酸、镁盐、牛血清白蛋白、变性剂等。

在一些情况下，一旦主样本处理规程完成，则样本有必要在被收集到收集腔室中之前进一步与另一试剂相互作用。可通过选择性地在该设备中包括附加腔室、在样本处理腔室和收集腔室之间的后处理腔室来实现该最后步骤。在已经从样本处理洗提出处理过的样本后，其进入后处理腔室并与试剂相互作用，该试剂例如是在逆转录聚合酶链反应核酸扩增中逆转录酶步骤中所需的试剂。或者，该设备可设有后处理腔室，其位于收集腔室的下游并包含所关心的最终试剂。然后，可施加真空以将处理过的样本从样本处理腔室引导通过收集腔室并进入后处理腔室中，

从而允许处理过的样本进一步与其中的任何试剂相互作用，然后断开真空并将通过废物腔室重新施加真空，以将完全处理的样本引导回到收集腔室中。与其它腔室一样，优选地，该设备可定量有任何这种试剂，以使得使用者必须处理这些材料的必要性最小化。当该设备用于制备用于

5 核酸扩增的样本时，优选地所述试剂包括从下组中选择的一种或多种试剂，该组包括核酸引物、核酸探针、荧光染料、酶缓冲剂、核苷酸、镁盐、牛血清白蛋白、变性剂等。

该设备自身可具有多种不同的设计、形状、尺寸，并且可根据特定用途而由多种不同的材料制成。为了使设备成本最小并且确保对于单一

10 用途而经济可行地生产，优选地，该设备由诸如热塑性材料的廉价材料制成，例如聚乙烯或聚丙烯、聚碳酸酯、丙烯酸、尼龙或丁二烯-苯乙烯共聚物或者它们的混合物。优选地，该设备由尽可能少的元件制成。这样，优选地，设备主要部分制成为单独的注塑单元，包括腔室和主要通道。优选地，通过将注塑单元的基底超声焊接到包括通道路径的板上而

15 形成复杂的通道。稍后增加任何活塞（可以为盖子），以防止在使用后任何材料泄漏以及污染废物的逃逸。进一步优选该设备由可焚化的材料制成，从而在使用后，可容易地处理包括任何废物的该设备，而不会增加废物或者使得使用者暴露于所涉及化学制品的任何危险。该设备可以为透明或者半透明的。有利地，也可以对任何活塞进行颜色标记，以帮助

20 指导不熟练的使用者正确使用该设备。

该设备还可选择地设计成，使其可以与另一额外设备集成，该额外设备例如可以为流体样本瓶，从而一旦从病人或者环境收集流体样本，就可以将其引入流体处理设备中而不会有任何溢出，或者该额外设备是样本收集锥形物，从而样本可以直接收集在流体处理设备中。这两个设

25 备可通过使用密封件（例如，快速配合密封件、螺钉密封件或其它装置）而集成在一起。如果本发明的设备由塑料模制而成，则这些密封装置可以容易地结合成形。这种集成进一步简化了在非实验室环境中具有很少或者没有科学训练的人员对该设备的使用，并且还使得使用者与样本本身的相互作用最小。

另外，该设备可集成有机械设备。这是由于多个原因，包括为了用物理设备（例如，真空或者活塞压下）将该设备用于使流体运动，或者用于对设备的一个或多个腔室实施物理处理步骤，例如热、光学或声学处理、传感或监测。如果需要这种集成，则重要的是确保该设备设计成使其可有效地与这样的额外物理设备相集成。还重要的是，确保这种集成尽可能的简单，以使其可由非熟练工作人员有效地使用。这可包括将该设备设计成使其仅可沿单一取向被集成，使用色标来帮助取向等。

本发明还涉及一种处理流体样本的方法，包括：

- (i) 将样本放置在根据本发明设备的样本处理腔室中；
- 10 (ii) 施加正压或负压以使流体运动通过该设备；
- (iii) 使该样本经受一个或多个处理步骤；以及
- (iv) 从所述分叉的分析物流动通道收集处理过的样本。

所述处理步骤可以为化学步骤或物理步骤。

根据第三方面，本发明涉及将根据本发明的设备用于从流体样本纯化并浓缩核酸材料。优选可以这样制备这种样本，以使其可经受核酸扩增，例如聚合酶链反应扩增。

附图说明

现在将参照在下列附图中示出的本发明设备的具体实施方式来描述本发明，其中：

- 图 1 从侧面显示了设备的立体图；
- 图 2 从底部显示了设备的立体图；
- 图 3 从顶部显示了设备的立体图，其中移除了顶板从而可看到内部腔室；
- 25 图 4 显示了设备底板的内部视图；
- 图 5 是沿着 A-A 的设备的剖视图，显示了对于 PCR 使用该设备来处理流体样本的第一步骤；
- 图 6 是沿着 B-B 的设备的剖视图，显示了对于 PCR 使用该设备来处理流体样本的第二步骤；

图 7 是沿着 C-C 的设备的剖视图, 显示了对于 PCR 使用该设备来处理流体样本的第三步骤;

图 8 是沿着 D-D 的设备的剖视图, 显示了对于 PCR 使用该设备来处理流体样本的第四步骤; 以及

- 5 图 9 是沿着 E-E 的设备的剖视图, 显示了对于 PCR 使用该设备来处理流体样本的第五步骤。

具体实施方式

- 图 1 显示出本发明的设备 2, 其包括样本腔室 4、具有第一活塞 8 的第一缓冲剂腔室 6、具有第二活塞 12 的第二缓冲剂腔室 10。第一活塞 8 和第二活塞 12 包括插口 34, 以允许它们与外部设备集成从而在使用过程中使活塞运动。设备 2 还包括小容积水腔室 14, 其延伸超过设备 2 的主体。该小容积水腔室可包括环绕该腔室的膜密封件, 从而腔室中的水不会在存储期间或者样本处理的初期阶段汽化。该膜例如为 0.1-0.2 mm 的薄塑料片, 由丙烯腈丁二烯苯乙烯制成表层。该设备还包括第一出口部 16 和第二出口部 18, 通过这些出口可以将一个或多个真空与设备 2 相连。样本腔室 4 包括盖 20, 其通过臂 22 安装在设备 2 的主体上, 臂 22 可绕着栓 24 枢转。在将样本 (未示出) 引入样本腔室 4 中后, 将盖 20 绕着栓 24 枢转到将样本腔室 4 密封的位置。盖 20 还包括入口 26, 空气可通过该入口借助泵 (未示出) 而被引入设备 2 中。设备 2 还包括通道 28, 该通道从设备 2 的底部延伸到顶部, 并且位于设备 2 主体的外部。该通道 28 形成了该设备的流体连通网的一部分。将设备 2 的底板 30 和设备 2 的顶板 32 作为单独的单元制造, 并且在制造的最后阶段装配在设备 2 上。

- 参照图 2, 设备 2 包括顶板 32、底板 30 以及外部通道 28。该视图显示该设备具有三个容器 50、52 和 54, 它们也位于设备 2 的主体的外部。容器 50 在样本腔室的下方, 容器 52 在第一缓冲剂腔室的下方, 而容器 54 在第二缓冲剂腔室的下方。这些容器 (50、52 和 54) 用作机构的一部分, 以防止来自这些腔室每一个的样本或缓冲剂以不适当的方式流过该设备的流体连通网。设备 2 的底板 30 还包括收集腔室 56, 该收集

腔室也位于设备 2 主体的外部。一旦流体样本（未示出）已经完全纯化，则其就进入分叉的分析物流动通道并然后进入收集腔室 56，在那里可以对其进行 PCR 扩增反应。优选地，收集腔室 56 涂覆有导电聚合物（未示出），并且包括两个透明的面 58，通过这些面可以监测核酸扩增反应。

- 5 参照图 3，设备 2 包括样本腔室 4、第一缓冲剂腔室 6 和第二缓冲剂腔室 10。设备 2 包括废物腔室 100，该废物腔室是在设备主体中包围其它内部腔室的死空间。该设备包括样本处理腔室 102。该腔室通过预处理通道 104 与样本腔室 4 和缓冲剂腔室 6、10 流体连通。样本处理腔室 102 通过废物通道 28 与废物腔室 100 流体连通，该废物通道通过废物端口 106
10 与废物腔室 100 相连。该设备还包括后处理腔室 108，其与第二真空出口部（18，在该立体图中未示出）相连并且还与样本处理腔室 102 相连（连通未示出）。

- 参照图 4，底板 30 包括样本容器 50、第一缓冲剂容器 52 和第二缓冲剂容器 54。底板还包括样本通道 152、第一缓冲剂通道 154 和第二缓冲剂通道 156，其提供了分别从样本腔室、第一缓冲剂腔室和第二缓冲剂腔室（未示出）通过预处理通道到样本处理腔室（未示出）的流体连通，
15 该预处理通道的基底如 158 所示。样本处理腔室的基底 160 与废物腔室的基底 162 流体连通。样本处理腔室的基底 160 也通过分叉的分析物流动通道和收集腔室（未示出）与后处理腔室的基底 164 流体连通。

- 20 参照图 5，样本 200 通过样本腔室 4 被引入设备 2 中。一旦处于样本腔室中，就关闭样本腔室盖 20。该盖包括过滤器 202，该过滤器防止来自空气的污染物进入设备中并还防止雾化样本离开设备。在样本腔室中，该设备与第一试剂珠 204 相互作用，该试剂珠包括溶解试剂，该溶解试剂包含离液序列高的盐（例如，盐酸胍），以溶解样本中的任何细菌。
25 第一试剂可选择地包括核酸靶，其在后来能够用作使随后的 PCR 扩增反应的效率规格化的手段。在样本与第一试剂相互作用后，通过第一真空出口部向设备施加真空（在该剖视图中示出了真空，但是没有示出第一真空出口部 16）。该真空首先将样本引入样本腔室容器 50 中，沿着样本通道 152 到达预处理通道的基底 158。然后样本被沿着预处理通道 104 向

上引入样本处理腔室 102 中。样本处理腔室 102 包括过滤装置 206, 例如玻璃纤维过滤器, 在样本经过该过滤器时该过滤装置能够从样本中分离任何核酸。然后, 真空将样本从过滤器引出到样本处理腔室的基底 160、到达废物通道的基底 162 并然后向上进入废物通道 28 中。在废物通道的顶部处, 已经在此除去了所有核酸的样本通过废物通道出口 106 进入废物腔室 100 中。该图并没有显示在废物腔室中的废料。该废物通道包括小珠 208, 该小珠位于废物通道的基底 162 中。当施加真空时, 小珠 208 在废物通道 28 中上升, 使得流体通过通道 28 进入废物腔室 100 中。当除去真空时, 小珠 208 下降并覆盖废物通道的基底 162, 因此密封了入口。这防止了废物流体回流到样本处理腔室 102 中。该设备的视图还显示出水腔室 14、第一缓冲剂腔室 6 和活塞 8、后处理腔室 108、以及后处理腔室出口部 18, 但是在该视图中没有显示这些腔室之间的流体连通。

参照图 6, 设备 2 的第一缓冲剂腔室 6 包括第一缓冲剂 252, 例如乙酸钾/三羟甲基氨基甲烷盐酸盐的水溶液, 例如可在 Promega Wizard™ 试剂盒中获得的缓冲剂。通过废物腔室出口部 (未示出, 但是在图 5 中显示) 向设备施加真空。同时, 活塞 8 在第一缓冲剂腔室 6 内压下, 这促使第一缓冲剂 252 流过容器 52, 并通过在预处理通道的基底 158 处相连的第一缓冲剂通道 154 和预处理通道 104 而进入样本处理腔室 102 中。第一缓冲剂通道 154 设计成在其离开第一缓冲剂容器 52 的点处具有非常窄的直径。这确保了由于第一缓冲剂的表面张力而使其不能够泄漏到第一缓冲剂通道 154 中直到活塞 8 压下为止。一旦处于样本处理腔室 102 中, 缓冲剂就与样本一样流过过滤装置 206, 因此在过滤膜上清洗核酸材料。然后通过真空 (未示出) 引导第一缓冲剂 252 经过废物通道 28 以及废物通道出口部 106, 以进入废物腔室 100 (没有显示在废物通道中的废料)。

参照图 7, 第二缓冲剂腔室 10 包括第二缓冲剂 302, 例如乙酸钾/三羟甲基氨基甲烷盐酸盐的乙醇水溶液, 例如可在 Promega Wizard™ 试剂盒中获得的缓冲剂。通过废物腔室出口部 (未示出, 但是在图 5 中显示) 向设备施加真空。同时, 活塞 12 在第二缓冲剂腔室 10 内压下, 这促使

第二缓冲剂 302 流过容器 54，并通过在预处理通道的基底 158 处相连的第二缓冲剂通道 156 和预处理通道 104 而进入样本处理腔室 102 中。与前面一样，第二缓冲剂通道 156 设计成在其离开第二缓冲剂容器 54 的点处具有非常窄的直径。这确保了第二缓冲剂 302 不会泄漏。同样，一旦
5 处于样本处理腔室 102 中，缓冲剂就再次流过过滤装置 206，从而在过滤膜上清洗核酸材料。然后通过真空（未示出）引导第二缓冲剂 302 经过废物通道 28 以及废物通道出口部 106，以进入废物腔室 100（没有显示在废物通道中的废料）。

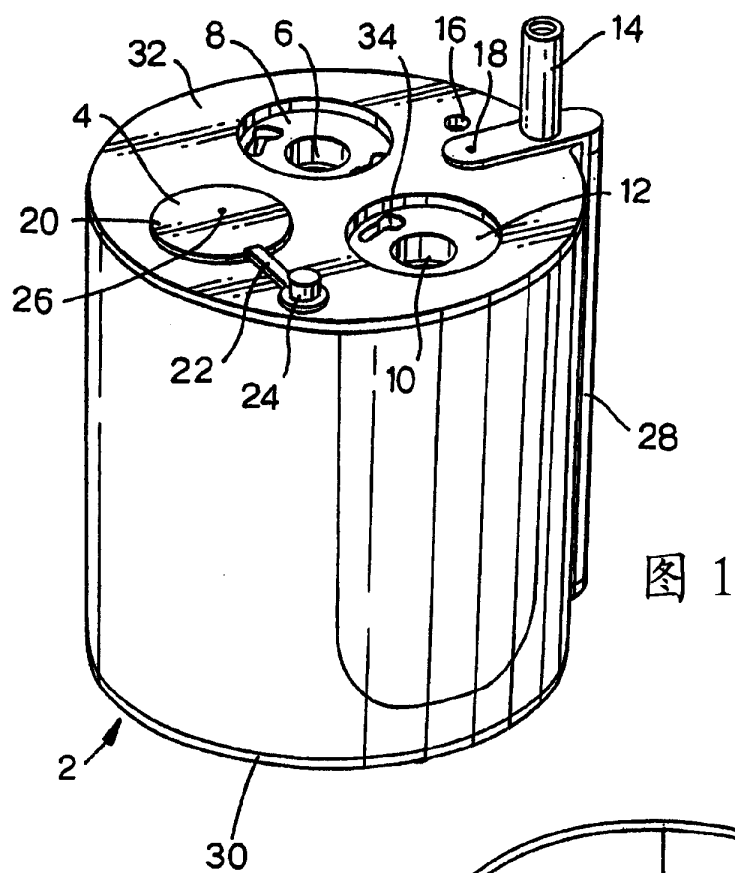
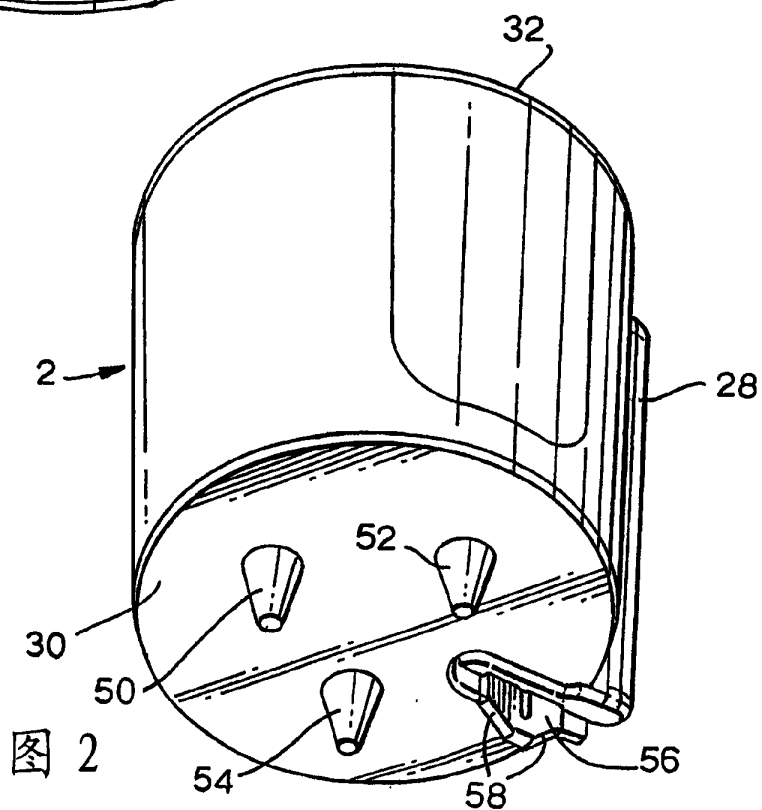
参照图 8，构造该设备以风干包括经纯化的核酸的过滤膜，以从过
10 滤器除去任何过多的溶剂。为了实现这一点，通过第一真空出口部 16（未示出）向设备 2 施加真空。这使得空气通过样本腔室盖 20 中的入口部 26 而被引入设备中。该空气经过过滤器 202 以除去空气中的物质，因此防止了样本污染。然后其通过真空被引导通过样本腔室 4、样本腔室容器 50、样本腔室通道 152、预处理通道 104、样本处理腔室 102、过滤装置
15 206、废物通道 28，并且通过废物腔室 100 而引出设备。然后除去用于通过出口部 16 向设备 2 施加真空的装置。

参照图 9，小容积腔室 14 包括纯净水，优选地为大约 100 μl 。使用用于加热的外部装置（未示出）对其加热，直到水温优选地大于 80°C。然后通过第二真空出口部 18 向设备施加第二真空。将活塞 305 压下，以
20 将加热的水从水腔室 14 释放进入样本处理腔室 102 中。锥形物 315 用于将小量水直接引导到过滤装置 206。将水引导通过过滤装置 206，当其经过时洗提出纯化的核酸物质，并通过第二真空进入收集腔室 56 中。第二真空还将水引导通过分叉的分析物流动通道、收集腔室 56 并进入后处理腔室 108 中。后处理腔室 108 包含有第二固体试剂 310，该第二固体试剂
25 310 包括另一 PCR 试剂，例如探针、荧光染料和另一核酸对照物。将该试剂 310 溶解在溶液中。然后除去第二真空，以允许溶液由于重力而落进收集腔室 56 中。或者，可再次施加第一真空，以将溶液引导回到收集腔室 56 中。

一旦处于收集腔室中，准备对核酸就进行实施 PCR 扩增所需的热循

环。收集腔室优选地设计成使其壁由导热聚合物制成。然后收集腔室可在原地经受热循环，或者被除去并放置在另一设备中以进行循环。

该设备的实施方式已经被开发出来以从 10 ml 的流体样本中纯化核酸材料。设备的主体具有从大约 70 到大约 80 mm 的高度，并且具有从大约 70 到大约 80 mm 的直径。样本腔室具有大约 20 ml 的容积，并且第一
5 和第二缓冲剂腔室具有大约 30 ml 的容积。小容积水腔室具有大约 500 μ l 的容积，而样本处理腔室具有大约 2 ml 的容积并且具有大约 5 mm 的直径。预处理通道和废物通道各自具有大约 3 mm 的直径。由主体内的的死空间形成的废物腔室具有大约 120 ml 的容积。通过将成形的底板超声焊
10 接到腔室的底侧而形成流体连通通道。这些通道具有大约 1 mm 的直径。在通道离开样本容器的点处，该直径减少到大约 0.6 mm，以防止不期望的流体从腔室流到样本处理腔室中。



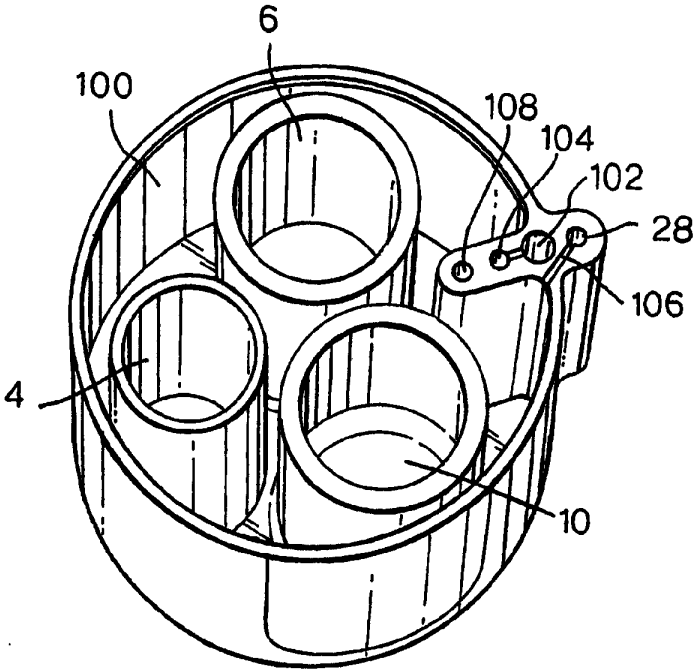


图 3

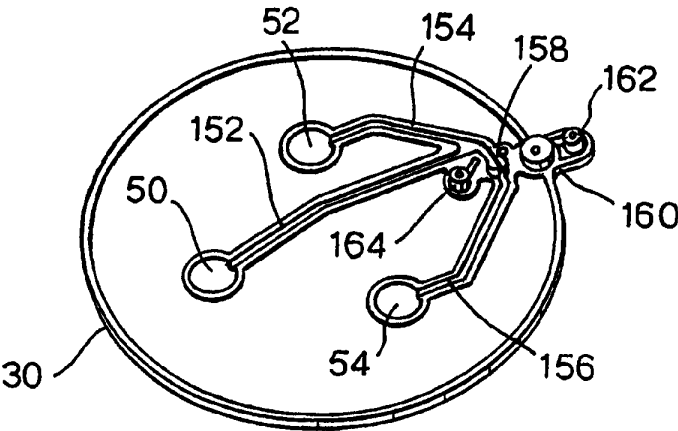


图 4

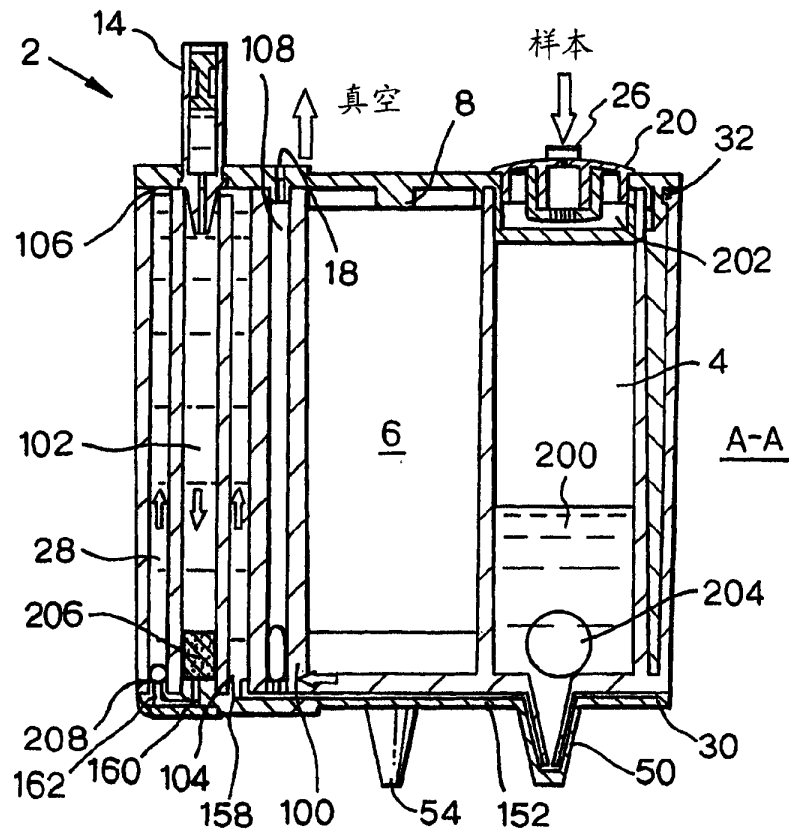


图 5A

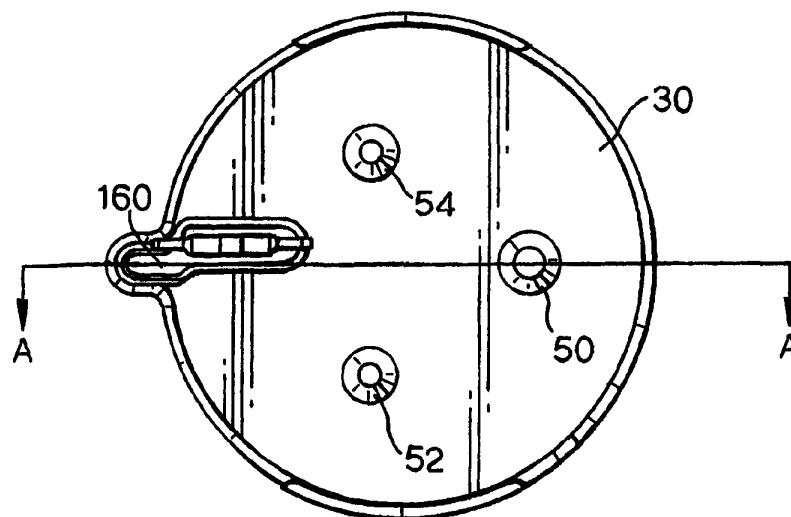


图 5B

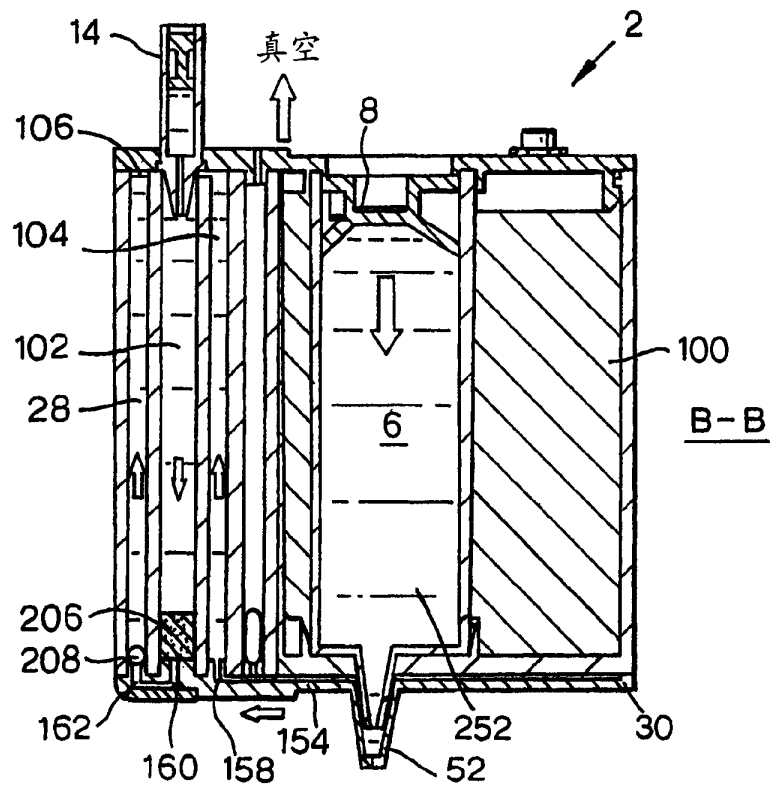


图 6A

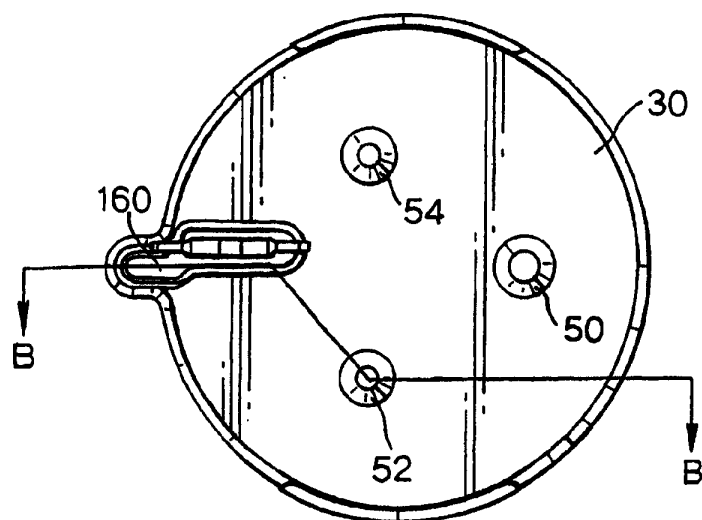


图 6B

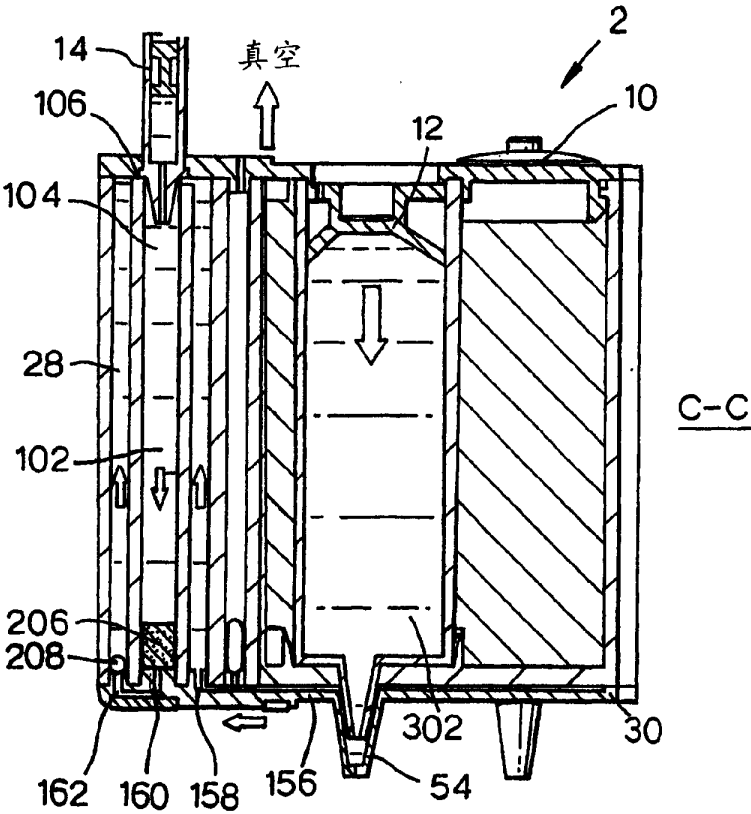


图 7A

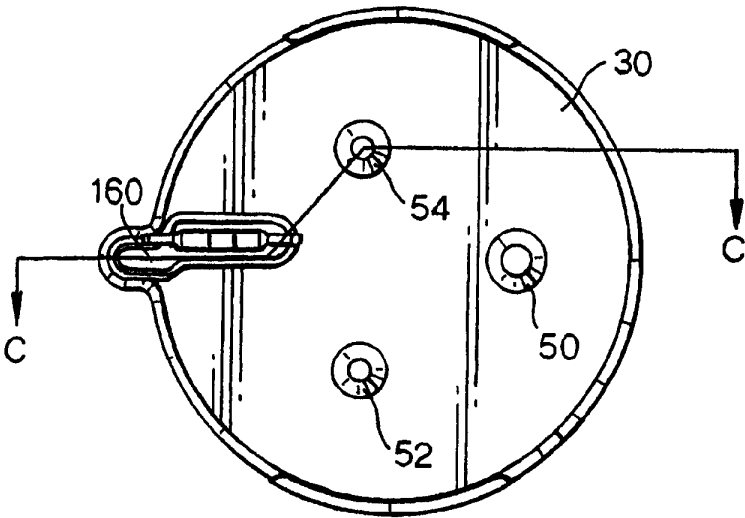


图 7B

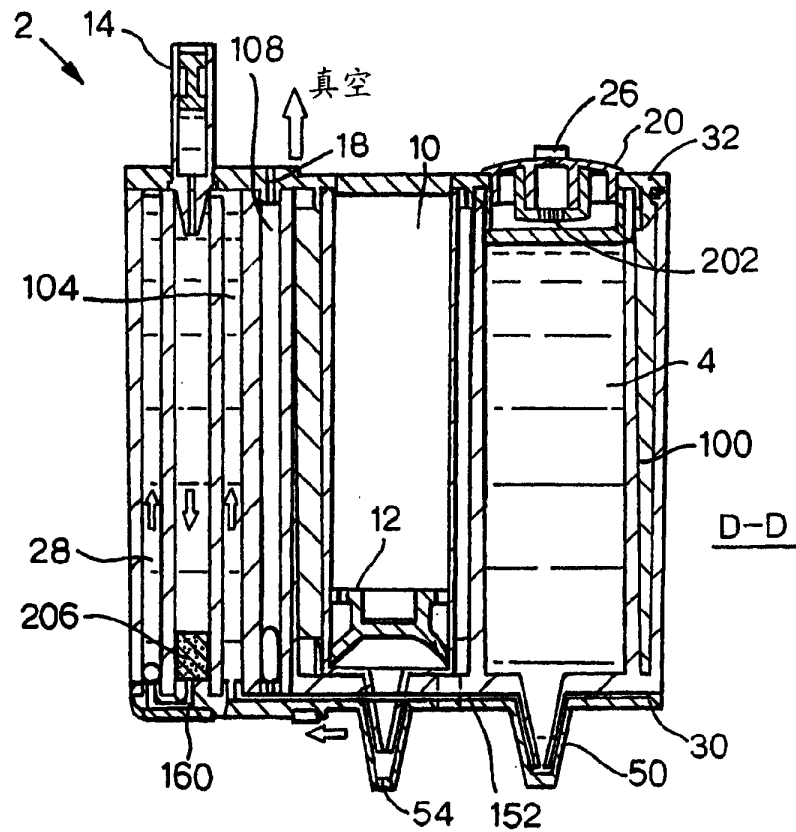


图 8A

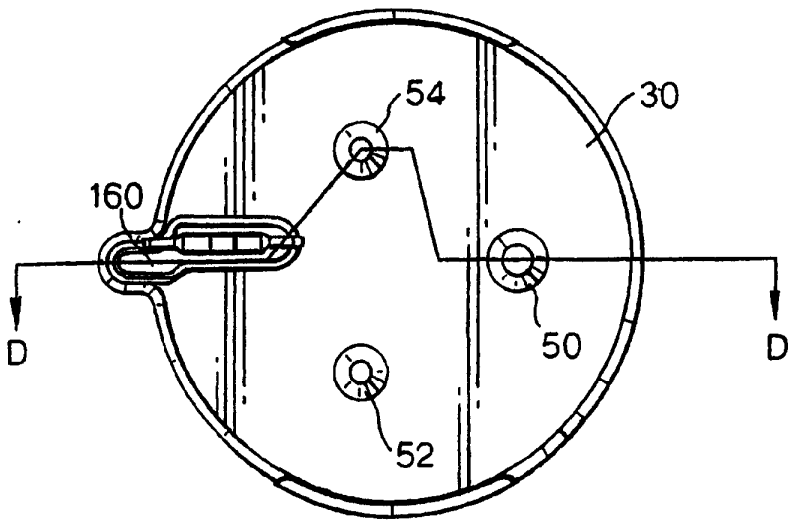


图 8B

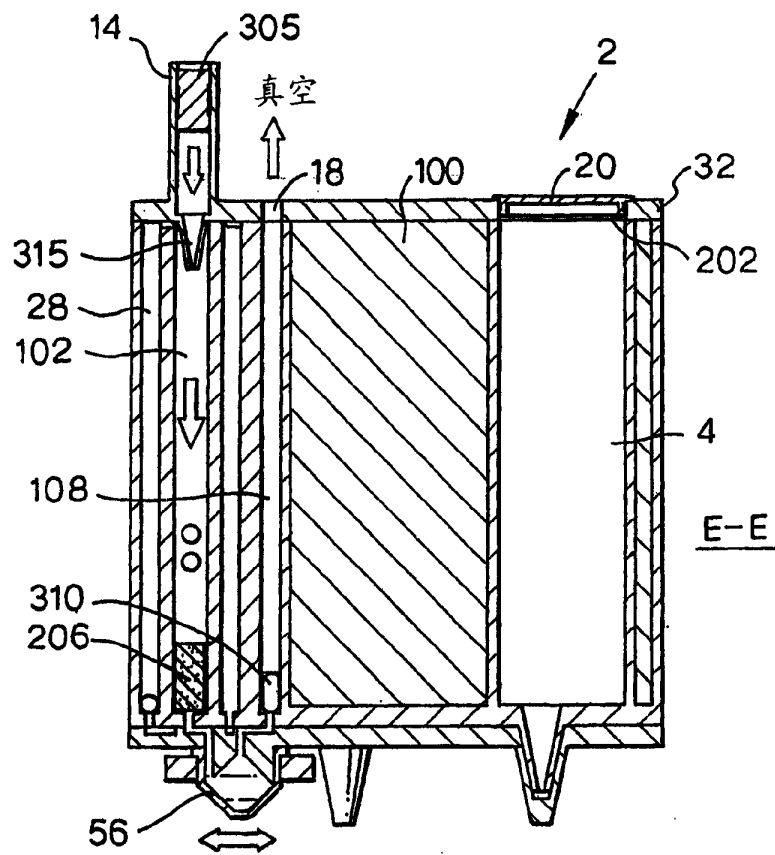


图 9A

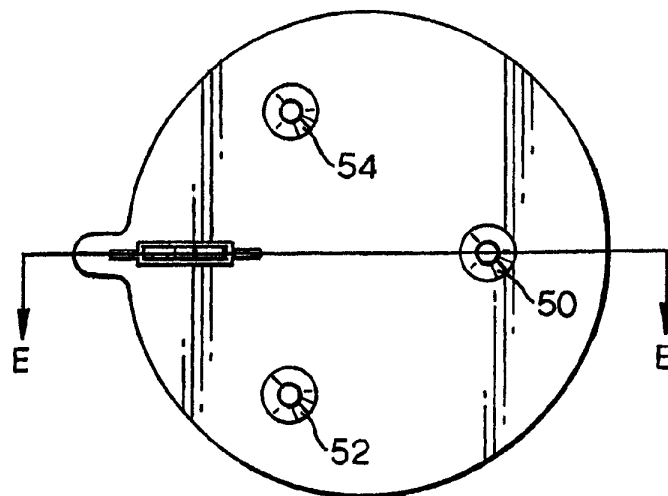


图 9B

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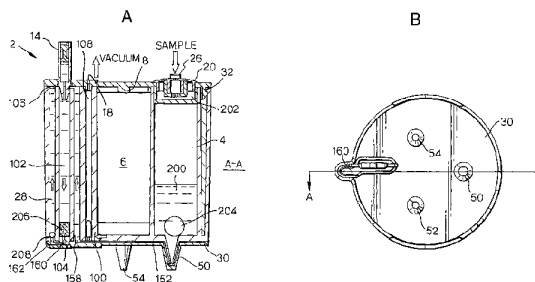
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[Continued on next page]

(54) Title: APPARATUS FOR PROCESSING A FLUID SAMPLE



(57) Abstract: This invention relates to an apparatus for an apparatus for processing a fluid sample comprising: (i) a sample processing chamber comprising a fluid inlet and a fluid outlet; (ii) a waste chamber downstream from the sample processing chamber and in fluid communication with the sample processing chamber fluid outlet and wherein the fluid communication between the sample processing chamber outlet and the waste chamber comprises a divergent analyte flow path; (iii) at least two further chambers up stream from the sample processing chamber both of which are in fluid communication with the sample processing chamber fluid inlet; (iv) a means for moving fluid from each of the at least two further chambers through the sample processing chamber and into the waste chamber or into the divergent analyte flow path as desired by applying positive or negative pressure to the desired flow path; and (v) a passive means for restricting the flow of fluid. This invention also relates to a method and use of the same.



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Apparatus for Processing a Fluid Sample

This invention relates to an apparatus and associated method for processing a fluid sample.

The analysis of fluid samples, for example clinical or environmental samples, may be conducted for several reasons. One current area of interest is the development of a method to positively identify biological material in a fluid sample, for example a clinical or environmental sample. This is important since it would help in the early diagnosis of disease states, which in turn would enable rapid treatment and infection control, or the identification of environmental contaminants and the like. Although nucleic acid amplification, for example the polymerase chain reaction (PCR) is a very useful and commonly used method for positive identification of biological material, several problems exist when trying to successfully develop it for use on a day to day basis for the rapid identification of biological material in many individual fluid samples in a non-laboratory environment, for example to achieve near patient or point of care disease diagnosis.

One of the key problems lies in the fact that, prior to subjecting a typical clinical or environmental sample to nucleic acid amplification, it needs to undergo a sequence of processing steps using reagents, some of which are hazardous, to purify and concentrate the biological material. However, nucleic acid amplification is just one of many different possible examples of a technique where manipulation of a sample,

especially a fluid sample, is required which involves a number of simultaneous or sequential processing steps. The processing steps themselves may be many and varied and may include for example chemical, optical, electrical, thermal, mechanical, acoustical, processing, sensing or monitoring, in addition to possible dilution and concentration steps. To date such complex processing is conducted in laboratories where samples are either treated manually one by one, or by using specialist robotics facilities to process many different samples in parallel. However, there are several problems associated with these methods. These include that they are slow, resource intensive, expensive, subject to error and to cross sample contamination. In addition, conventional fluid processing systems require fluid samples to flow sequentially through a series of different chambers where each chamber is utilised for a single step in a sequence which may result in loss of sample, and automation of such processes requires the use of complex fluidic assemblies and processing algorithms.

As such there remains a need to develop an improved apparatus whereby a fluid sample can be processed using a series of pre-determined sequential steps, to obtain a desired end product. Such an apparatus should be readily adapted for use in a non-laboratory environment and by an operator with little or no laboratory training such that it can be used to manipulate a fluid sample, for example a clinical or environmental sample, prior to analysis, for example by nucleic acid amplification. Such an apparatus would ensure that analytical results could be rapidly obtained, would free the skilled worker from repetitive tasks and would reduce costs. Furthermore such an apparatus should have sufficient consistency and accuracy to prevent the failure of later tests, should be cheap to produce, and disposable, to

minimise the likelihood of cross contamination and to eliminate the need to sterilise large amounts of equipment.

A prior art search has identified US 6,374,684 which discloses a fluid control and processing system comprising a plurality of chambers and a moveable valve body that can be used to facilitate the processing of a fluid sample according to a given protocol. Although this provides a development in the field of an apparatus for processing a fluid sample, several problems remain. One such problem is that, in order to expose the fluid sample sequentially to different solutions, it is necessary to rotate the valve body to connect in turn, via several external ports, a sample processing chamber with a reservoir of each solution. Such an apparatus is not well suited for use in a non-laboratory environment by a non-skilled laboratory worker because, for among other reasons, there is a need to connect the external ports to reservoirs of each required solution which is impractical and in the case of hazardous chemicals may be a safety risk. In addition such an apparatus, due to its complexity, has a high associated cost, and is unlikely to be cost effective as a disposable apparatus and that result in the potential for cross sample contamination. Furthermore, the apparatus utilises a single fluid displacement chamber to deliver each processing solution to the sample in turn, and to remove any waste materials, which may result in mixing of residual material in the fluid displacement chamber and potential failure of sensitive processing sequences. There remains a need to develop an apparatus for processing a fluid sample that overcomes the above problems.

WO 00/62931 discloses a microfluidic apparatus with a sample inlet port connected via a microchannel to a detection module. Fluidic movement within the apparatus is

controlled by on or off chip pumps which apply an electric field. The apparatus can optionally comprise a storage module, a waste module, reaction modules and the like and the application discloses as an example the use of the apparatus for a nucleic acid amplification reaction. Such an apparatus is useful for conducting nucleic acid amplification reactions on micro-scale volume samples but the problem remains as to how to develop such an apparatus which can be used in the field wherein the volume of the sample is several millilitres as is the case for clinical or environmental samples.

Furthermore US 6,391,541 discloses a cartridge for separating a desired analyte from a fluid sample comprising a sample flow path, a sample lysing chamber, a waste chamber, an analyte flow path and a flow controller for directing fluid flow. Again the patent discloses as an example the use of the apparatus for the separation of a nucleic acid sample from a fluid sample. Again this apparatus presents a development in the field of processing a fluid sample but several problems remain. These include that in order that the sample may be processed in the desired manner, including the desired chemical and physical processing steps, the apparatus comprises complex fluidic channels. This has required the use of many valves through the apparatus which require mechanical opening / closing in order to ensure that the fluid proceeds in the desired manner. Furthermore this complex arrangement may result in some sample remaining inside the fluid cartridge thereby reducing the amount of sample that is ultimately processed. This can lead to inaccurate results in the case of high volumes of sample which retain a low concentration of the desired analyte. Finally the complexity of the cartridge makes the apparatus more difficult to operate in the field by the unskilled user.

An apparatus, and associated method, have now been developed which overcome the above problems. The apparatus comprises a sample processing chamber comprising a fluid inlet and a fluid outlet; a waste chamber downstream from the sample processing chamber and in fluid communication with the sample processing chamber fluid outlet and wherein the fluid communication between the sample processing chamber outlet and the waste chamber comprises a divergent analyte flow path; at least two further chambers up stream from the sample processing chamber both of which are in fluid communication with the sample processing chamber fluid inlet; a means for moving fluid from each of the at least two further chambers through the sample processing chamber and into the waste chamber or into the divergent analyte flow path as desired by applying positive or negative pressure to the desired flow path; and a passive means for restricting the flow of fluid.

A fluid sample is introduced into the sample processing chamber, optionally via a sample chamber where it may optionally interact with a functional agent. One or more fluid processing solutions are then moved concomitantly or sequentially from at least one of the further chambers, through the sample processing chamber where they interact with the fluid sample, and then into a waste chamber. By ensuring that the further chambers are both in communication with the sample processing chamber, the fluids can move through the apparatus without the need for each fluid communication route to be established in turn. By controlling the means for moving fluid through the fluid communication routes it is possible to ensure that each fluid passes via a pre-determined protocol into the sample processing chamber and if necessary, it is possible to minimise the interaction of each fluid with another prior to reaching the sample processing chamber. By utilising a means for the application of positive or

negative pressure to move fluid through the apparatus the correct fluid flow paths can be established with minimum complexity and by using a passive means for restricting the flow of fluid the fluid pathways can be simply controlled. The apparatus can be enhanced in several ways. These include optionally utilising a combination of application of positive pressure and negative pressure, ie a vacuum, to move fluids through the apparatus in a controlled manner; pre-loading chambers with any reagents or fluids during production thus eliminating the need for the user of the apparatus to handle such materials; using more than one passive valve to prevent the back flow of fluids through the apparatus; and integrating a collection chamber into the apparatus such that the processed sample can be collected directly for further use, for example for nucleic acid amplification. In addition, one or more of the chambers may optionally be adapted such that one or more of the fluids, including the fluid sample, may also be subjected to physical processing for example thermal, acoustic, optical, electrical processing, sensing or monitoring techniques.

The apparatus of the present invention has several advantages. These include that it can be easily designed to accommodate a wide variety of pre-determined processing sequences, including chemical and physical steps, to provide an easy to use fluid processing device; the apparatus utilises a single processing chamber thus minimising sample loss; the apparatus, including all chemical reagents and any waste produced, is completely integrated in a single unit therefore minimising sample contamination and reducing exposure of the user to potentially hazardous materials; due to the use of a reduced number of moving parts the apparatus is likely to have increased reliability and simplicity of use even for a user with little or no laboratory training; and it is

cheap to manufacture which means that the apparatus can be designed to be disposable further reducing the risk of sample cross contamination.

It is an object of the present invention to develop an apparatus, and associated method, for processing a fluid sample. It is a further object of this invention to design such an apparatus which is capable of subjecting a fluid sample to a series of sequential chemical or physical processing steps in a pre-determined sequence, preferably to purify and concentrate a fluid sample prior to a nucleic acid amplification reaction. It is another object of this invention to design such an apparatus to be simple to use by a worker with little or no laboratory training in a non-laboratory environment. It is yet another object of this invention to design the apparatus such that any required chemicals or waste product remain integrated within the apparatus to minimise user exposure to the sample, chemicals or waste. It is yet another object of this invention to design such an apparatus to be cheap to manufacture such that it can be disposed of after a single use thus reducing the likelihood of sample cross contamination and eliminating the need for sterilising large amounts of equipment. These, and other objects of this invention, will become apparent in light of the following disclosure.

Summary of the Invention

According to a first aspect this invention relates to an apparatus for processing a fluid sample comprising:

- (i) a sample processing chamber comprising a fluid inlet and a fluid outlet;
- (ii) a waste chamber downstream from the sample processing chamber and in fluid communication with the sample processing chamber fluid outlet and wherein the fluid communication between the sample processing chamber outlet and the waste chamber comprises a divergent analyte flow path;
- (iii) at least two further chambers up stream from the sample processing chamber both of which are in fluid communication with the sample processing chamber fluid inlet;
- (iv) a means for moving fluid from each of the at least two further chambers through the sample processing chamber and into the waste chamber or into the divergent analyte flow path as desired by applying positive or negative pressure to the desired flow path; and
- (v) a passive means for restricting the flow of fluid.

According to a second aspect this invention relates to a method of processing a fluid sample comprising:

- (i) placing the sample in the sample processing chamber of an apparatus according to the present invention;
- (ii) applying a positive or negative pressure to move fluid through the apparatus;
- (iii) subjecting the sample to one or more processing steps; and

- (iv) collecting the processed sample from the divergent analyte flow path.

According to a third aspect this invention relates to the use of an apparatus according to the present invention for purification and concentration of nucleic acid material from a fluid sample.

Detailed Description of the Invention

All publications cited herein are hereby incorporated by reference in their entirety, unless otherwise indicated.

As used herein the term “fluid communication” means that a path through which fluid can in principle flow exists between the chambers in question although fluid flow may be restricted by one or more passive means for restricting the flow of fluid.

As used herein the term “continuous fluid communication” means that a path through which fluid can flow exists at all times between the chambers in question.

As used herein the term “a passive means for restricting the flow of fluid” shall be taken to mean a means that restricts fluid flowing through a given path but wherein the restriction can be overcome passively namely purely by the application of positive or negative pressure to either the means or to the flow path itself, thereby allowing fluid flow along the given path. Optionally such means may be opened by passive action or closed by passive action. Furthermore such means may allow flow of fluid

in either direction through the fluid flow path in which the means is situated depending on the position of application of a pressure or alternatively the means may only allow the flow of fluid in a single direction through the fluid flow path.

As used herein the term “fluid sample” means any sample that exists as a gas, a liquid, a solution comprising a sample solvated by a solvent, or a fluid system comprising one or more phases for example an emulsion. A “fluid sample” is also taken to mean a sample which may initially be introduced into the apparatus as a solid or a viscous liquid but which is then diluted or dissolved by the adding of a volume of solvent.

As used herein the term “functional agent” means a solid chemical or physical agent which is used in the apparatus or method of the present invention. It may comprise one or more chemical reagents dosed as a solid powder, bead, capsule, pressed tablet and the like comprising a reagent to interact with the fluid sample. Suitable examples of such reagents include, but are not limited to, lysis reagents for example chaotrophic salts, nucleic acid targets, nucleic acid synthetic controls, bacteriophage, lyophilised enzymes, dyes, detergents and the like. However, the term functional agent should also be understood to comprise physical means for interacting with the fluid sample. These could include, but are not limited to, a magnetic stirrer bead, a heating means, magnetic beads coated with antibodies and the like.

The elements of the apparatus are described in more detail below.

This invention relates to an apparatus for processing a fluid sample comprising a sample processing chamber, a waste chamber, at least two further chambers, a means for moving fluid from each of the at least two further chambers through the sample processing chamber and into the waste chamber or divergent analyte flow path; and is characterised in that each of the at least two further chambers are in fluid communication with the sample processing chamber and in that the sample processing chamber is in fluid communication with the waste chamber. Embodiments of the invention facilitate processing of a fluid sample according to a pre-determined protocol.

The sample processing chamber is the region of the apparatus in which the fluid sample itself is subjected to one or more processing steps. These processing steps can include chemical processing steps such as diluting the sample, washing the sample sequentially with one or more buffer solutions, reacting the sample with one or more chemical reagents, but may also include physical steps for example radiating the fluid sample with one or more thermal radiation, subjecting the fluid sample to acoustical processing and the like. The sample processing chamber may optionally comprise an active member, preferably a trapping member selected from the group consisting of a microfluidic chip, a solid phase material, a filter, a filter stack, an affinity matrix, a magnetic separation matrix, a size exclusion column, a capillary tube and mixtures thereof. It is preferred that the sample processing chamber comprises a trapping member capable of trapping the biological material in a fluid sample for example capable of trapping cells, spores, viruses, large or small molecules, proteins and the like. The exact trapping member chosen will depend on the nature of the material to be trapped. The preferred trapping member for use herein is a glass fibre filter that

extends across part or all of the internal surface area of the sample processing chamber.

The sample processing chamber comprises a fluid inlet and a fluid outlet and is in fluid communication with at least two further chambers on the one hand and a waste chamber on the other hand. The waste chamber is down stream from the sample processing chamber and in fluid communication with the sample processing chamber fluid outlet and the at least two further chambers are up stream from the sample processing chamber both of which are in fluid communication with the sample processing chamber fluid inlet. At least one of these fluid communications may be a continuous fluid communication. The fluid communication between the sample processing chamber outlet and the waste chamber comprises a divergent analyte flow path. Again this may be a continuous fluid communication. The apparatus also comprises a means for moving fluid from the at least two further chambers through the sample processing chamber into the waste chamber or into the divergent analyte flow path as desired by applying positive or negative pressure to the desired flow path. It is preferred that the means for moving fluid from each of the two further chambers through the sample processing chamber and into the waste chamber or the divergent analyte flow path moves the fluid sequentially from the first at least two further chambers through the sample processing chamber and into the waste chamber and then from another further chambers through the sample processing chamber and into the waste chamber or the divergent analyte flow path.

Many different means are acceptable for moving the fluid. The means moves fluid by the application of either a positive pressure or a negative pressure to the desired flow path. One example of a means for the application of negative pressure is a means for generating a vacuum that is attached to the apparatus via an outlet port, for example an outlet port on the waste chamber or an outlet port on the divergent analyte flow path and that is able to draw fluid through the apparatus as desired. The vacuum can be attached to the outlet port using one of several different means known to one of ordinary skill in the art. One effective way of attaching the vacuum to the outlet port is by the use of bellows since these can be readily attached to even a small outlet port giving a high tolerance and reducing the need for very accurate handling. Such an adaptation is particularly useful if the apparatus is to be operated mechanically or by a non-skilled worker. It is preferred that the waste chamber of the apparatus comprises an outlet port to which a means for generating a vacuum can be attached. This has the result that the vacuum is able to draw the fluid from at least one of the further chambers, through the sample processing chamber and into the waste chamber. It is also preferred that the divergent analyte flow path comprises an outlet port such that a means for generating a vacuum can be readily attached here. The means for generating a vacuum can also be adapted in several ways. For example it can be adapted to draw the fluid through the apparatus in a pre-determined sequence. Optionally the apparatus can be designed to comprise a passive means for restricting the flow of fluid through the apparatus such that an increased vacuum force is required to sequentially release the fluids from each chamber, such that by increasing the vacuum during use it is possible to sequentially draw the fluids from first one chamber and then another for example by controlling the dimensions of fluid flow paths or by incorporating membranes or gates which need to be passively opened to

allow fluid flow. The use of a vacuum can also be adapted to pull air through the apparatus as an interim step between the moving of each fluid such that the fluid communication routes are cleared and the different fluids do not interact with each other prior to entering the sample processing chamber. This can be important in sample processing protocols that are very sensitive for example where the interaction of a first buffer with a second prior to entering the sample processing chamber may neutralise its effects, or where it is important that the whole of a very small volume of material reaches the sample. If a vacuum is used it is also preferred to consider that any material within the apparatus may be aerosolised by the vacuum and drawn out of the apparatus into the atmosphere. If the apparatus is adapted for use with reagents which may prove a safety hazard if released it is important to adapt the apparatus to minimise or eliminate release of the aerosolised material. One such possible adaptation is to incorporate filter membranes into the apparatus, or into the means for applying a vacuum, such that the aerosolised material is captured and not released into the atmosphere.

An example of another suitable means for moving fluid through the apparatus is a means for applying positive pressure or force behind the fluid. Again such a force can be applied by many means known to one of ordinary skill in the art. One example is the use of a plunger in one of more of the further chambers, the depression of which would expel any fluid in that a chamber through the fluid communication routes into the sample processing chamber and then into the waste chamber. Again, the use of a means for applying force behind the fluid, for example by the use of a plunger, can be adapted such that the fluids from the at least two further chambers move concomitantly or sequentially, preferably sequentially, from the further chamber

through the sample processing chamber and into the waste chamber or the divergent analyte flow path. For example it would be possible to sequentially depress one or more of a series of plungers to move fluid sequentially from a first further chamber through the sample processing chamber into the waste chamber and then from a another and so on. In both instances described it is possible that the means for moving the fluid could be provided manually by the use of syringes, plungers, pumps and the like or mechanically by integrating the apparatus of the present invention into a further apparatus able to provide the power and means as required. Again such a means for applying positive pressure can be used in conjunction with a passive means for restricting the flow of fluid through the apparatus.

It is preferred in the apparatus of the present invention to utilise a combination of both a means for generating a vacuum and a means for applying force behind the fluid to move fluid from at least one of the further chambers through the sample processing chamber and into the waste chamber. The use of the two together has the advantage that the initial force behind the fluid initiates release of the fluid from any given chamber that the vacuum could direct the fluid flow through the apparatus thus preventing it from being diverted from the desired path. This enables the apparatus to be readily designed such that fluid can flow sequentially from the further chambers through the sample processing chamber according to a pre-determined protocol.

The fluid communication routes of the present invention are provided by one or more channels that pass through the apparatus connecting the chambers in the desired manner. The apparatus is designed such that at least two further chambers are in fluid

through the sample processing chamber and into the waste chamber or the divergent analyte flow path. For example it would be possible to sequentially depress one or more of a series of plungers to move fluid sequentially from a first further chamber through the sample processing chamber into the waste chamber and then from a another and so on. In both instances described it is possible that the means for moving the fluid could be provided manually by the use of syringes, plungers, pumps and the like or mechanically by integrating the apparatus of the present invention into a further apparatus able to provide the power and means as required. Again such a means for applying positive pressure can be used in conjunction with a passive means for restricting the flow of fluid through the apparatus.

It is preferred in the apparatus of the present invention to utilise a combination of both a means for generating a vacuum and a means for applying force behind the fluid to move fluid from at least one of the further chambers through the sample processing chamber and into the waste chamber. The use of the two together has the advantage that the initial force behind the fluid initiates release of the fluid from any given chamber that the vacuum could direct the fluid flow through the apparatus thus preventing it from being diverted from the desired path. This enables the apparatus to be readily designed such that fluid can flow sequentially from the further chambers through the sample processing chamber according to a pre-determined protocol.

The fluid communication routes of the present invention are provided by one or more channels that pass through the apparatus connecting the chambers in the desired manner. The apparatus is designed such that at least two further chambers are in fluid

communication with the sample processing chamber. These chambers are optionally designed to each have an individual outflow channels which connect at a common point prior to entering the sample processing chamber. It is preferred that there is only a single entry point for solutions to pass into the sample processing chamber, ie the sample processing chamber inlet, to allow for reduced design complexity. As such it is preferred that the outflow channels from each further chamber meet and then flow into a common sample processing channel prior to entering the sample processing chamber. One or more of these fluid communications may be a continuous fluid communication.

In order to minimise the flow of fluid through the chamber in an inappropriate manner it is preferred that the apparatus comprises a passive means for restricting the flow of fluid through the apparatus which is designed to contain features which limit any particular fluid flow route until such time as that flow route is required. Failure to do this could result in fluid flowing from more than one chamber simultaneously and thus could destroy the sample processing sequence or could result in fluid flowing from the waste chamber back through the apparatus. Examples of suitable means to control such flow include use of one or more of membranes covering channels that are broken when pressure is applied behind them or in front of them, very small diameter channels through which a fluid is unable to flow due to its surface tension without the application of a force, pre-filling any chambers comprising buffer solutions using suction which then acts to hold such a fluid in place until a force is applied to release it, using valves throughout the apparatus which are operated by vacuum, pressure, magnets and the like, designing the fluid communication routes to comprise a small reservoir which needs to be filled completely in order for fluid communication to be

established which allows for small leaks to be accommodated without overflows, and the like. It is preferred that the apparatus comprise one or more of such features to ensure appropriate fluid flow. In the apparatus of the present invention it is preferred that the passive means for restricting the flow of fluid comprises a reservoir located in the fluid communication between at least one of the at least two further chambers and the sample processing chamber. It is also preferred that the passive means for restricting the flow of fluid comprises a fluid pathway of small diameter such that fluid can not flow through the pathway without the application of a positive or negative pressure, located in the fluid communication between at least one of the at least two further chambers and the sample processing chamber. It is even more preferred that the continuous fluid communication between at least one of the at least two further chambers comprises both of these features. Such examples of passive means for restricting the flow of fluid allow continuous fluid communication pathways to be established within the apparatus whilst at the same time controlling fluid flow within the apparatus. This further reduces the complexity of the apparatus.

The sample processing chamber is similarly in fluid communication with a waste chamber via a waste channel. It is also important that material in the waste chamber is not able to flow back into the sample chamber. It is therefore preferred to design the apparatus to incorporate a passive means for restricting the flow of fluid between the sample processing chamber and the waste chamber. It is preferred that this comprises a passive valve, preferably a 1-way valve, located in the fluid communication between the sample processing chamber and the waste chamber to prevent such back flow. It is preferred that the passive valve is down stream of the divergent analyte flow path. One simple solution is to utilise a small bead, for

example a glass bead, that is positioned in the opening of the waste channel at a point in the fluid path connecting it to the sample processing chamber. When the apparatus is in use and fluid is moving from the sample processing chamber to the waste chamber the movement of fluid, or the use of a vacuum, will release the bead from the opening thus allowing fluid flow. When there is no fluid flow the bead will return to sit in the opening of the waste channel thus preventing the back flow of liquid through the apparatus. It is preferred that the application of a vacuum via the waste chamber is used to operate this valve.

Another example of a passive means for restricting the flow of fluid is to control the flow of fluid by the use of gravity. It is preferred that prior to entering the sample processing chamber the fluid is directed, preferably by a vacuum, up through a pre-processing channel. The fluid then enters the sample processing chamber from above where it can fall by gravity through the chamber. Again it is preferred that when the fluid leaves the sample processing chamber via the waste channel it again passes up and enters the waste chamber from the top. This arrangement can also prevent fluid flowing backwards through the apparatus eg from the waste chamber into the sample processing chamber and from the sample processing chamber into the further chambers. Depending on the particular use in question, one of ordinary skill in the art would be able to design the apparatus to comprise any necessary fluid flow control mechanisms selected from those mentioned and others.

The waste material from the sample processing is collected in a waste chamber. It is preferred that the waste chamber is fully integrated into the apparatus of the present invention such that additional bottles are not required for collecting and then

disposing of such waste. This is especially preferred if the materials in question are either hazardous or infectious since this minimises the need for user handling. The waste chamber should have sufficient volume to be able to readily hold all of the fluids used during the sample processing. It is preferred that the waste chamber is housed within any redundant space inside the apparatus between and around the sample processing chamber and the at least two further chambers. This enables the most efficient use of space thus keeping the overall size of the apparatus to a minimum. As mentioned previously it is preferred that the waste chamber comprises an outlet which can be connected to a means for generating a vacuum such that a vacuum can be applied to the apparatus to direct fluid flow directly through the apparatus into the waste chamber.

The apparatus also comprises at least two further chambers. Depending on the use of the apparatus these further chambers may have several roles. Possible examples of such chambers may include a buffer chamber which comprises a buffer solution or water which are required in the sample processing protocol or a sample chamber into which a sample, either as a fluid or a solid, may be initially introduced into the apparatus and which may optionally comprise a first reagent with which the sample interacts, or optionally where a solid sample is initially dissolved in a solvent, or alternatively where the sample may be subjected to physical processing. The chambers can be pre-filled with the required solutions or reagents during manufacture. This has several advantages including that the user need not be concerned with accurately measuring aliquots of chemical solution from bulk, the chambers do not themselves need to be attached to a reservoir of solution and the chambers can be pre-loaded filled with an air pocket which, when the fluid is drawn through the apparatus,

can follow the fluid flow to ensure that the fluid channels are cleared prior to the use of a subsequent fluid. The chambers may optionally comprise internal partial barriers, for example a plastic spindle extending through part of the internal chamber which can be used to minimise the movement of solid reagents within the chamber if a vacuum or force is applied. Similarly the chambers may comprise a membrane to prevent early release of the contents or disruption, for example by contamination or evaporation, of the contents during prior sample processing steps. In one embodiment of the present invention it is preferred that at least one of the at least two further chambers is pre-filled with a buffer solution selected from the group consisting of an aqueous solution of potassium acetate and Tris.hydrochloride, or an aqueous ethanolic solution of potassium acetate and Tris.hydrochloride. It is also preferred that at least one of the at least two further chambers acts as a sample chamber which comprises an inlet port through which a sample can be introduced into the apparatus. Furthermore it is preferred that the sample chamber comprises a reagent, preferably a reagent comprising a lysis reagent, more preferably chaotropic salts. This may be in the form of a solid bead or freeze dried onto one or more surfaces inside the chamber.

The chambers of the apparatus, including one or more of the further chambers and or the sample processing chamber itself, can be designed if required such that the contents of the chamber can be subjected to physical steps in the processing sequence. For example the walls of the chamber may comprise heating elements which allow their contents to be warmed, they may be flexible to allow acoustic processing, they may be transparent to one or more wavelengths of light to allow optical processing, sensing or monitoring and the like. It is preferred that at least one of the chambers of the apparatus is coated with an electrically conducting polymer such as that disclosed.

in WO98/24548. If such physical processing is required the apparatus should be designed such that the chamber is positioned for easy and efficient access to the source of the physical processing. For example the chamber may be positioned towards the external face of the apparatus or may extend partially or fully outside of the main body of the apparatus such that a part of the chamber is able to interact with a source of the physical processing eg a light source or a heating source. It is preferred that at least one chamber of the apparatus is located externally to the main body of the apparatus whilst remaining in fluid communication with the sample processing chamber and it is further preferred that this chamber has walls which are coated at least partially with an electrically conducting polymer. Examples of chambers which may be preferentially be located externally to the main body of the apparatus include any chamber in which the analyte or any buffers are required to be heated.

In addition the apparatus may also be designed to comprise one or more filter membranes. As already discussed it is preferred that the sample processing comprise a trapping member. Again, as already discussed, if the apparatus comprises an outlet which is attached to a means for generating a vacuum it is preferred that a filter is incorporated either in the apparatus or in the means for generating a vacuum to prevent aerosolised material being released into the atmosphere. Furthermore the apparatus may comprise other filters for example in the communication routes to prevent solid particulate causing blockages. Another optional use of a filter could be at the inlet port of the sample chamber to filter a sample prior to entering the apparatus. Alternatively, if the apparatus comprises an inlet port through which air is drawn from the atmosphere into the apparatus it may be necessary to use a filter

membrane to ensure that any contamination from the atmosphere does not enter the apparatus and potentially contaminate the sample being processed. It is preferred that the sample chamber inlet port comprises a filter membrane which can be positioned either before or after the sample has been introduced into the sample.

The apparatus of the present invention may optionally comprise a collection chamber into which the processed sample can be directly collected. The chamber may be integrated into the apparatus or the apparatus may be designed such that the chamber can be simply and securely clipped into place when required. When in place such a chamber would be downstream of the analyte flow path and in fluid communication with the divergent analyte flow path outlet and thereby the sample processing chamber. The apparatus could be operated such that the sample could be directed into this chamber using a means for moving fluid within the apparatus. For example the apparatus would also be provided with a means for moving the processed sample from the sample processing chamber into the collection chamber. It would therefore be possible to direct fluid from the sample processing chamber into the collection chamber by disconnecting the means for moving fluid into the waste chamber and connecting the means for moving fluid into the collection chamber. It is preferred that such a means comprise a means for generating a vacuum connected to the collection chamber via a second outlet, in this instance where the path of the vacuum flows from the sample processing chamber through the collection chamber thus diverting any fluid from the waste chamber but instead into the collection chamber. As mentioned previously, if a vacuum is used it may be advantageous to fit a filter membrane into the apparatus upstream of the vacuum to prevent aerosolised material from the sample entering the atmosphere. As with other chambers the collection chamber can be

designed such that it can be subjected to physical processing, sensing or monitoring and may extend either in whole or part outside of the main body of the apparatus in order to facilitate the interaction of the collection chamber with a source of the physical processing. It is highly preferred that the collection chamber is adapted for use in a nucleic acid amplification. It is therefore preferred that the collection chamber is external to the main body of the apparatus, comprises walls which are at least partially coated with an electrically conducting polymer to facilitate thermal cycling of the sample and also comprises a transparent section through which the nucleic acid amplification reaction can be optically monitored, preferably by fluorescence. Alternatively the collection chamber may be detachable such that, once the processed sample is collected, it can be removed for use elsewhere. One of the main advantages of an integrated, if detachable, collection chamber, is that the processed sample can be collected without the need for any intervention or additional apparatus. Again this simplifies the apparatus for the user, minimises cross sample contamination and minimises user exposure to the sample. However if the collection chamber is to be pre-dosed with reagents which degrade it may be useful to store the collection chamber separately and attach it to the apparatus when required. Examples of such reagents include those known by one skilled in the art to be required for a nucleic acid amplification reaction and detection system for example nucleic acid primers, nucleic acid probes, fluorescing dyes, enzyme buffers, nucleotides, magnesium salts, bovine serum albumin, denaturants, and the like.

In some circumstances it may be necessary that, once the main sample processing protocol is complete, that the sample further interacts with yet another reagent prior to being collected in the collection chamber. This final step could be provided by

optionally including in the apparatus a further chamber, a post processing chamber between the sample processing chamber and the collection chamber. After the processed sample has been eluted from the sample processing, it enters the post processing chamber and interacts with a reagent such as that required for a reverse transcriptase step in reverse transcriptase polymerase chain reaction nucleic acid amplification. Optionally the apparatus could be provided with a post processing chamber downstream from the collection chamber containing the final reagent in question. It is then possible to apply a vacuum to draw the processed sample from the sample processing chamber through the collection chamber and into the post processing chamber, allowing the processed sample to further interact with any reagent therein and then disconnecting the vacuum and reapplying the vacuum through the waste chamber to draw the fully processed sample back into the collection chamber. As with the other chambers it is preferred that the apparatus is pre-dosed with any such reagents to minimise the need for the user to have to handle these materials. When the apparatus is used for preparing a sample for nucleic acid amplification preferably the reagent comprises one or more reagents selected from the group consisting of nucleic acid primers, nucleic acid probes, fluorescing dyes, enzyme buffers, nucleotides, magnesium salts, bovine serum albumin, denaturants, and the like.

The apparatus itself can have a wide variety of different designs, shapes, sizes and can be made of many different materials depending on the specific use. In order to minimise the cost of the apparatus and to ensure that it is economically feasible to produce for a single use it is preferred that the apparatus is manufactured from a cheap material such as a thermoplastic material for example polyethylene or polypropylene,

polycarbonate, acrylic, nylon or butadiene-styrene copolymer or mixtures thereof. It is preferred that the apparatus is manufactured from as few components as possible. As such it is preferred that the main bulk of the apparatus is manufactured as a single injection moulded unit containing the chambers and key channels. It is preferred that the intricate channels are formed by the ultrasonic sealing of the base of the injection moulded unit to a plate containing the channel routes. Any plungers are added later, as can be a lid, to prevent the leaking of any materials and the escape of contaminated waste after use. It is further preferred that the apparatus is manufactured from a material which can be incinerated such that after use the apparatus, including any waste, can be easily disposed of without the build up of waste or any risk of exposure of the user to the chemicals involved. The apparatus can be transparent or translucent. Advantageously any plungers can also be colour coded to help direct the unskilled user as to the correct use of the apparatus.

The apparatus may also be optionally designed such that it can integrate with further additional apparatus for example a sample bottle such that the fluid sample, once collected from the patient or environment, can be introduced into the fluid processing apparatus without any spillage, or a sample collection cone such that the sample can be collected directly into the fluid processing apparatus. The two apparatus could integrate via the use of a seal for example a quick fit seal, a screw seal or other means. If the apparatus of the present invention is moulded from plastic then such sealing devices can be integrated easily into the shape. This integration further simplifies the use of the apparatus in a non-laboratory environment for staff with little or no scientific training and again minimises user interaction with the sample itself.

Additionally the apparatus may integrate with a mechanical apparatus. This could be for several reasons including for applying the means for moving the fluid using a physical apparatus, such as the vacuum or plunger depression, or for subjecting one or more of the chambers of the apparatus to a physical processing step for example thermal, optical or acoustical processing, sensing or monitoring. If such integration is required it is important to ensure that the apparatus is designed such that it can integrate effectively with such an additional physical apparatus. It is also important to ensure that such an integration is as simple as possible such that it can effectively be used by a non-skilled worker. This may include designing the apparatus such that it can only be integrated in a single orientation, using colour coding to aid the orientation and the like.

This invention also relates to a method of processing a fluid sample comprising:

- (i) placing the sample in the sample processing chamber of an apparatus according to the present invention;
- (ii) applying a positive or negative pressure to move fluid through the apparatus;
- (iii) subjecting the sample to one or more processing steps; and
- (iv) collecting the processed sample from the divergent analyte flow path.

The processing steps can be chemical steps or physical steps.

According to a third aspect this invention relates to the use of an apparatus according to the present invention for purification and concentration of nucleic acid material

from a fluid sample. Such a sample should preferably be prepared such that it can then undergo a nucleic acid amplification, for example polymerase chain reaction amplification.

Figures

This invention will now be described by reference to a specific embodiment of the apparatus of the present invention shown in the following figures in which;

Figure 1 shows a perspective view of the apparatus from the side;

Figure 2 shows a perspective view of the apparatus from the base;

Figure 3 shows a perspective view of the apparatus from the top, with the top plate removed such that the internal chambers can be seen;

Figure 4 shows an internal view of the base plate of the apparatus;

Figure 5 is a cross sectional view of the apparatus along A-A showing the first step of use of the apparatus for processing a fluid sample for PCR;

Figure 6 is a cross sectional view of the apparatus along B-B showing the second step of use of the apparatus for processing a fluid sample for PCR;

Figure 7 is a cross sectional view of the apparatus along C-C showing the third step of use of the apparatus for processing a fluid sample for PCR;

Figure 8 is a cross sectional view of the apparatus along D-D showing the fourth step of use of the apparatus for processing a fluid sample for PCR; and

Figure 9 is a cross sectional view of the apparatus along E-E showing the fifth step of use of the apparatus for processing a fluid sample for PCR.

Figure 1 shows an apparatus of the present invention 2 comprising a sample chamber 4, a first buffer chamber 6 with a first plunger 8; a second buffer chamber 10 with a

second plunger 12. The first plunger 8 and the second plunger 12 comprise sockets 34 that allow them to integrate with an external apparatus to move the plungers during use. The apparatus 2 additionally comprises a small volume water chamber 14 that extends beyond the main body of the apparatus 2. This comprises a membrane seal enclosing the chamber such that the water within the chamber does not evaporate during storage or the initial stages of sample processing. The membrane is a thin plastic sheet for example 0.1mm-0.2mm, skin of acrylonitrile butadiene styrene. The apparatus also comprises a first outlet port 16 and a second outlet port 18 by which one or more vacuums can be attached to the apparatus 2. The sample chamber 4 comprises a lid 20 which is attached to the main body of the apparatus 2 via an arm 22 which is able to pivot around a peg 24. After the introduction of the sample (not shown) into the sample chamber 4 the lid 20 is pivoted around the peg 24 into position to seal the sample chamber 4. The lid 20 also comprises an inlet outlet port 26 through which air can be drawn into the apparatus 2 via a pump (not shown). The apparatus 2 also comprises a channel 28 that extends from the bottom to the top of the apparatus 2 and which is external to the main body of the apparatus 2. This channel 28 forms part of the fluid communication network of the apparatus. The base plate 30 of the apparatus 2 and the top plate 32 of the apparatus 2 are manufactured as separate units and are fitted to the apparatus 2 during the final stages of manufacture.

Referring to Figure 2, the apparatus 2 comprises a top plate 32, a base plate 30, and an exterior channel 28. The view shows that the apparatus has three reservoirs 50, 52 and 54 that are also exterior to the main body of the apparatus 2. The reservoir 50 is below the sample chamber, the reservoir 52 is below the first buffer chamber and the reservoir 54 is below the second buffer chamber. These reservoirs (50, 52 & 54) are

used as part of the mechanism to prevent sample or buffer from each of these chambers flowing through the fluid communication network of the apparatus in an inappropriate manner. The base plate 30 of the apparatus 2 also comprises a collection chamber 56 that is also exterior to the main body of the apparatus 2. Once the fluid sample (not shown) has been fully purified it enters the divergent analyte flow path and then the collection chamber 56 where it is able to undergo the PCR amplification reaction. It is preferred that the collection chamber 56 is coated with an electrically conducting polymer (not shown) and that it comprises two transparent faces 58 through which a nucleic acid amplification reaction can be monitored.

Referring to Figure 3, the apparatus 2 comprises a sample chamber 4, a first buffer chamber 6 and a second buffer chamber 10. The apparatus 2 comprises a waste chamber 100 that is the dead space within the main body of the apparatus surrounding the other internal chambers. The apparatus comprises a sample processing chamber 102. This is in fluid communication with the sample chamber 4 and the buffer chambers 6, 10 via a pre-processing channel 104. The sample processing chamber 102 is in fluid communication with the waste chamber 100 via a waste channel 28 which links with the waste chamber 100 via the waste port 106. The apparatus also comprises a post processing chamber 108 which is linked to the second vacuum outlet port (18, not shown in this perspective) and also to the sample processing chamber 102 (communication not shown).

Referring to Figure 4, the base plate 30 comprises the sample reservoir 50, a first buffer reservoir 52 and a second buffer reservoir 54. It also comprises a sample channel 152, a first buffer channel 154 and a second buffer channel 156, which

provides the fluid communication from the sample chamber, the first buffer chamber, and the second buffer chamber (not shown) respectively to the sample processing chamber (not shown) via the pre-processing channel the base of which is shown at 158. The base of the sample processing chamber 160 is in fluid communication with the base of the waste chamber 162. The base of the sample processing chamber 160 is also in fluid communication with the base of the post processing chamber 164 via the divergent analyte flow path and the collection chamber (not shown).

Referring to Figure 5, the sample 200 is introduced into the apparatus 2 via the sample chamber 4. Once inside the sample chamber the sample chamber lid 20 is closed. This lid comprises a filter 202 that prevents contamination from the air entering the apparatus and also prevents aerosolised sample leaving the apparatus. In the sample chamber the apparatus interacts with a first reagent bead 204, which comprises lysis reagent containing chaotropic salts, for example guanidium hydrochloride, to lyse any bacteria within the sample. The first reagent may optionally comprise a nucleic acid target that is later able to act as a means for normalising the efficiency of the subsequent PCR amplification reaction. After the sample has interacted with the first reagent a vacuum is applied to the apparatus via the first vacuum outlet port (vacuum shown in this cross section, but first vacuum outlet port 16 is not shown). This vacuum draws the sample firstly into the sample chamber reservoir 50, along the sample channel 152 to the base of the pre-processing channel 158. The sample is then drawn up the pre-processing channel 104 and into the sample processing chamber 102. The sample processing chamber 102 comprises a filter means 206, for example a glass fibre filter, that is capable of isolating from the sample any nucleic acid as the sample passes through. The vacuum then draws the sample out of the filter to the

base of the sample processing chamber 160, to the base of the waste channel 162 and then up into the waste channel 28. At the top of the waste channel the sample, from which all of the nucleic acid has been removed, enters into the waste chamber 100 through the waste channel outlet 106. This figure does not show the waste material in the waste chamber. The waste channel comprises a small bead 208 that is positioned in the base of the waste channel 162. When the vacuum is applied the bead 208 rises within the waste channel 28 allowing the passage of fluid through the channel 28 into the waste chamber 100. When the vacuum is removed the bead 208 falls and covers the base of the waste channel 162 thus sealing the entrance. This prevents waste fluid from flowing back into the sample processing chamber 102. This view of the apparatus also shows the water chamber 14, the first buffer chamber 6 and plunger 8 and the post processing chamber 108, and the post processing chamber outlet port 18, but the fluid communication between these chambers are not shown in this view.

Referring to Figure 6, the first buffer chamber 6 of the apparatus 2 comprises the first buffer 252, for example an aqueous potassium acetate / Tris.hydrochloride solution such as that available in Promega Wizard™ kit. A vacuum is applied to the apparatus via the waste chamber outlet port (not shown but as in Figure 5). Simultaneously the plunger 8 is depressed within the first buffer chamber 6 which initiates the flow of the first buffer 252 through the reservoir 52 and into the sample processing chamber 102 via the first buffer channel 154 and the pre-processing channel 104 which are linked at the base of the pre-processing channel 158. The first buffer channel 154 is designed to have a very narrow diameter at the point it leaves the first buffer reservoir 52. This ensures that, due to the surface tension of the first buffer, it is unable to leak into the first buffer channel 154 until depression of the plunger 8. Once in the sample

processing chamber 102, as with the sample, the buffer flows through the filter means 206 thus washing the nucleic acid material on the filter membrane. The first buffer 252 is then drawn by the vacuum (not shown) via the waste channel 28, and the waste channel outlet port 106, into the waste chamber 100 (waste material in the waste channel is not shown).

Referring to Figure 7, the second buffer chamber 10 comprises the second buffer 302, for example an aqueous ethanolic solution of potassium acetate / Tris.hydrochloride such as that available in Promega WizardTM kit. A vacuum is applied to the apparatus via the waste chamber outlet port (not shown but as in Figure 5). Simultaneously the plunger 12 is depressed within the second buffer chamber 10 which initiates the flow of the second buffer 302 through the reservoir 54 and into the sample processing chamber 102 via the second buffer channel 156 and the pre-processing channel 104 which are linked at the base of the pre-processing channel 158. As before the second buffer channel 156 is designed to have a very narrow diameter at the point it leaves the second buffer reservoir 54. This ensures that the second buffer 302 does not leak. Again, once in the sample processing chamber 102, the buffer flows through the filter means 206 again washing the nucleic acid material on the filter membrane. The second buffer 302 is then drawn by the vacuum (not shown) via the waste channel 28, and the waste channel outlet port 106, into the waste chamber 100 (waste material in the waste chamber is not shown).

Referring to Figure 8, the apparatus is configured to air dry the filter membrane comprising the purified nucleic acids to remove any excess solvent from the filter. In order to do this a vacuum is applied to the apparatus 2 via the first vacuum outlet port

16 (not shown). This draws air into the apparatus through the inlet port 26 in the sample chamber lid 20. This air passes through a filter 202 to remove material in the air thus preventing sample contamination. It is then drawn by the vacuum through the sample chamber 4, the sample chamber reservoir 50, the sample chamber channel 152, the pre-processing channel 104, the sample processing chamber 102, the filter means 206, the waste channel 28 and out of the apparatus through the waste chamber 100. The means for applying a vacuum to the apparatus 2 via the outlet port 16 is then removed.

Referring to Figure 9, the small volume chamber 14 comprises purified water, preferably approximately 100µl. This is warmed using an external means for heating (not shown) until the temperature of the water is preferably greater than 80°C. A second vacuum is then applied to the apparatus via the second vacuum outlet port 18. A plunger 305 is depressed releasing the warmed water from the water chamber 14 into the sample processing chamber 102. A cone 315 is used to direct the small volume of water directly to the filter means 206. The water is drawn through the filter means 206, eluting the purified nucleic acid material as it passes through, into the collection chamber 56 by the second vacuum. The second vacuum further draws the water through the divergent analyte flow path, the collection chamber 56 and into the post processing chamber 108. The post processing chamber 108 contains a second solid reagent 310 comprising further PCR reagents for example probes, fluorescing dyes and further nucleic acid controls. This reagent 310 dissolves in the solution. Removing the second vacuum then allows the solution to fall by gravity into the collection chamber 56. Alternatively the first vacuum can be reapplied to draw the solution back into the collection chamber 56.

Once in the collection chamber the nucleic acids are ready to be subjected to the heat cycling required to conduct the PCR amplification. The collection chamber is preferably designed such that its walls are made of a heat conducting polymer. The collection chamber can then either be subjected to the heat cycling in situ or removed and placed in a further apparatus for cycling.

This embodiment of the apparatus has been developed to purify the nucleic acid material from a 10ml fluid sample. The main body of the apparatus has a height of from about 70 to about 80mm and has a diameter of from about 70 to about 80mm. The sample chamber has a volume of about 20ml and the first and second buffer chamber have a volume of about 30ml. The small volume water chamber has a volume of about 500 μ l and the sample processing chamber has a volume of about 2ml and has a diameter of about 5mm. The pre-processing channel and the waste channel each have a diameter of about 3mm. The waste chamber which is formed by the dead space within the main body has a volume of about 120ml. The fluid communication channels are formed by ultrasonically welding a shaped base plate to the underside of the chamber. The channels have a diameter of about 1mm. At the point where the channels leave the sample reservoirs this diameter is reduced to approximately 0.6mm to prevent unwanted fluid flow from the chambers into the sample processing chamber.

CLAIMS

1. An apparatus for processing a fluid sample comprising:
 - (i) a sample processing chamber comprising a fluid inlet and a fluid outlet;
 - (ii) a waste chamber downstream from the sample processing chamber and in fluid communication with the sample processing chamber fluid outlet and wherein the fluid communication between the sample processing chamber outlet and the waste chamber comprises a divergent analyte flow path;
 - (iii) at least two further chambers up stream from the sample processing chamber both of which are in fluid communication with the sample processing chamber fluid inlet;
 - (iv) a means for moving fluid from each of the at least two further chambers through the sample processing chamber and into the waste chamber or into the divergent analyte flow path as desired by applying positive or negative pressure to the desired flow path; and
 - (v) a passive means for restricting the flow of fluid.
2. An apparatus according to Claim 1 wherein the means for moving fluid from at least one of the at least two further chambers through the sample processing chamber comprises a means for generating a vacuum.

3. An apparatus according to Claim 2 wherein the waste chamber comprises an outlet port which is connected to the means for generating a vacuum.
4. An apparatus according to Claim 2 wherein the analyte flow path comprises an outlet port which is connected to the means for generating a vacuum.
5. An apparatus according to Claim 1 wherein the means for moving fluid from at least one of the at least two further chambers through the sample processing chamber comprises a plunger capable of being depressed to expel fluid from the at least one further chamber.
6. An apparatus according to Claim 5 wherein the means for moving fluid from at least one of the two further chambers through the sample processing chamber additionally comprises a means for generating a vacuum.
7. An apparatus according to any of Claims 1 to 6 wherein the means for moving fluid from each of the two further chambers through the sample processing chamber moves the fluid sequentially from the first at least two further chambers through the sample processing chamber and into the waste chamber and then from the second at least two further chambers through the sample processing chamber and into either the waste chamber or the divergent analyte flow path.

8. An apparatus according to any of Claims 1 to 7 wherein the passive means for restricting the flow of fluid comprises a valve located in the fluid communication between the sample processing chamber and the waste chamber.
9. An apparatus according to Claim 8 wherein the valve is down stream of the divergent analyte flow path.
10. An apparatus according to Claim 8 wherein the valve comprises a bead which is opened by applying a positive or negative pressure.
11. An apparatus according to any of Claims 1 to 10 wherein the passive means for restricting the flow of fluid comprises a reservoir located in the fluid communication between at least one of the at least two further chambers and the sample processing chamber.
12. An apparatus according to any of Claims 1 to 11 wherein the passive means for restricting the flow of fluid comprises a fluid pathway of small diameter such that fluid can not flow through the pathway without the application of a positive or negative pressure, located in the fluid communication between at least one of the at least two further chambers and the sample processing chamber.

13. An apparatus according to any of Claims 1 to 12 comprising a collection chamber downstream of the analyte flow path and in fluid communication with the analyte flow path outlet.
14. An apparatus according to Claim 13 wherein the collection chamber comprises a reagent, preferably a reagent comprising one or more nucleic acid amplification reagents, more preferably a reagent selected from the group consisting of nucleic acid primers, nucleic acid probes, fluorescing dyes, enzyme buffers, nucleotides, magnesium salts, bovine serum albumin, and denaturants.
15. An apparatus according to Claim 13 wherein collection chamber comprises an outlet port which optionally may be connected to a means for generating a vacuum.
16. An apparatus according to Claim 15 wherein the apparatus comprises a post processing chamber down stream from the collection chamber in fluid communication with the collection chamber outlet and which optionally itself comprises an outlet which may be connected to a means for generating a vacuum.
17. An apparatus according to any of Claims 1 to 16 wherein the sample processing chamber comprises an active member, preferably a trapping member selected from the group consisting of a microfluidic chip, a solid phase material, a filter, a filter stack, an affinity matrix, a magnetic separation matrix, a size exclusion column, a capillary tube, and mixtures thereof.

18. An apparatus according to Claim 17 wherein the sample processing chamber comprises a glass fibre filter membrane.
19. An apparatus according to any of Claims 1 to 18 wherein at least one of the at least two further chambers is pre-filled with a buffer solution, preferably a buffer solution selected from the group consisting of an aqueous solution of potassium acetate and Tris.hydrochloride, or an aqueous ethanolic solution of potassium acetate and Tris.hydrochloride.
20. An apparatus according to any of Claims 1 to 19 wherein at least one of the at least two further chambers acts as a sample chamber comprising an inlet port through which a sample is introduced into the apparatus.
21. An apparatus according to Claim 20 wherein the sample chamber inlet port comprises a filter membrane.
22. An apparatus according to any of Claims 20 to 21 wherein the sample chamber comprises a reagent, preferably a reagent comprising a lysis reagent, more preferably a chaotrophic salt.
23. An apparatus according to any of Claims 1 to 22 wherein the apparatus comprises at least one chamber located externally to the main body of the apparatus.

24. An apparatus according to Claim 23 wherein the chamber located externally to the main body of the apparatus is the collection chamber.
25. An apparatus according to Claim 23 wherein the chamber located externally to the main body of the apparatus is at least one of the at least two further chambers.
26. An apparatus according to Claim 23 wherein at least one chamber located externally has walls which are coated with an electrically conducting polymer.
27. A method of processing a fluid sample comprising:
- (i) placing the sample in the sample processing chamber of an apparatus according to Claim 1;
 - (ii) applying a positive or negative pressure to move fluid through the apparatus;
 - (iii) subjecting the sample to one or more processing steps; and
 - (iv) collecting the processed sample from the divergent analyte flow path .
28. Use of an apparatus according to Claim 1 for purification and concentration of nucleic acid material from a fluid sample.

29. Use according to Claim 28 wherein the nucleic acid material is then subjected to a polymerase chain reaction amplification.

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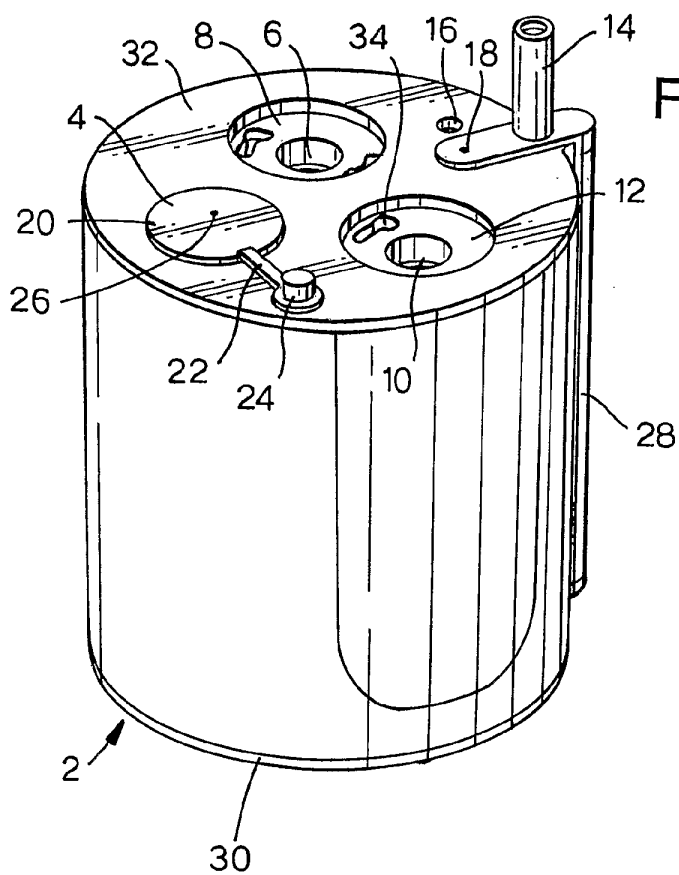
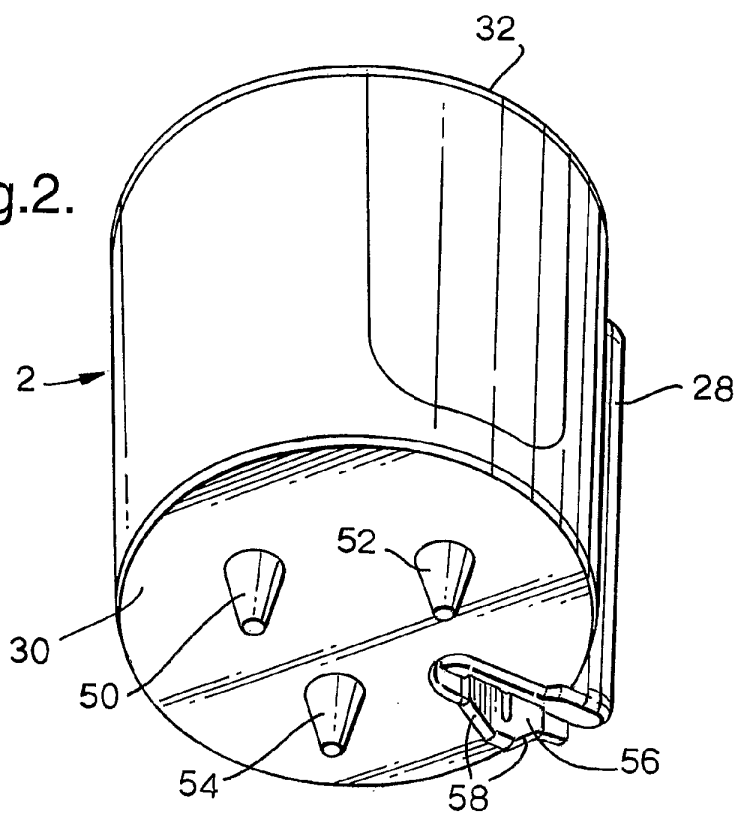


Fig.1.

Fig.2.



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Fig.3.

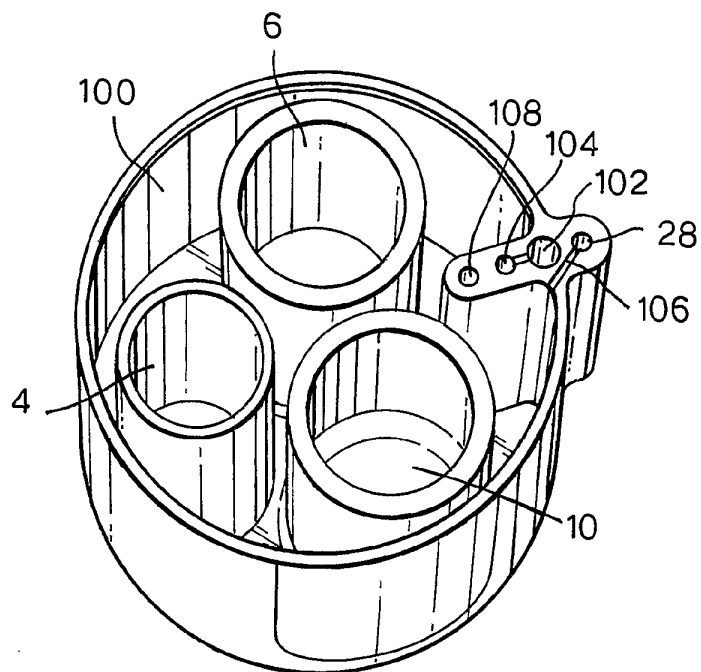
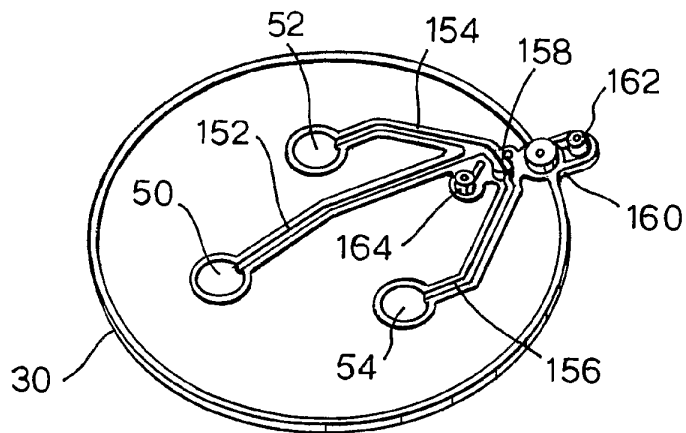


Fig.4.



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Fig.5 A.

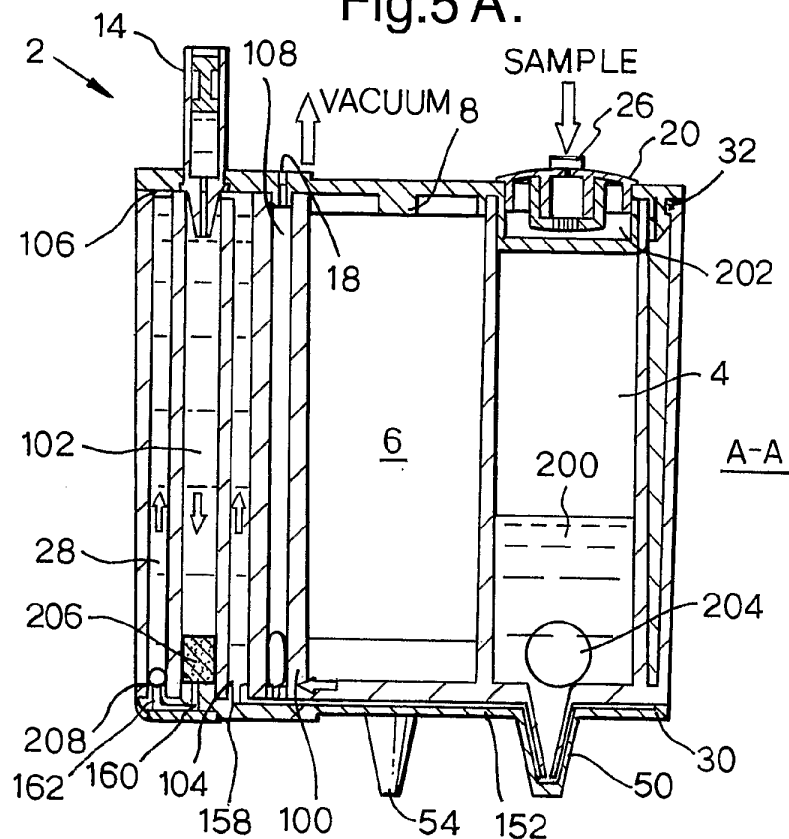
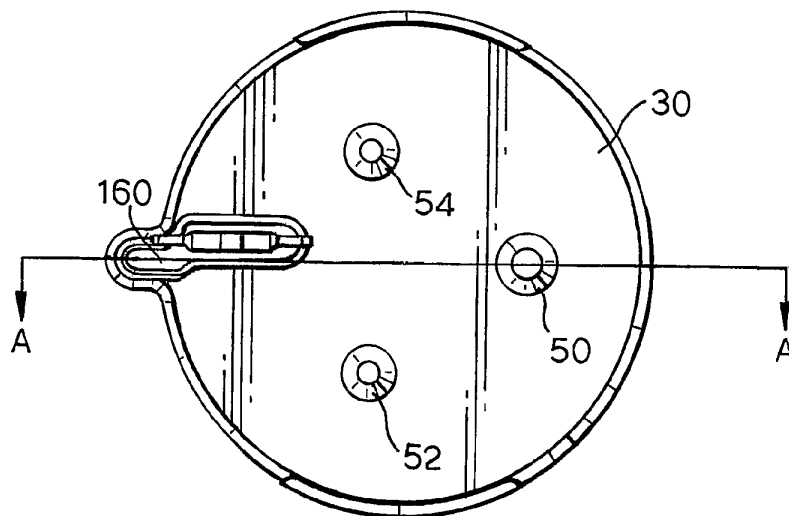


Fig.5 B.



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Fig.6 A.

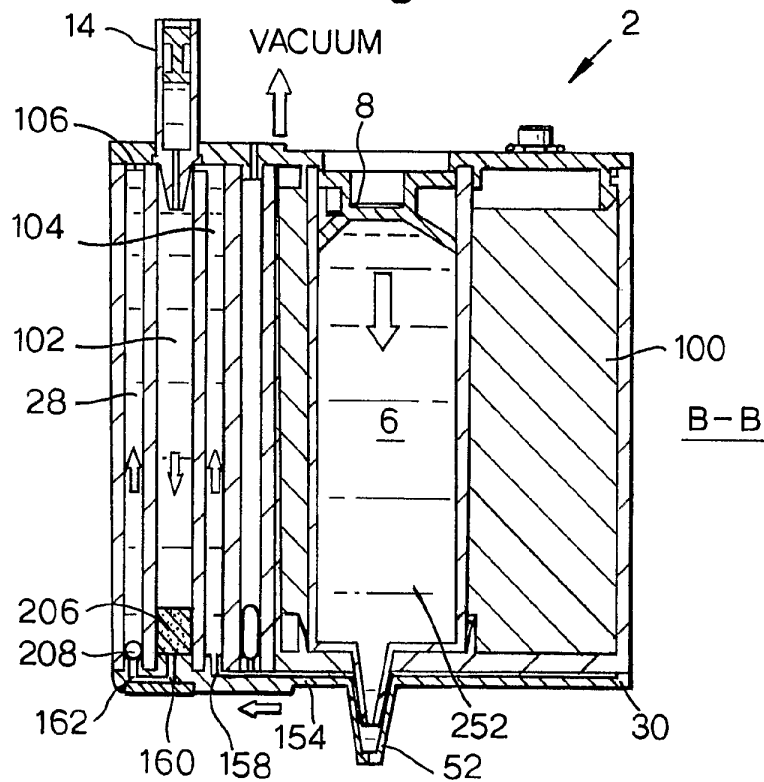
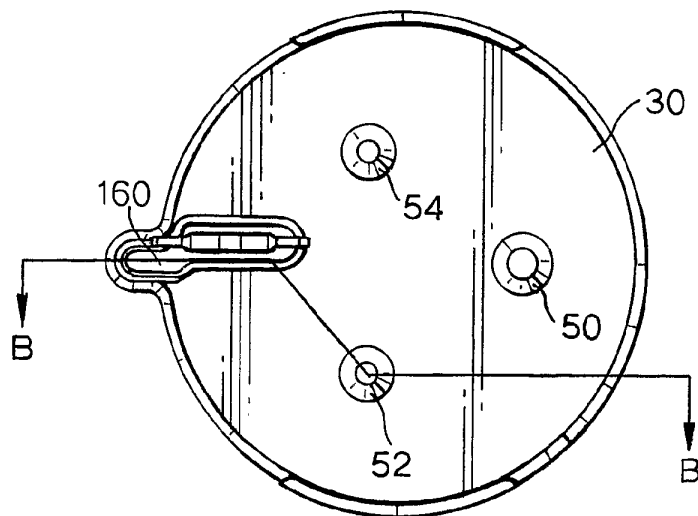


Fig.6 B.



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Fig.7A.

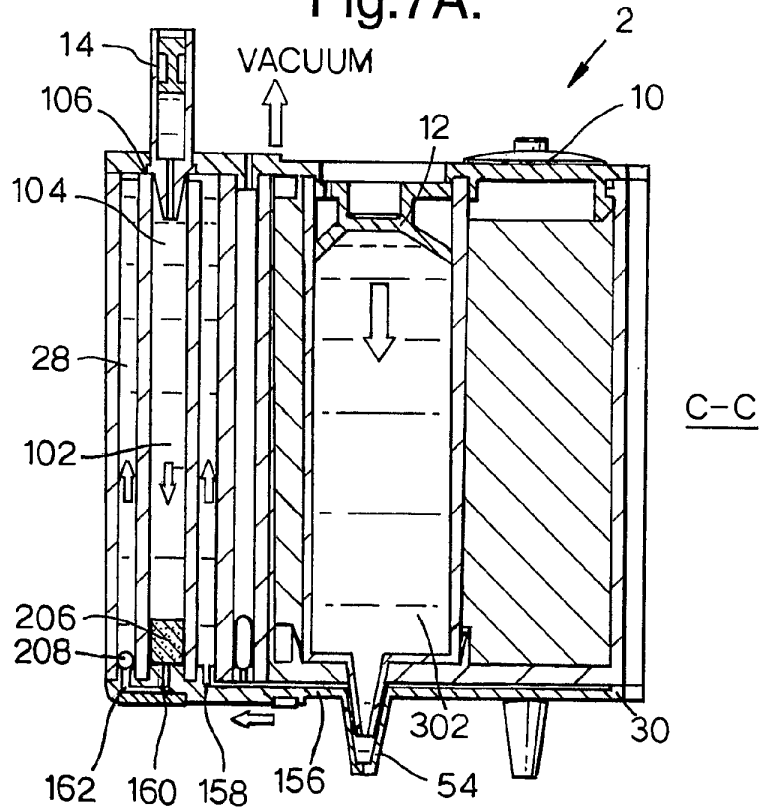
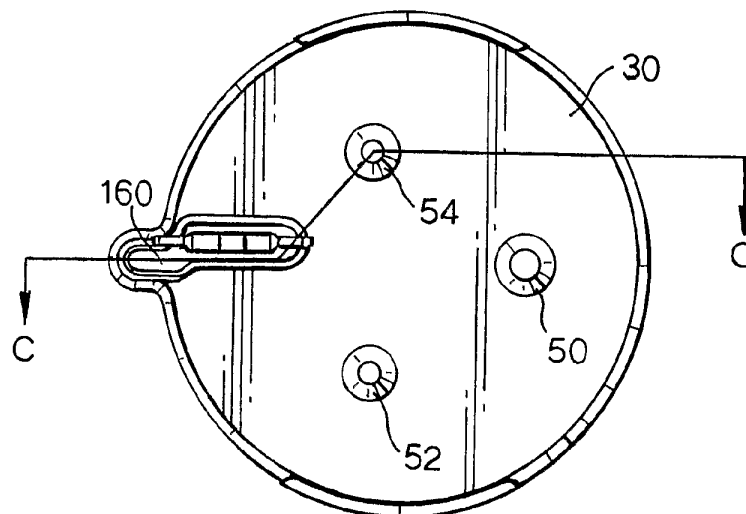
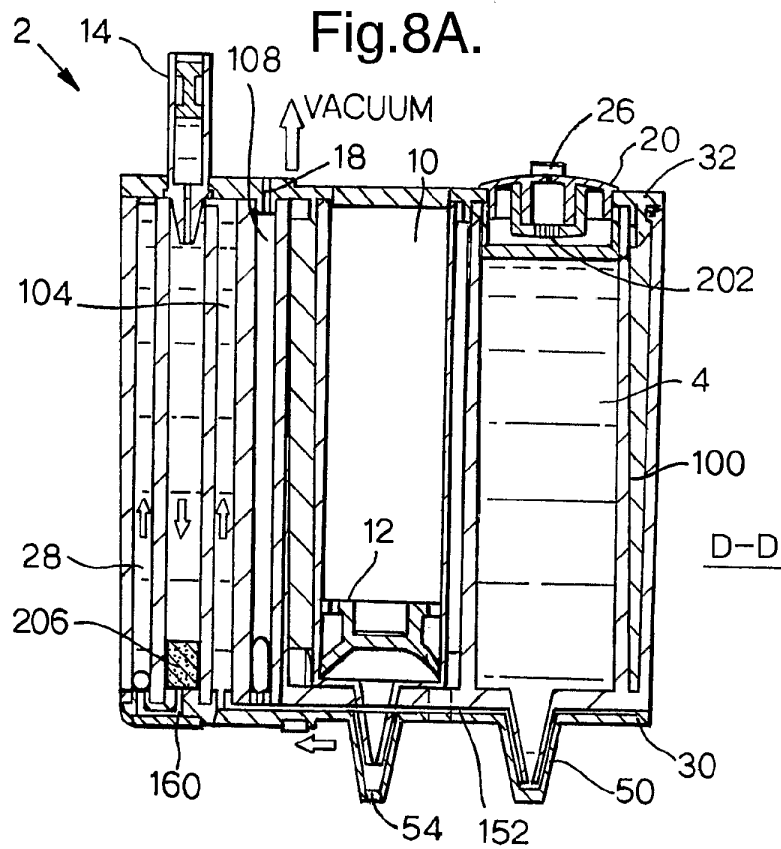
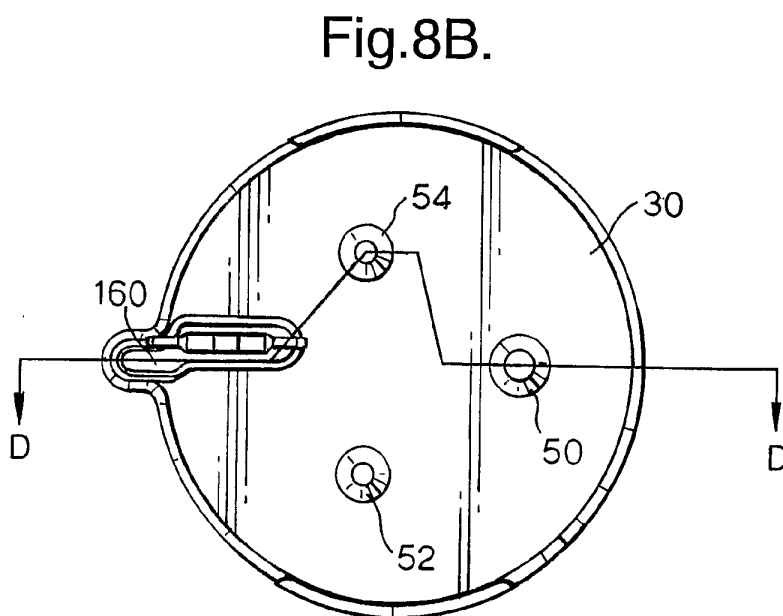


Fig.7B.



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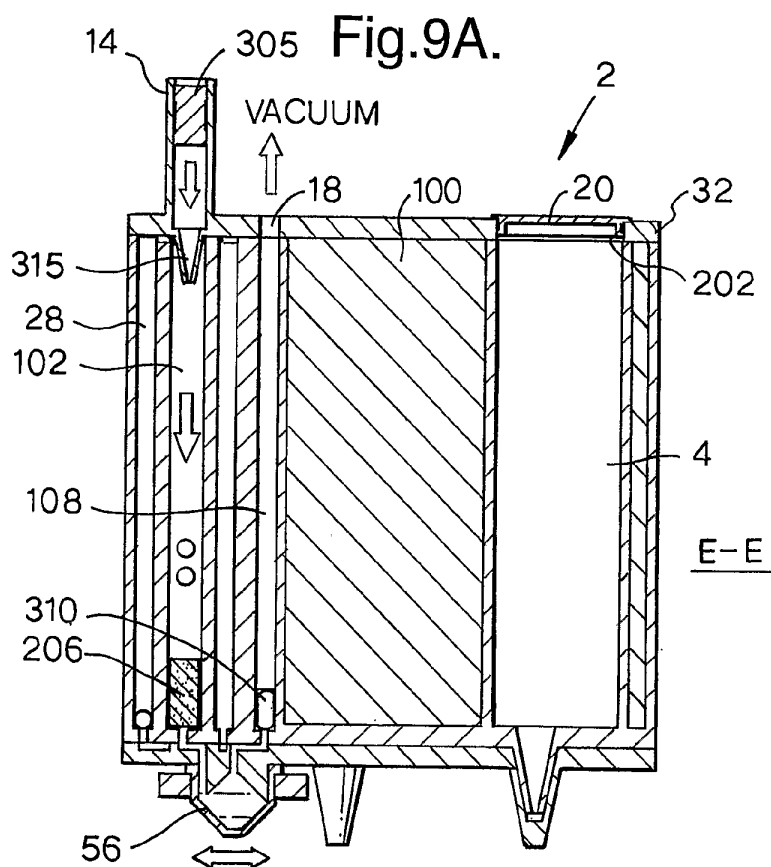
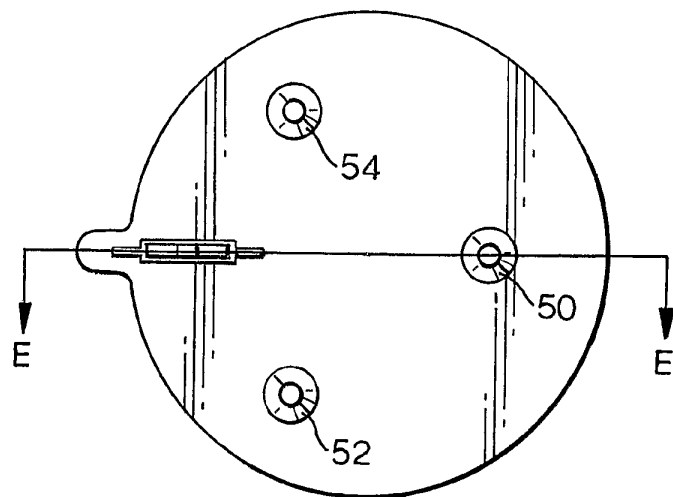


Fig.9B.



INTERNATIONAL SEARCH REPORT

In International Application No

PCT/GB 03/05173

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 B01L3/00 C12Q1/68 G01N1/40

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 B01L C12Q G01N C12M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	EP 0 381 501 A (EASTMAN KODAK CO) 8 August 1990 (1990-08-08) column 2, line 20 -column 4, line 3; figures 1-9 column 11, line 37 -column 13, line 4 column 17, line 50 -column 20, line 36 --- -/-	1,2,5,6, 11-14, 16,17, 19,20, 22,27-29



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

13 April 2004

Date of mailing of the international search report

20/04/2004

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

Int ional Application No

PCT/GB 03/05173

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INTERNATIONAL SEARCH REPORT

In International Application No

PCT/GB 03/05173

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 09/08/2023
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER

ABOUELELA, MAY A

ART UNIT PAPER NUMBER

3791

DATE MAILED: 09/08/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	12/08/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 09/08/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

18/113,710 02/24/2023 Bobby E. ROGERS 069366-0574153_KUR2C04US 2715

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	12/08/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-577000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via Patent Center or EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715
27500	7590	09/08/2023	EXAMINER	
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)			ABOUELELA, MAY A	
ATTENTION: DOCKETING DEPARTMENT			ART UNIT	
P.O BOX 10500			PAPER NUMBER	
McLean, VA 22102			3791	

DATE MAILED: 09/08/2023

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b) (2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 18/113,710	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 08/29/2023.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 17-31. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892) 2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____. 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material ____. 4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.	5. ☐ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☒ Other <u>A.NE.</u>
---	---

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	
--	--

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 05/10/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Allowable Subject Matter

3. Claims 17-31 are allowed.
4. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Christensen et al (2010/0057004) teaches a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable.

The prior art does not teach, disclose and/or fairly suggest a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

<i>Notice of References Cited</i>	Application/Control No. 18/113,710		Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA		Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20160073937-A1	03-2016	Burkholz; Jonathan Karl	A61B5/150251	604/524
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18113710
	Filing Date	2023-02-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	5200325		1993-04-06	BLATT JOEL M	
	2	5432084		1995-07-11	BRUBAKER DANIEL B	
	3	5972294		1999-10-26	SMITH JOHN L	
	4	6187347		2001-02-13	PATTERSON JAMES A	
	5	6599474		2003-07-29	EVTDIENKO VLADIMIR	
	6	8197420		2012-06-12	PATTON RICHARD G	
	7	8535241		2013-09-17	BULLINGTON GREGORY	
	8	9060724		2015-06-23	BULLINGTON GREGORY J	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	18113710
Filing Date	2023-02-24
First Named Inventor	Bobby E. ROGERS
Art Unit	-
Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

9	9155495		2015-10-13	BULLINGTON GREGORY J	
10	4412548		1983-11-01	HOCH LOUIS	
11	5222502		1993-06-29	KUROSE KATSUTOSHI	
12	5520193		1996-05-28	SUZUKI ISSEI	
13	9022951		2015-05-05	BULLINGTON GREGORY	
14	6569117		2003-05-27	ZIV DAVID	
15	3741197		1973-06-26	SANZ M	
16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
18	9877675		2018-01-30	BAID RISHI	
19	4444203		1984-04-24	ENGELMAN ALLAN	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	18113710
Filing Date	2023-02-24
First Named Inventor	Bobby E. ROGERS
Art Unit	-
Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

20	6398743		2002-06-04	HALSETH THOR R	
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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	18113710
Filing Date	2023-02-24
First Named Inventor	Bobby E. ROGERS
Art Unit	-
Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

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Art Unit	-
Examiner Name	
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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	08/31/2023
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Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Date
09.12.20

Reference EPA-150 670	Application No./Patent No. 20197213.0 - 1132
Applicant/Proprietor Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the European search report (R. 61 EPC) or the partial European search report/ declaration of no search (R. 63 EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

The following have been approved:

☐ Abstract

☐ Title

☒ The Abstract was modified and the definitive text is attached to this communication.

The following figure(s) will be published together with the abstract: 30B

Refund of search fee

If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued once the date of publication of the European search report has been mentioned in the European Patent Bulletin (R. 69(1), R. 70(2) EPC).





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Application No.:

20 197 213.0

The application and the invention to which it relates seem to meet the requirements of the EPC. Upon presence of a valid request for examination and consideration by the examining division, a communication under Rule 71(3) EPC may be issued.



EUROPEAN SEARCH REPORT

Application Number
EP 20 19 7213

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	US 2014/039348 A1 (BULLINGTON GREGORY J [US] ET AL) 6 February 2014 (2014-02-06) * the whole document *	1-7	INV. A61B5/15 A61B5/153 A61B5/154 A61B5/157
A	US 2014/107564 A1 (BULLINGTON GREGORY J [US] ET AL) 17 April 2014 (2014-04-17) * the whole document *	1-7	
A	US 4 813 433 A (DOWNEY JOHN M [US]) 21 March 1989 (1989-03-21) * the whole document *	1-7	
A	US 2013/317391 A1 (BULLINGTON GREGORY J [US] ET AL) 28 November 2013 (2013-11-28) * abstract * * paragraph [0048] - paragraph [0075]; figures 2-12 *	1-7	
A	WO 2013/181352 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]; BULLINGTON GREGORY J [US]; PAT) 5 December 2013 (2013-12-05) * abstract * * paragraph [1090]; figures 11,12 *	1-7	TECHNICAL FIELDS SEARCHED (IPC) A61B
The present search report has been drawn up for all claims			
Place of search Berlin		Date of completion of the search 19 November 2020	Examiner Nielsen, Michael
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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EPO FORM 1503 03.02 (P04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 20 19 7213

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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19-11-2020

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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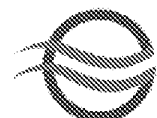
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82





אלברט אקראמן
 ברוך פטנטים בבית
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 רמת השרון : משרד המשפטים

ר. א.

בכבוד

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המשרד מודיע כי הבקשה נמצאת בשלבי הבחינה.

<https://israelipatents.justice.gov.il/#/en/patent-extract/300848>

המשרד מודיע כי הבקשה נמצאת בשלבי הבחינה. המשרד מודיע כי הבקשה נמצאת בשלבי הבחינה. המשרד מודיע כי הבקשה נמצאת בשלבי הבחינה.

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Claims

1. A device comprising:
 - an inlet port for receiving a blood sample;
 - an outlet port;
 - a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable; and
 - a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.
2. The device in accordance with claim 1, wherein the device is configured such that, when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber.
3. The device in accordance with claim 2, wherein the device is further configured such that an initial aliquot of blood will contact the material and back up into the chamber.
4. The device in accordance with claim 1, wherein the material is located at a distal end of the chamber.
5. The device in accordance with claim 1, wherein the material is a hydrophobic plug.
6. The device in accordance with claim 1, wherein the material is a hydrophobic membrane.
7. The device in accordance with claim 1, wherein the material is a hydrophilic membrane.

8. The device in accordance with claim 1, wherein the sampling channel further comprises a valve configured to close off the sampling channel.
9. The device in accordance with claim 8, wherein the valve is a clip.
10. The device in accordance with claim 1, further comprising a junction connecting the inlet port and the sampling channel and the chamber.
11. The device in accordance with claim 10, wherein the junction is configured to convey the subsequent portion of the blood sample to the outlet port while bypassing the chamber.
12. The device in accordance with claim 1, wherein the chamber has a larger cross-sectional area than the sampling channel.
13. The device in accordance with claim 1, further comprising a housing that defines the chamber and the sampling channel.
14. The device in accordance with claim 13, wherein the housing comprises a bottom member mated with a top member, each of the bottom member and the top member defining a part of each of the inlet port, the outlet port, the chamber, and the sampling channel.
15. The device in accordance with claim 1, further comprising a patient needle and a sample collection device.

BLOOD SAMPLE OPTIMIZATION DEVICE**ABSTRACT**

Blood sample optimization systems and methods are described that reduce or eliminate contaminants in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Non-Provisional Application Serial No. 15/140,443, filed on April 27, 2016 and titled “BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD” and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April 27, 2016 and titled “BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD”, both of which claim priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015 and titled “BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD”; U.S. Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled “BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING”; and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and titled “BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD,” the disclosures of which are incorporated by reference in their entirety.

BACKGROUND

[0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a “butterfly” set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a “Vacutainer,” which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe’s plunger that is drawn too quickly for the patient’s condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by

antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

[0013] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0016] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port

connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0017] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0018] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0019] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a

sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

[0020] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0021] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

[0024] FIG. 1 illustrates a blood sample optimization system.

[0025] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0026] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0027] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0028] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0030] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0031] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0032] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0033] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0034] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0035] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0036] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0037] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminants of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0038] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0039] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0040] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0041] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

[0042] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0043] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0044] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0045] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0046] FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0047] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0048] This document describes blood sample optimization systems and methods for reducing or eliminating contaminants in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other

sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0049] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0050] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0051] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term “air permeable blood barrier” means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0052] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a “duck bill” or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0053] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of

coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0054] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0055] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0056] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such

as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0057] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a “T” or “Y” connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0058] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient’s own blood pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0059] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a

certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0060] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0061] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A “T” or “Y” connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0062] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0063] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient’s own blood pressure to overcome the

ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0064] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0065] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indicator or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0066] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate

valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0067] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0068] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0069] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle

from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0070] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0071] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0072] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the

sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0073] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0074] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0075] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0076] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration

device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0077] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0078] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0079] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0080] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0081] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0082] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main

outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0083] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminants of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0084] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0085] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In

other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0086] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0087] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0088] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that

sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0089] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0090] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[0091] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations,

tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0092] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0093] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0094] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood

sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0095] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0097] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0098] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0099] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00100] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00101] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the

sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00102] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00103] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00104] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00105] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00106] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00107] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the

blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00108] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00109] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00110] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the

sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00111] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17D and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00112] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00113] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00114] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent

material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00115] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00116] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00117] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood

sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00118] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00119] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00120] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00121] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by

the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00122] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00123] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00124] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00125] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber

2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[00126] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel before the initial aliquot of blood is sequestered in the sequestration chamber 2306.

[00127] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

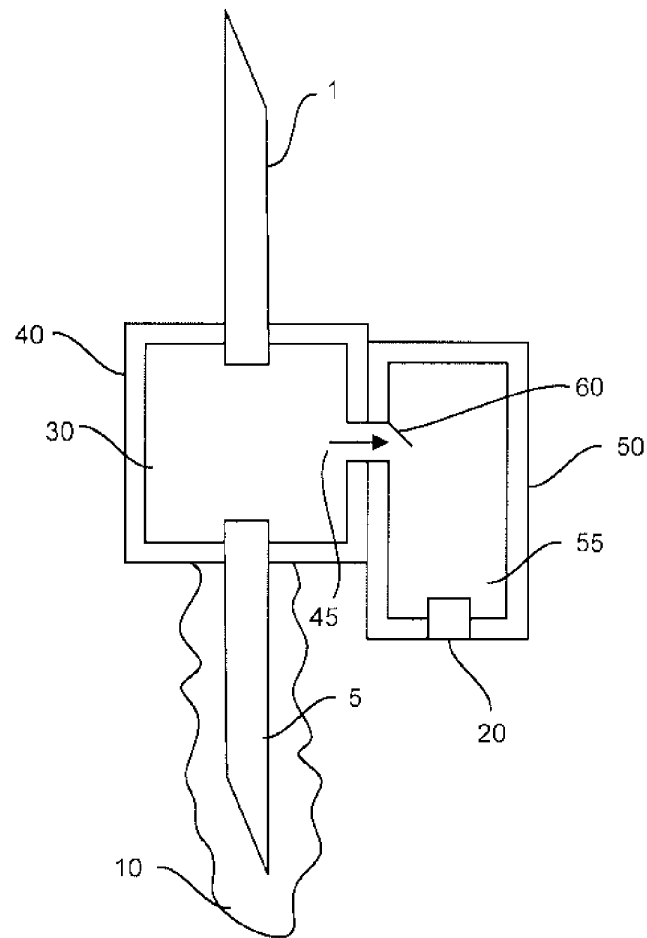


FIG. 1

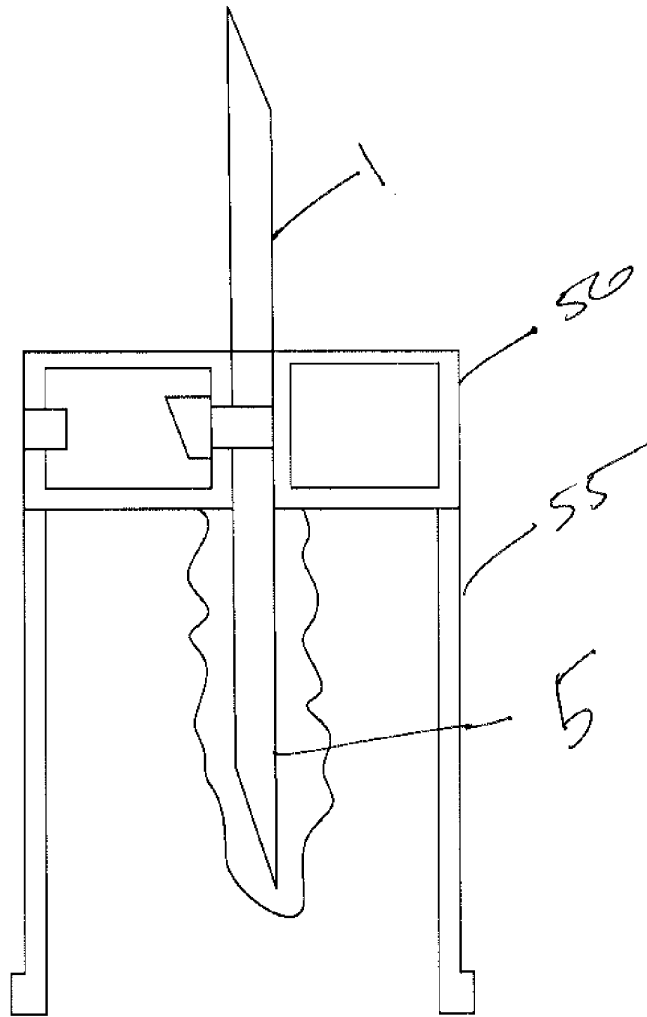
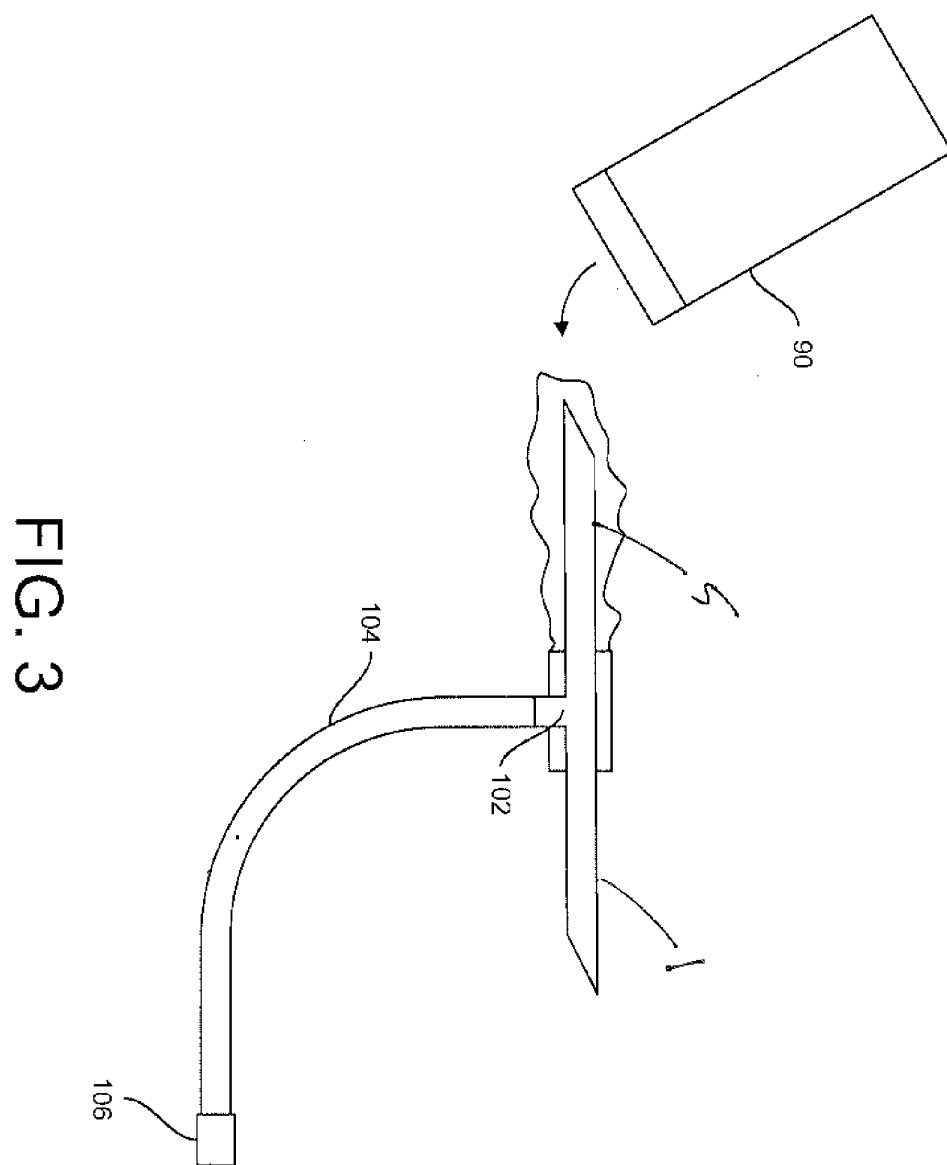


FIG. 2



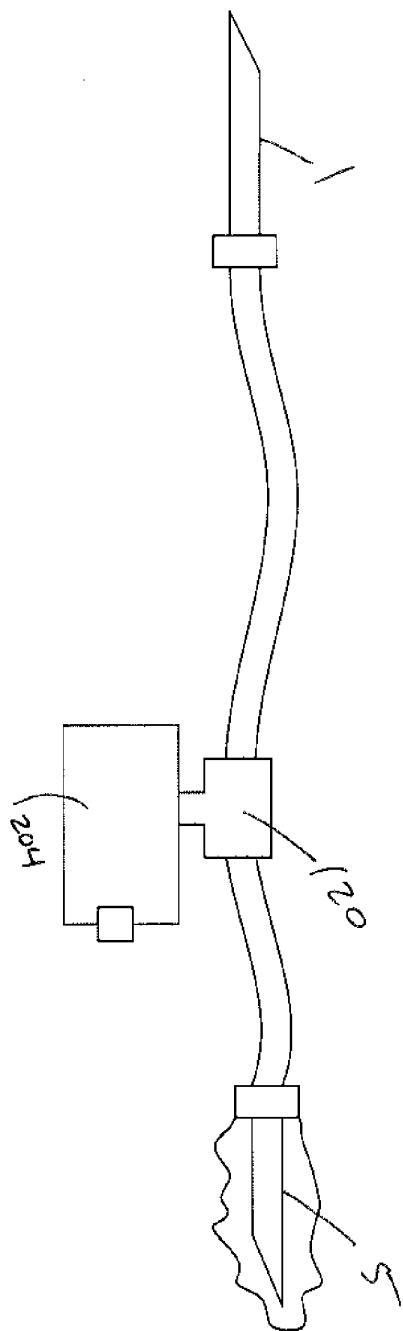


FIG. 5

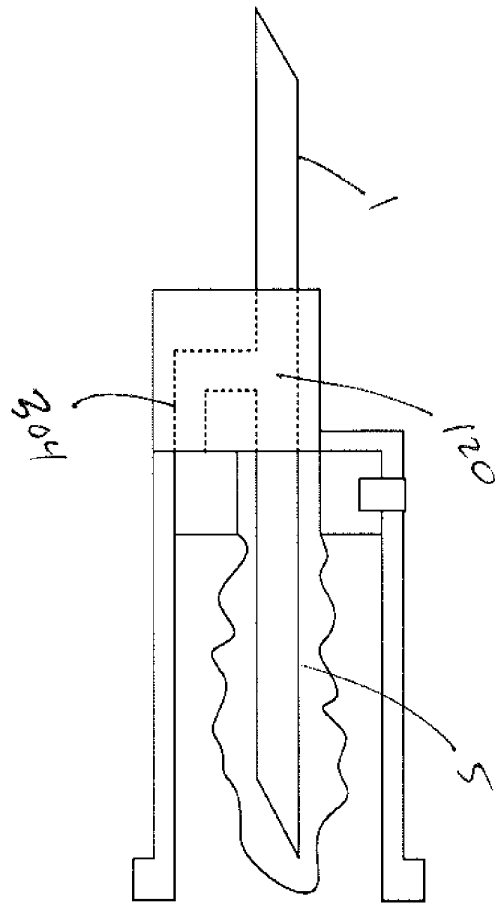


FIG. 6

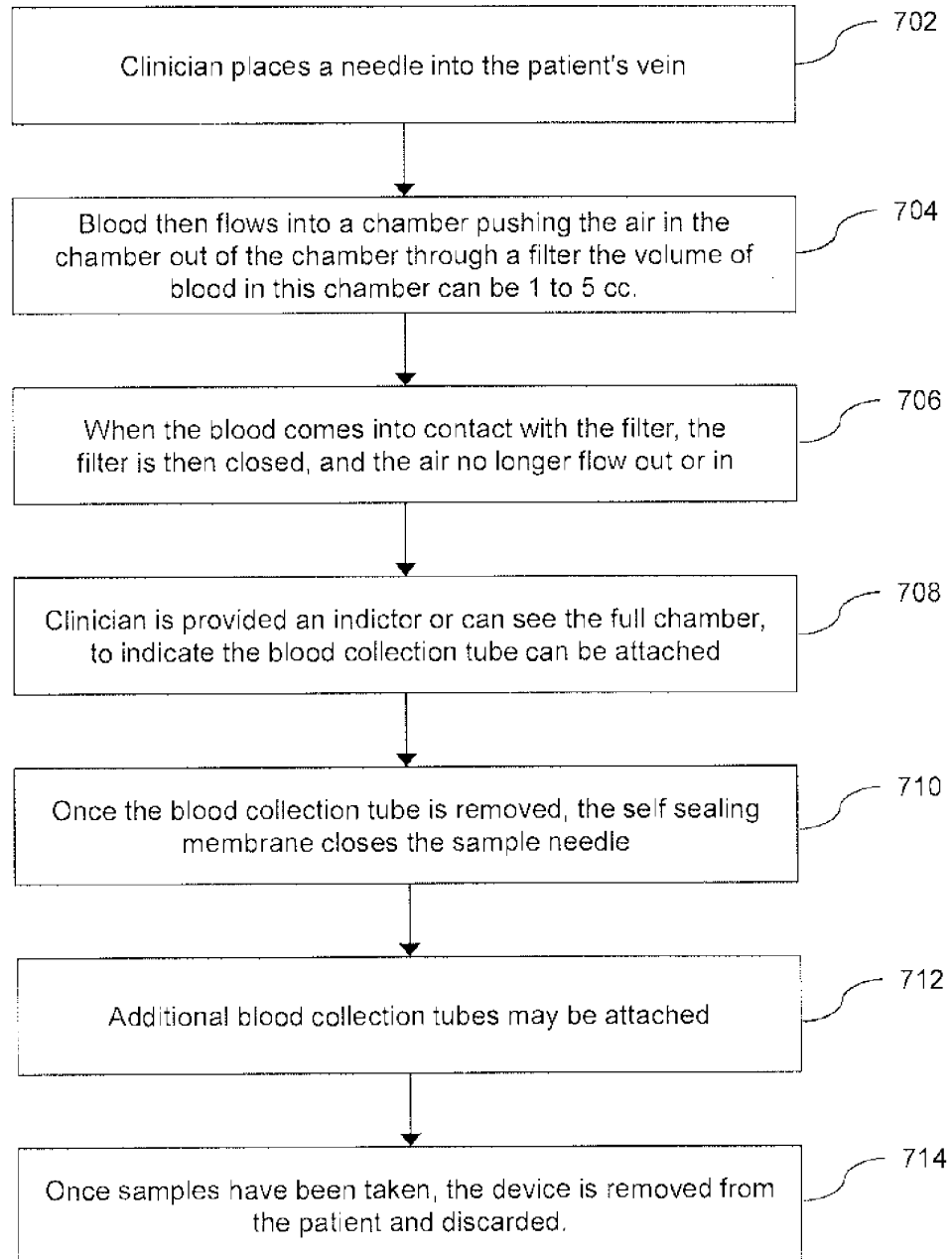


FIG. 7

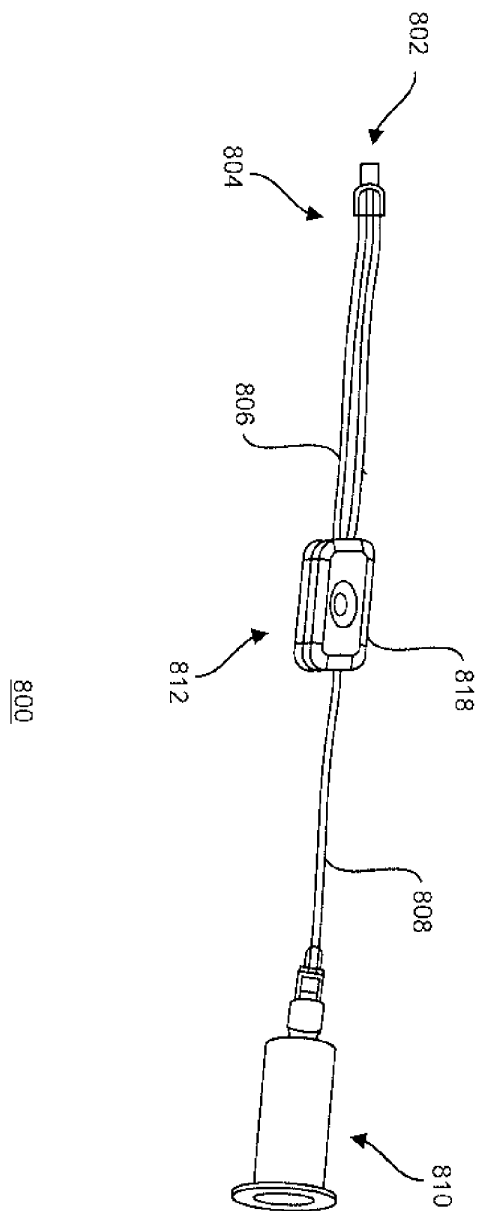


FIG. 8A

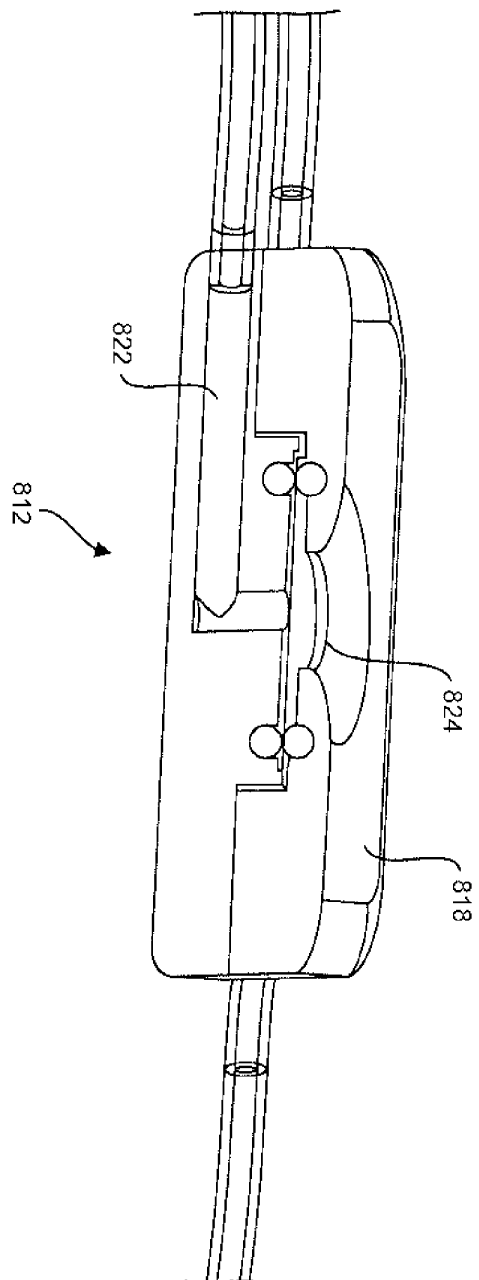


FIG. 8B

10/50

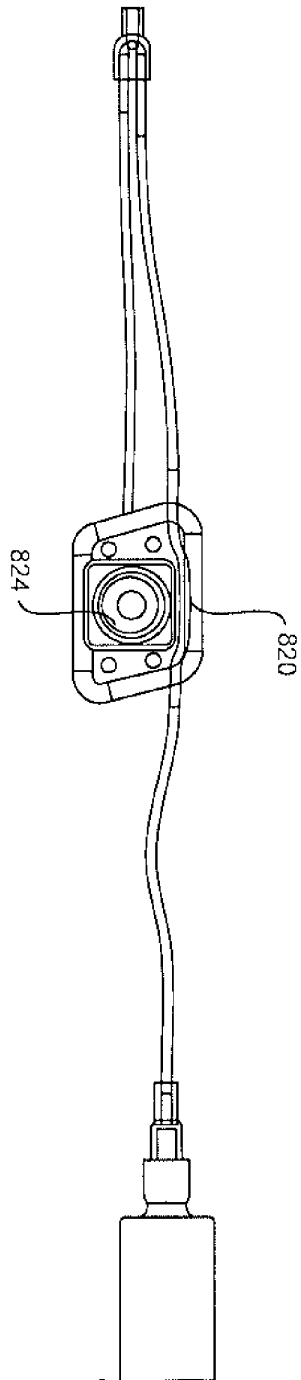


FIG. 8C

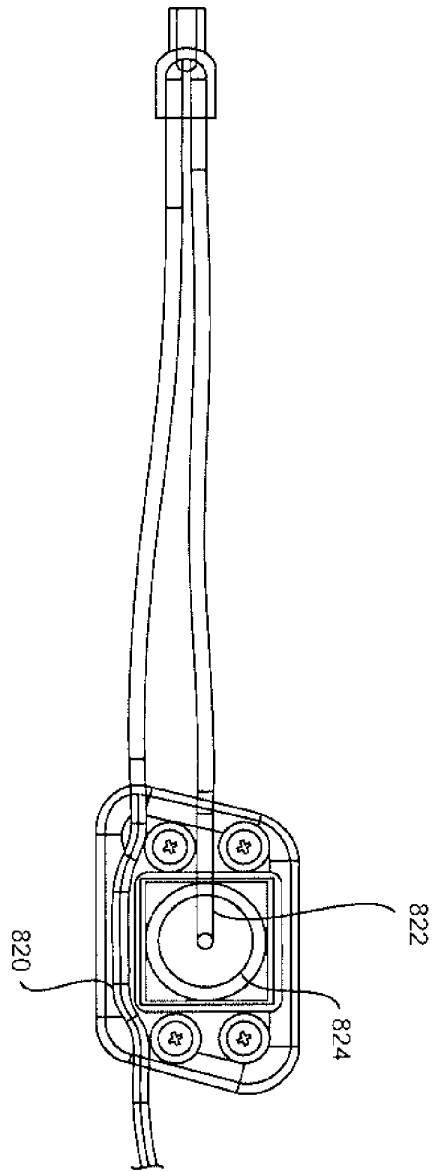


FIG. 8D

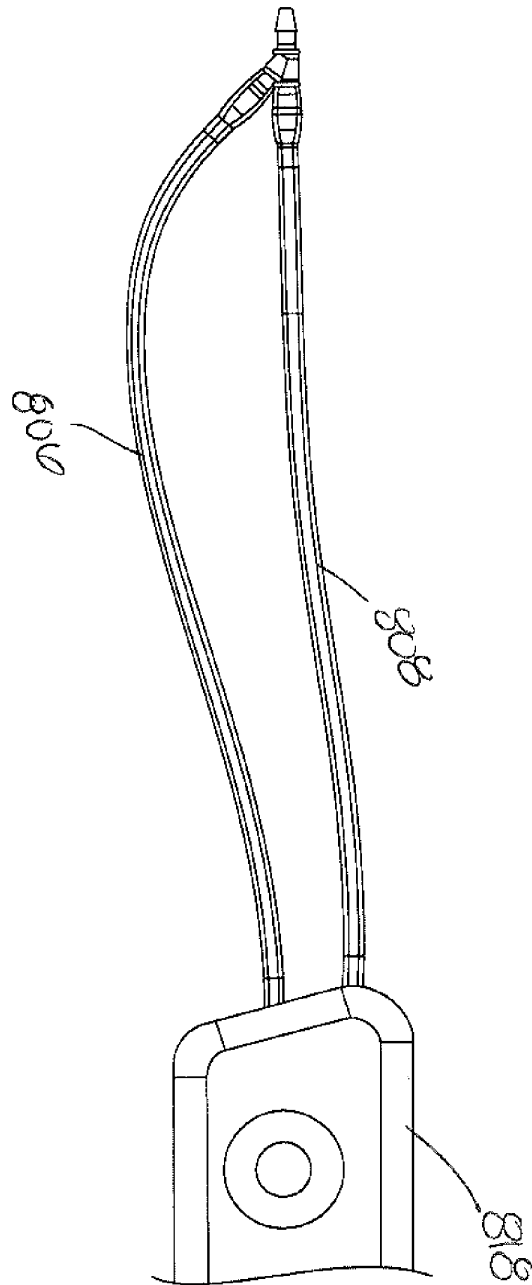


FIG. 8E

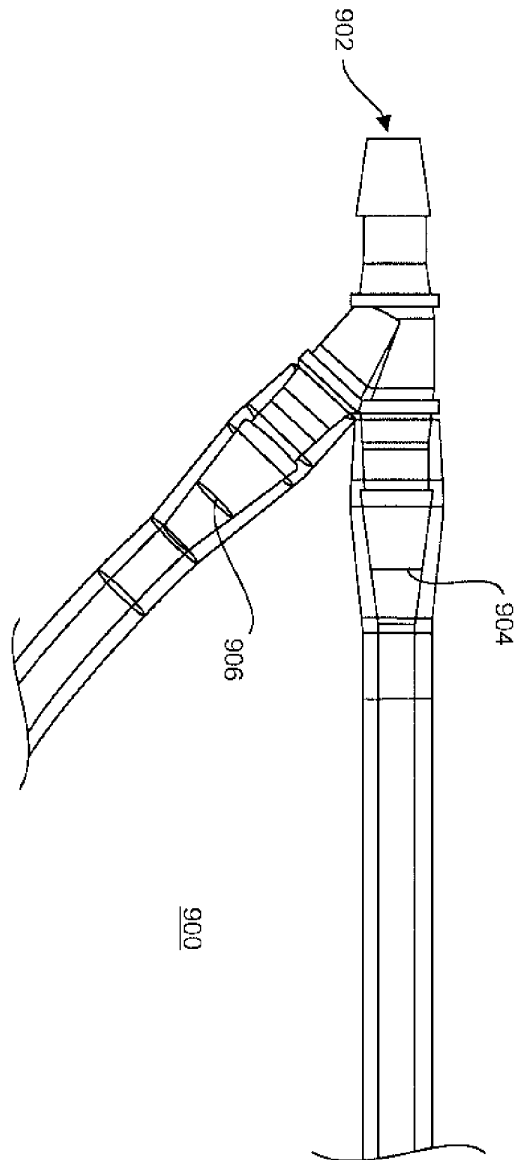
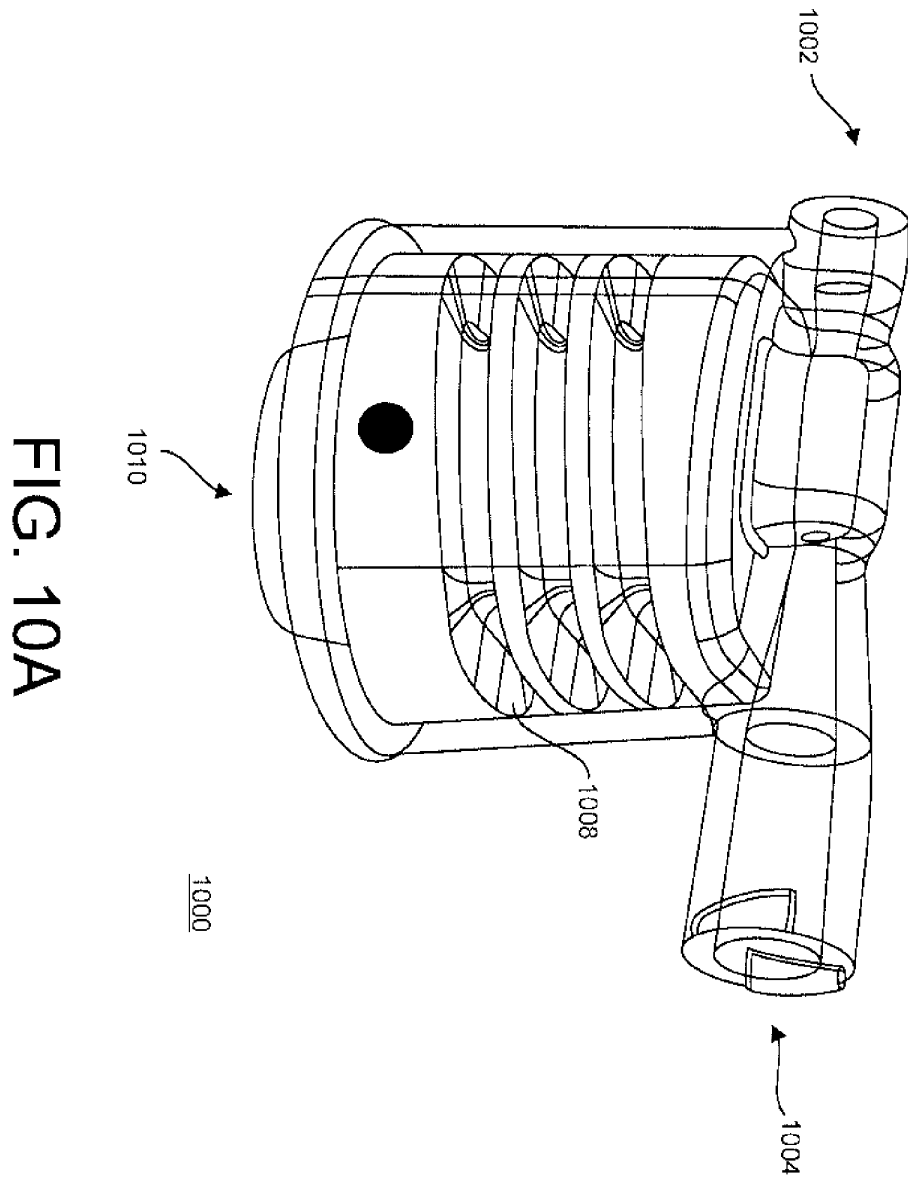


FIG. 9



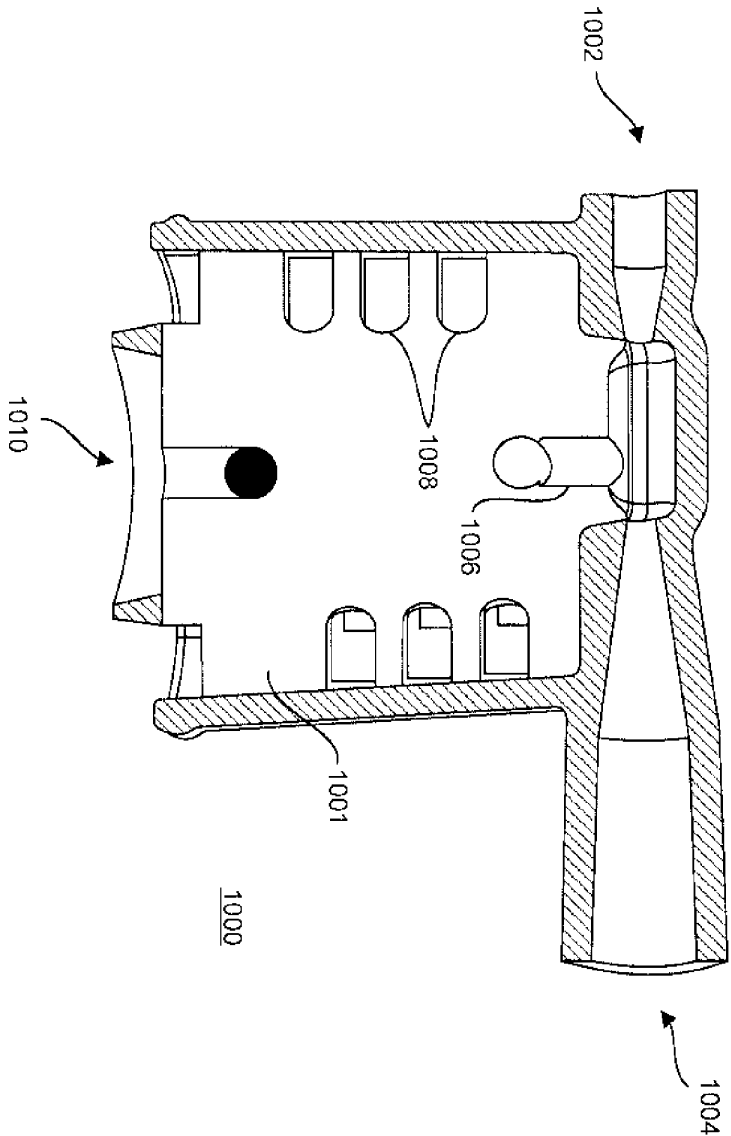
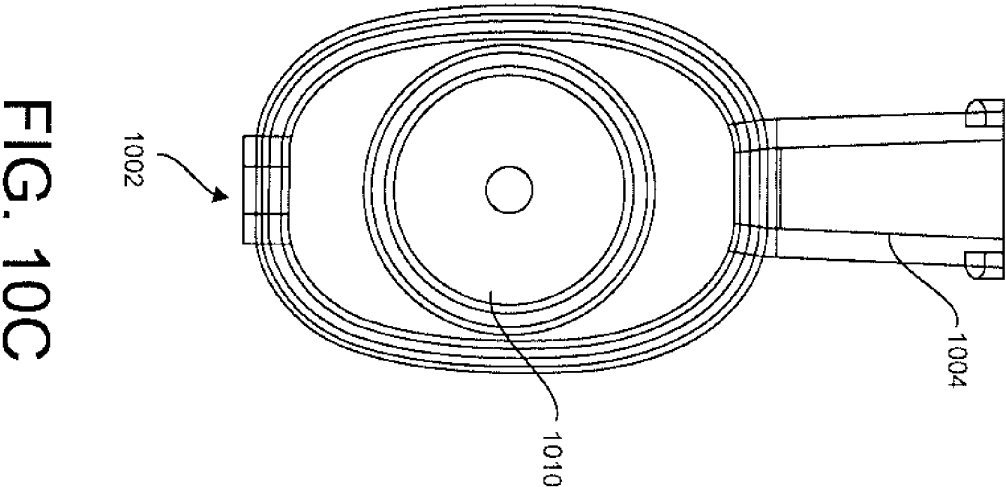


FIG. 10B



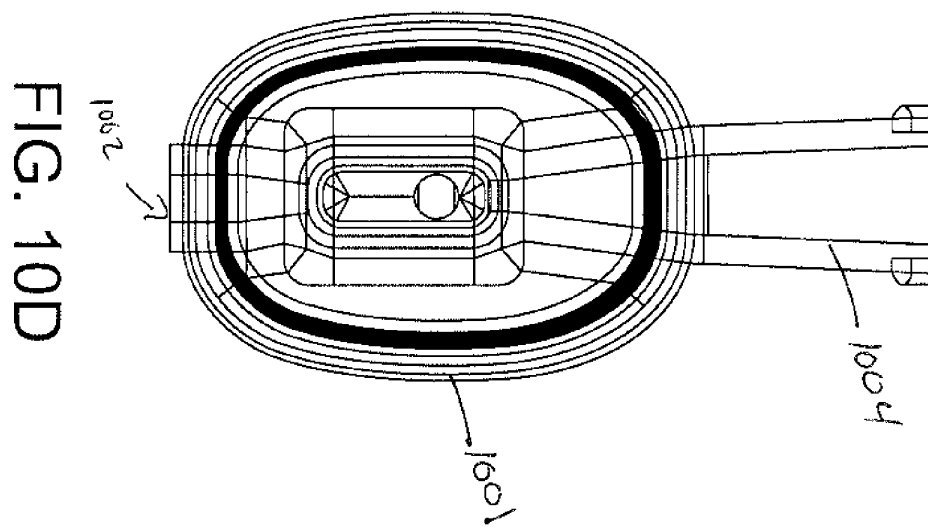
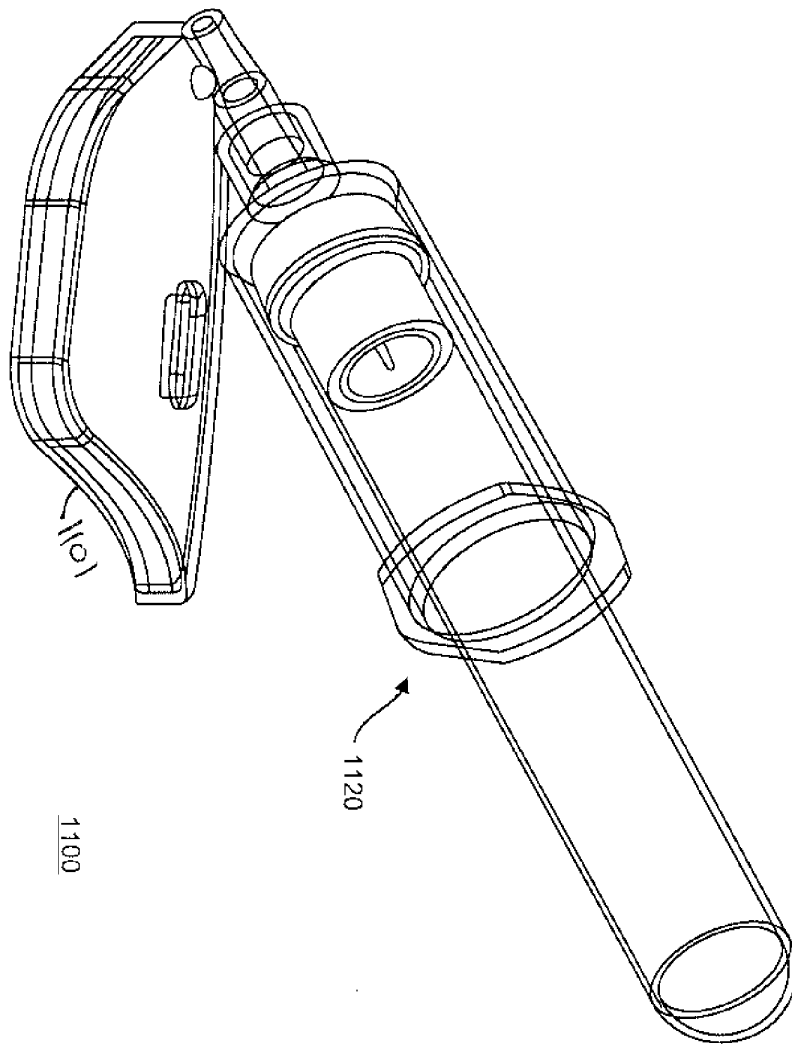


FIG. 11A



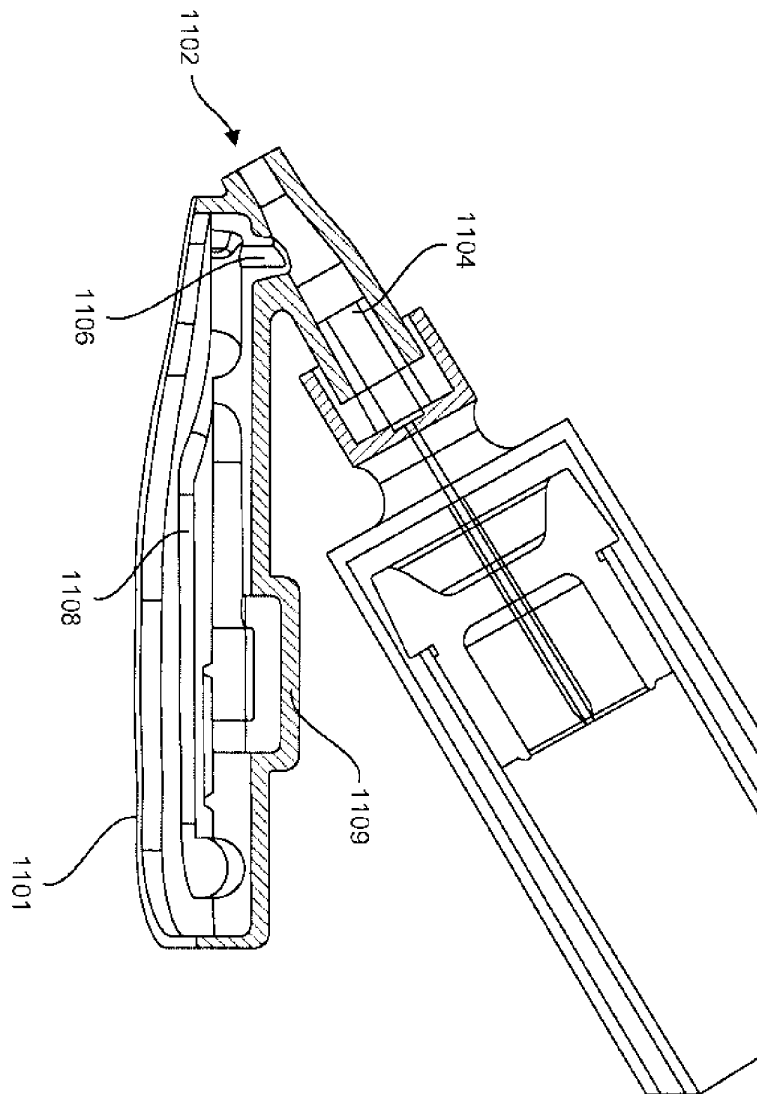


FIG. 11B

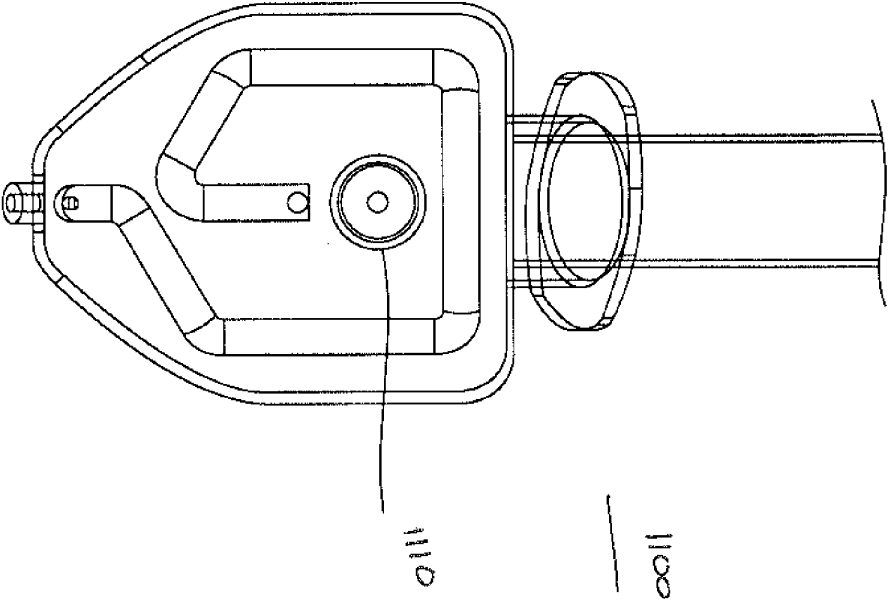
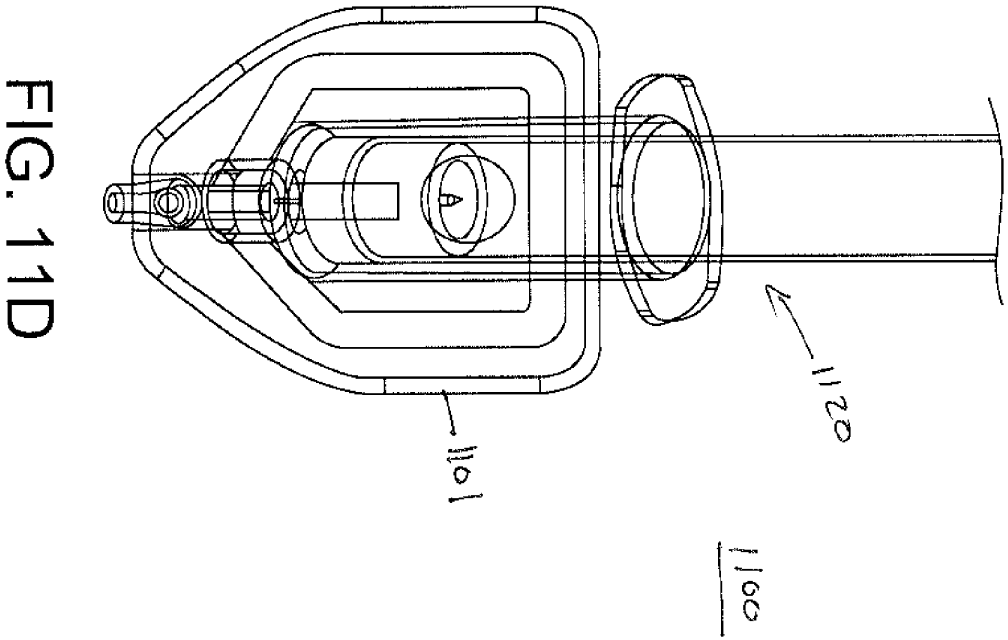


FIG. 11C



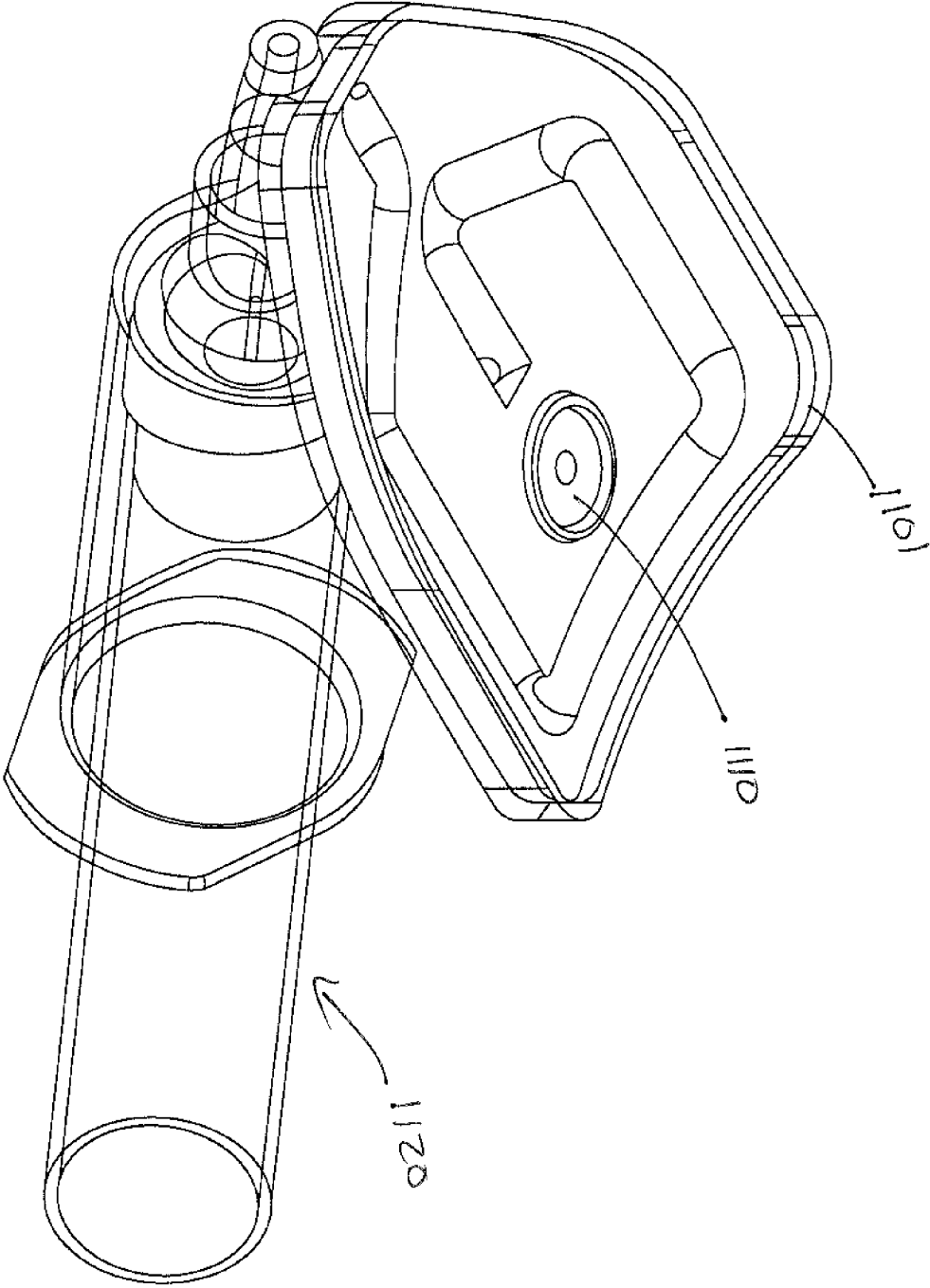


FIG. 11E

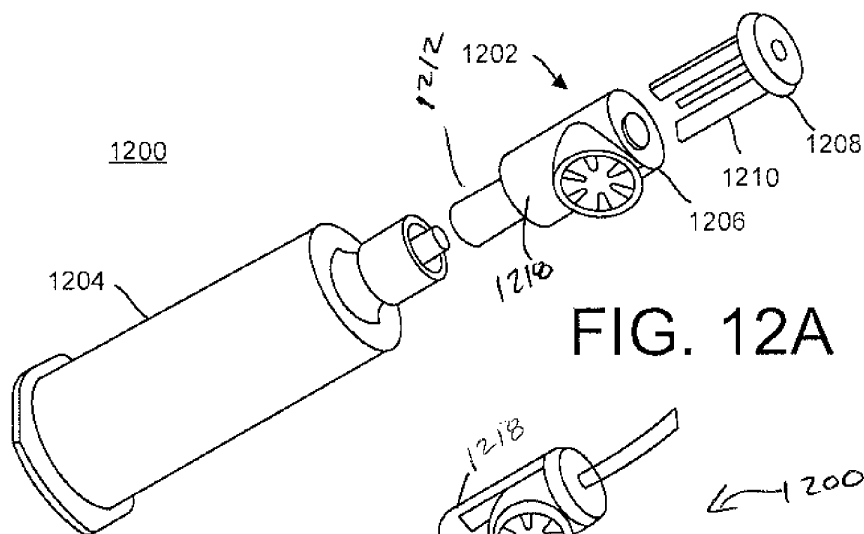


FIG. 12A

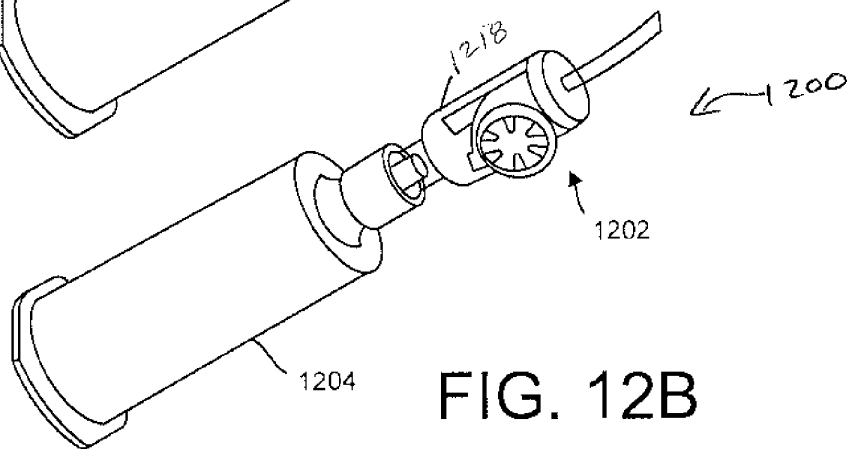


FIG. 12B

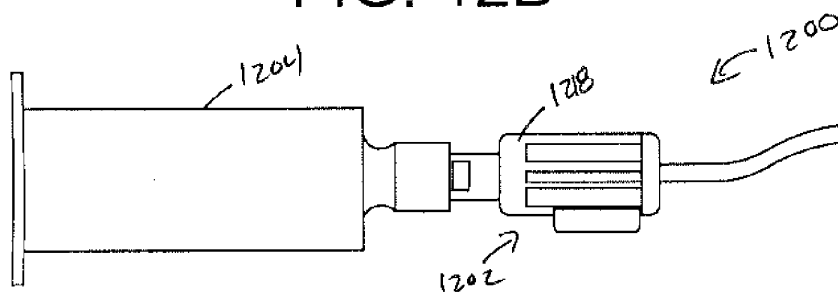


FIG. 12C

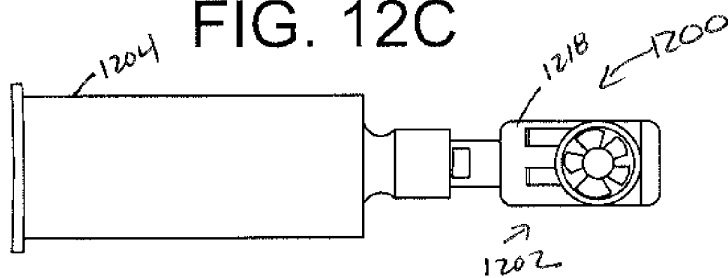


FIG. 12D

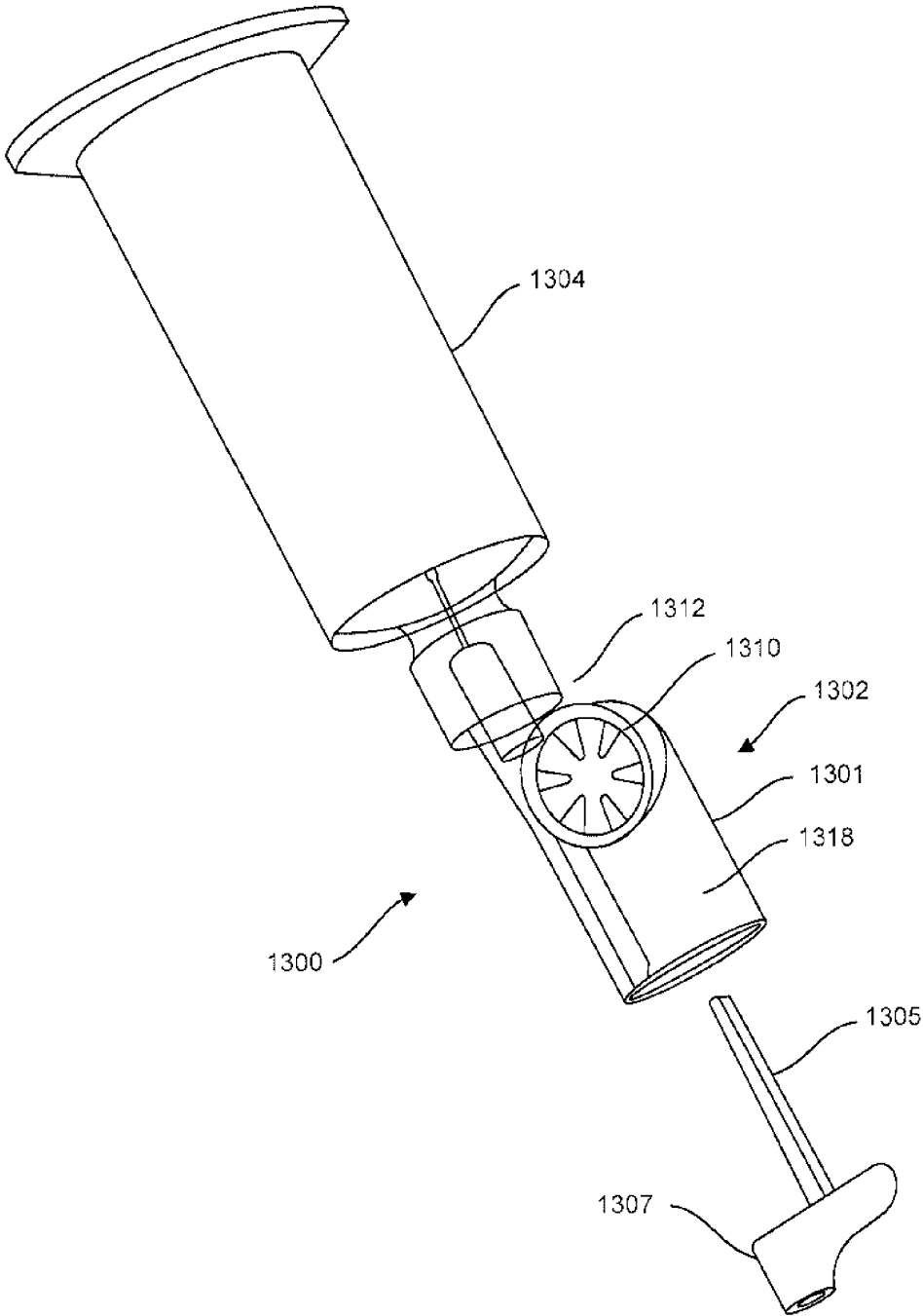


FIG. 13A

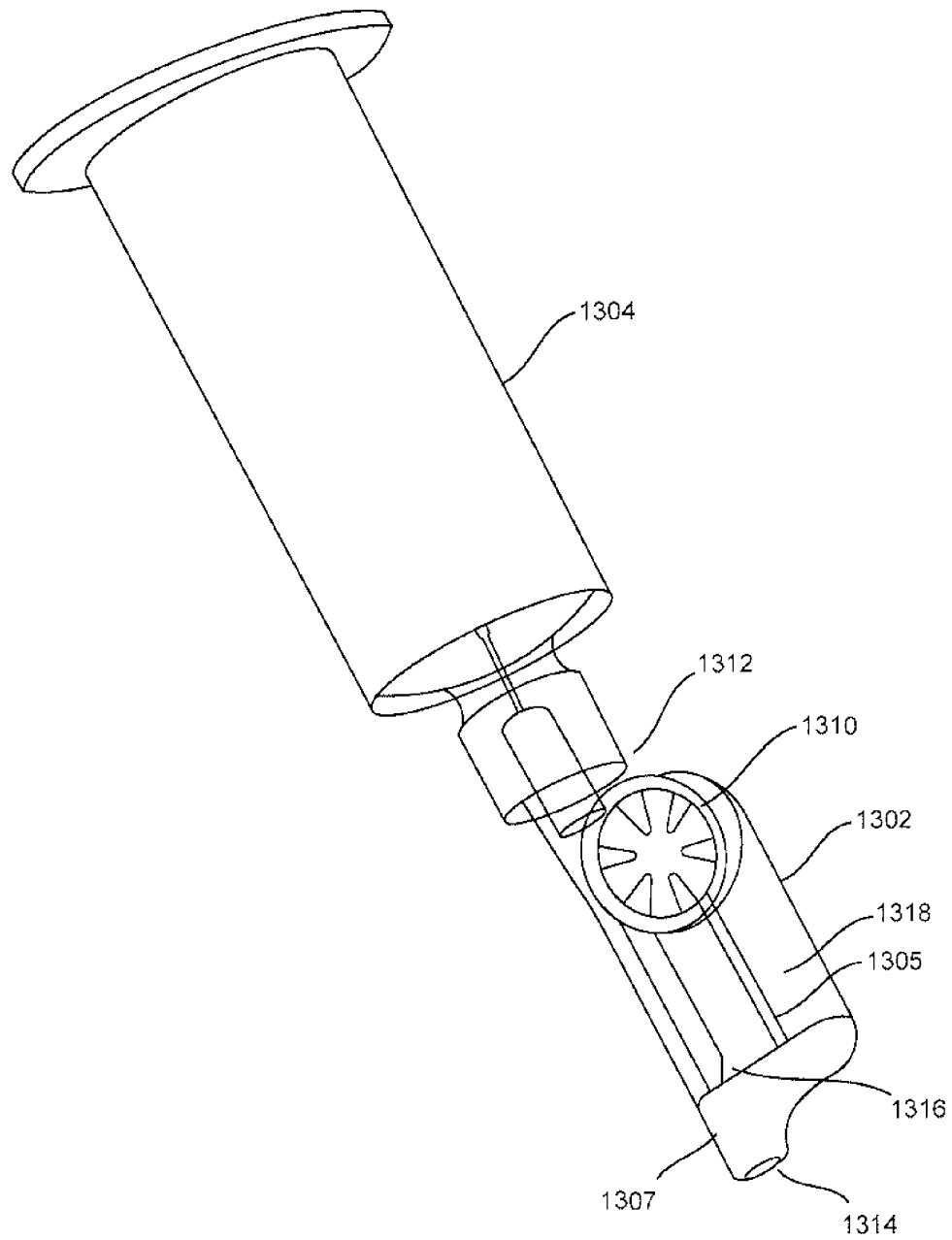


FIG. 13B

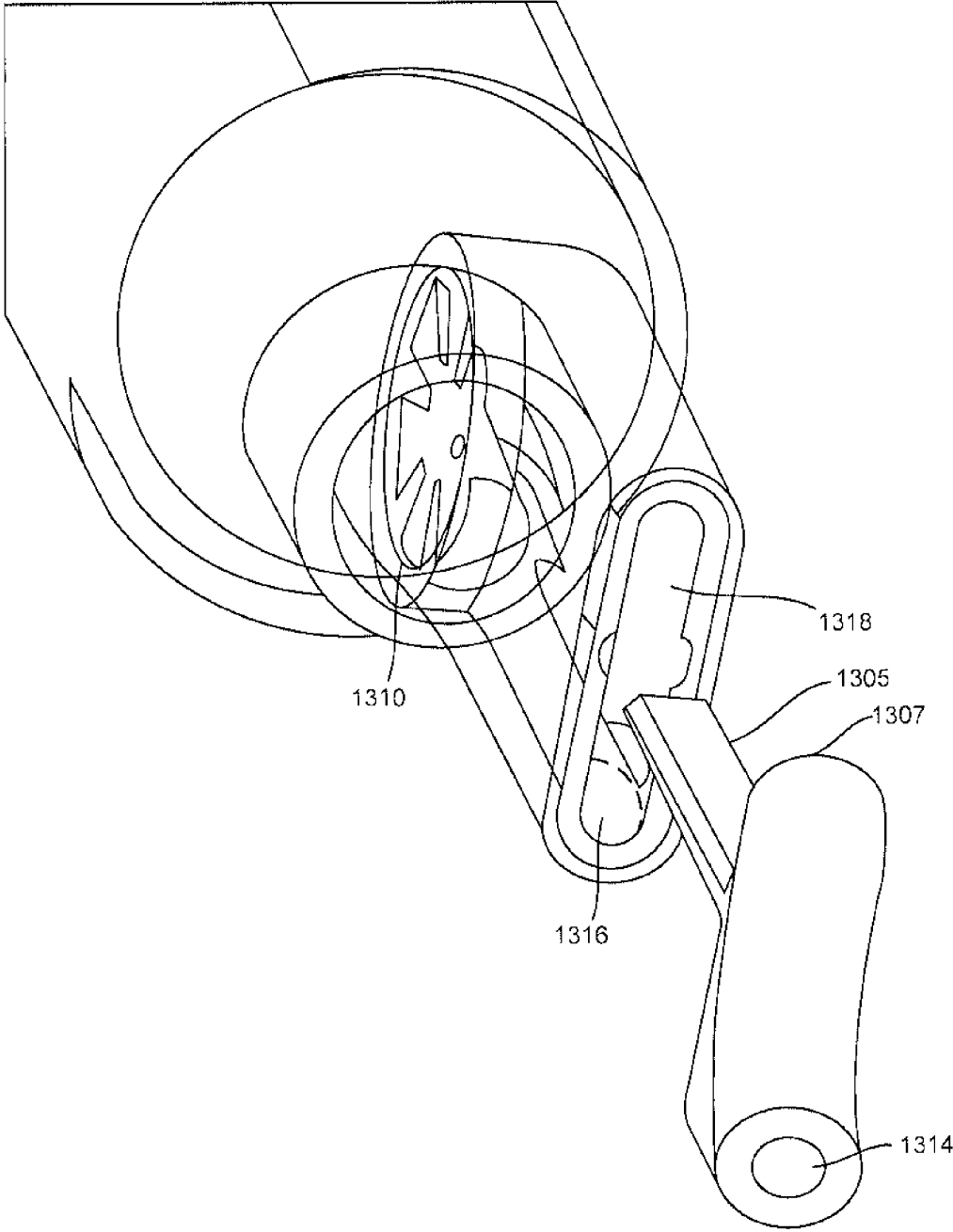


FIG. 13C

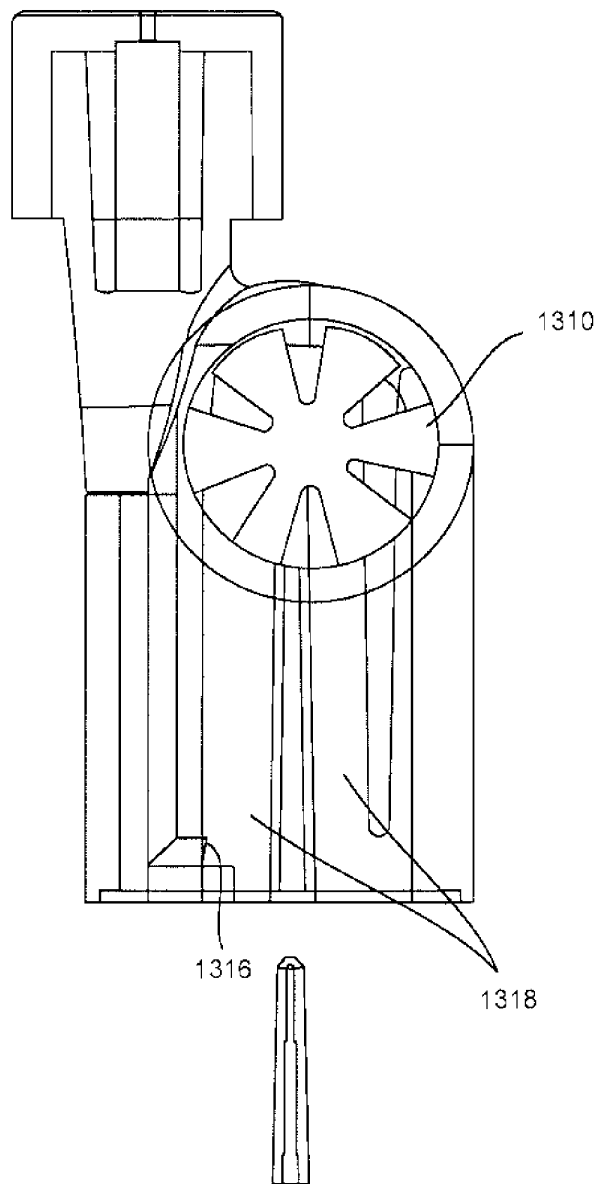


FIG. 13D

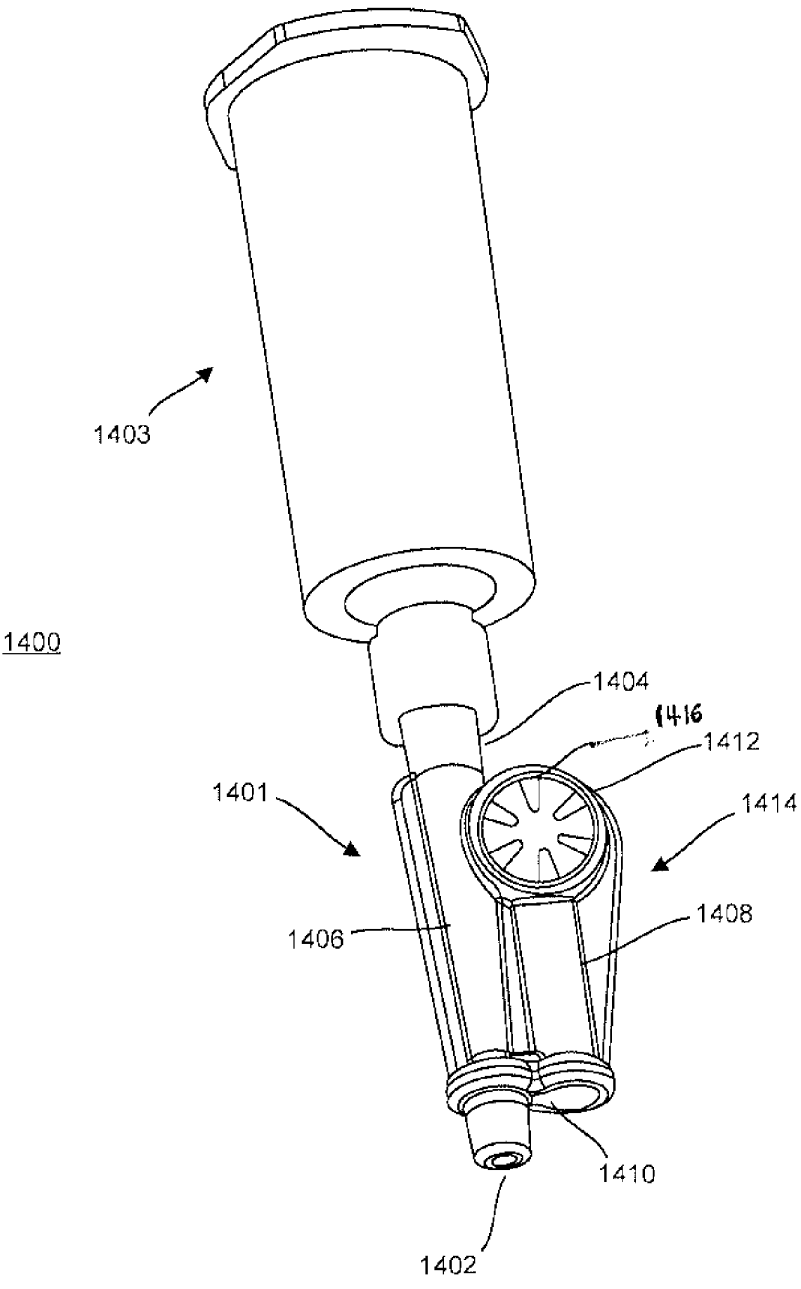


FIG. 14A

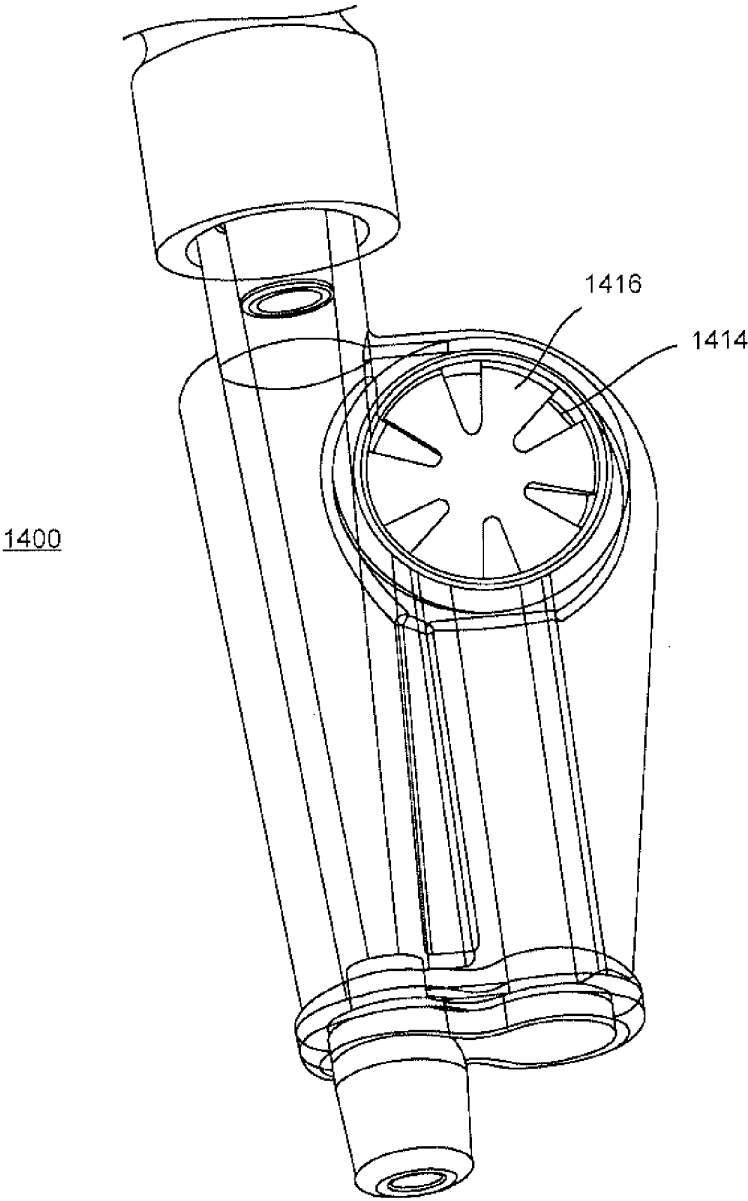


FIG. 14B

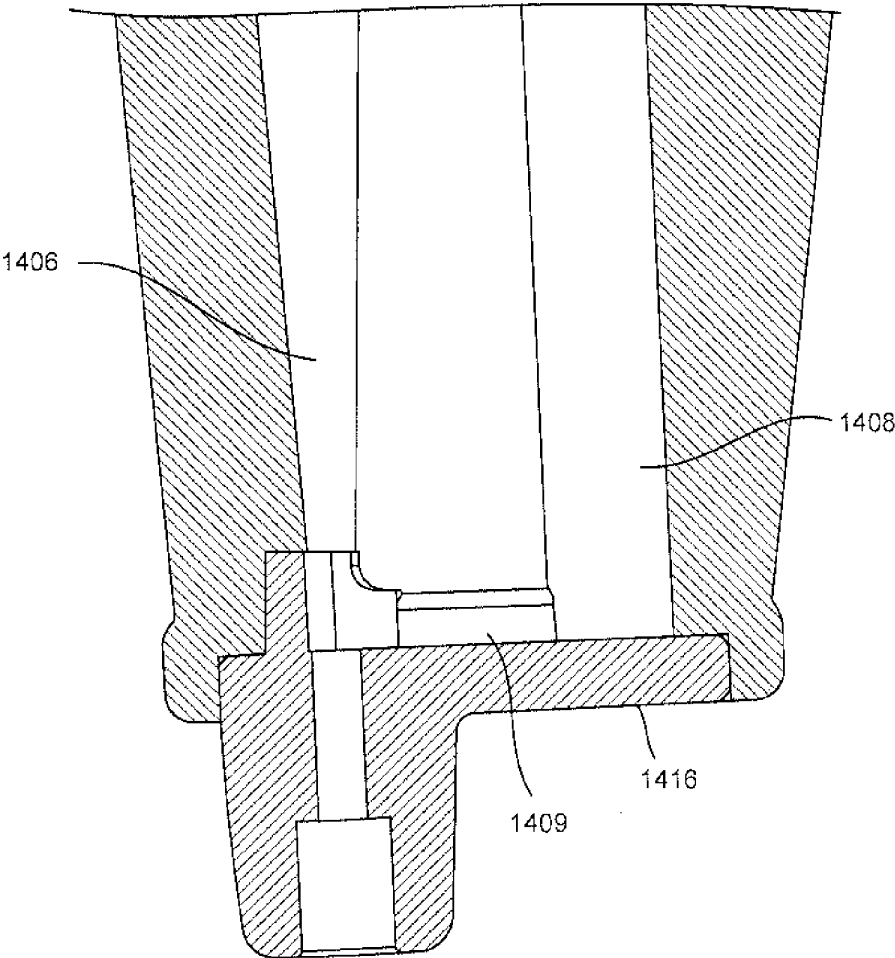


FIG. 14C

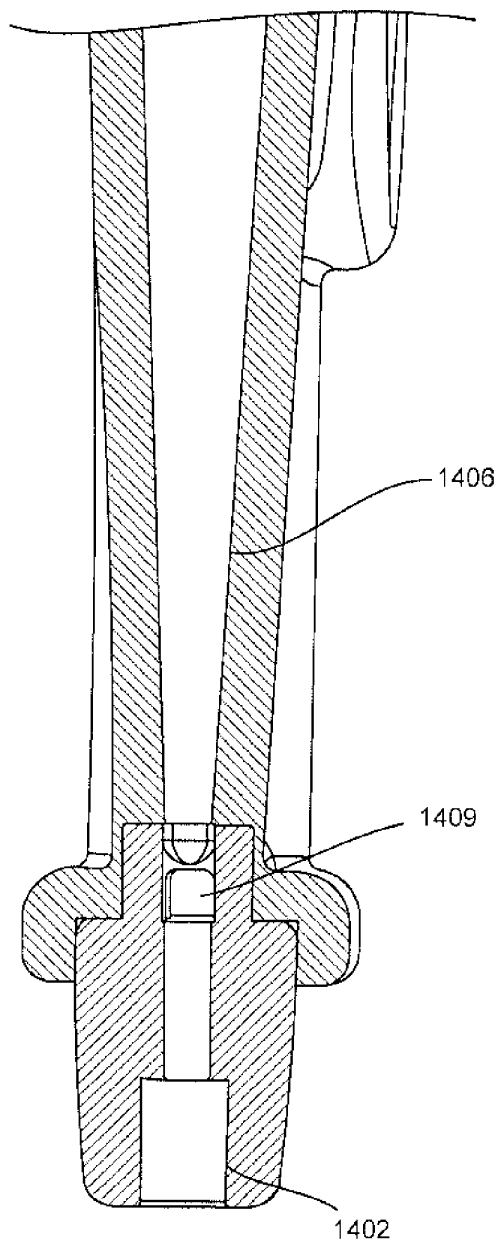


FIG. 14D

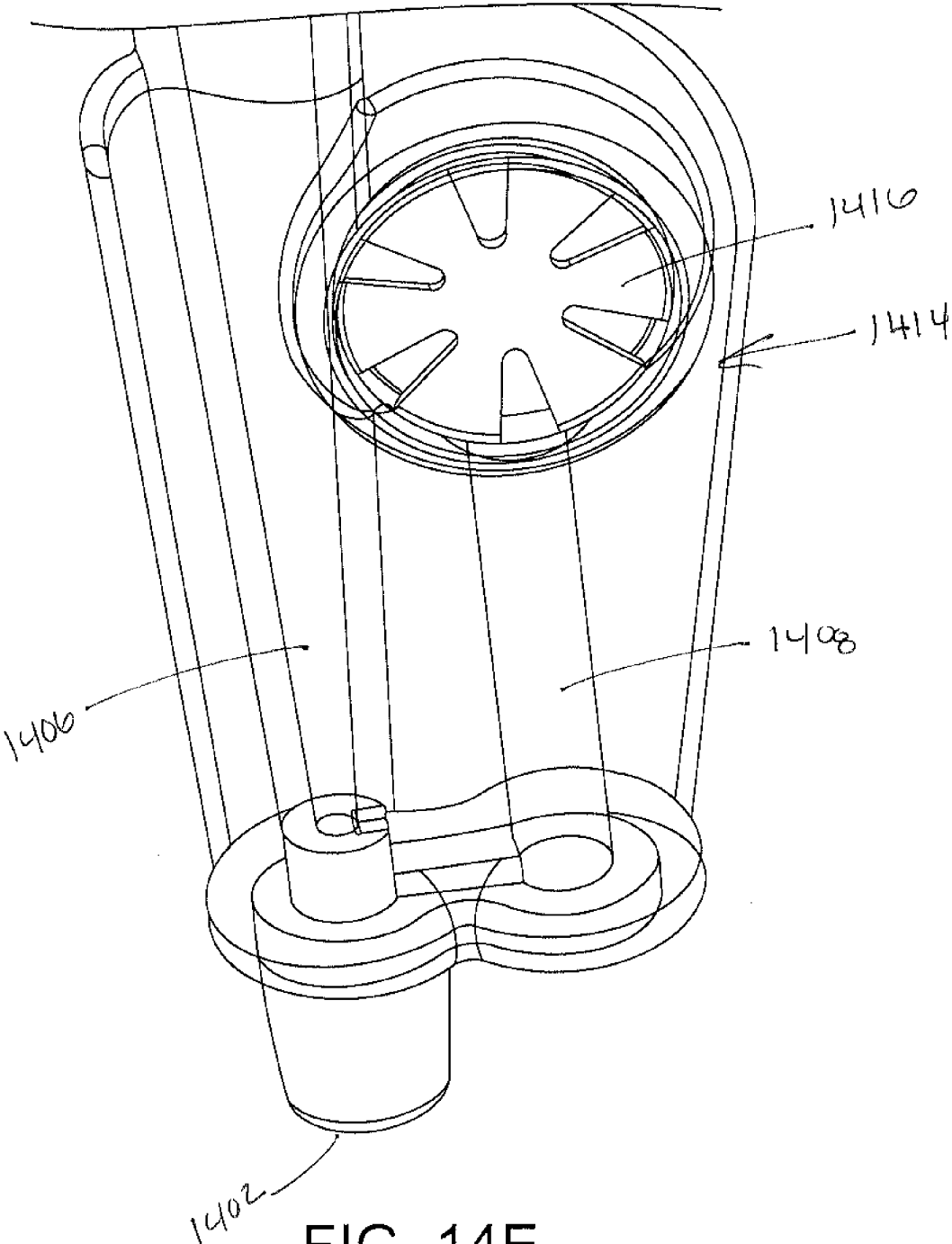


FIG. 14E

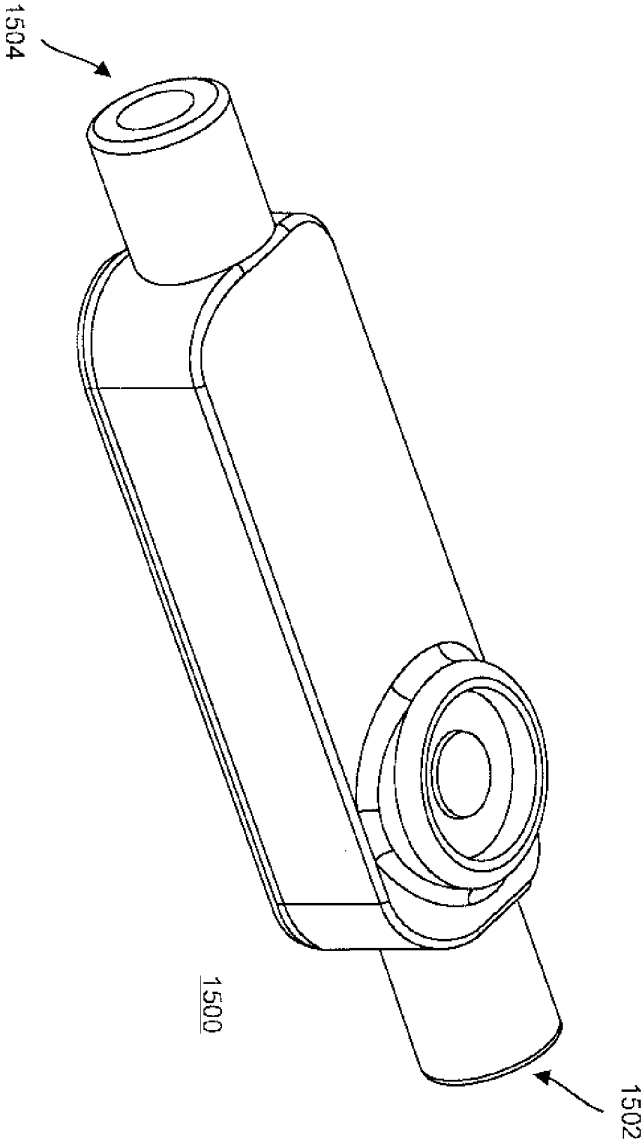


FIG. 15A

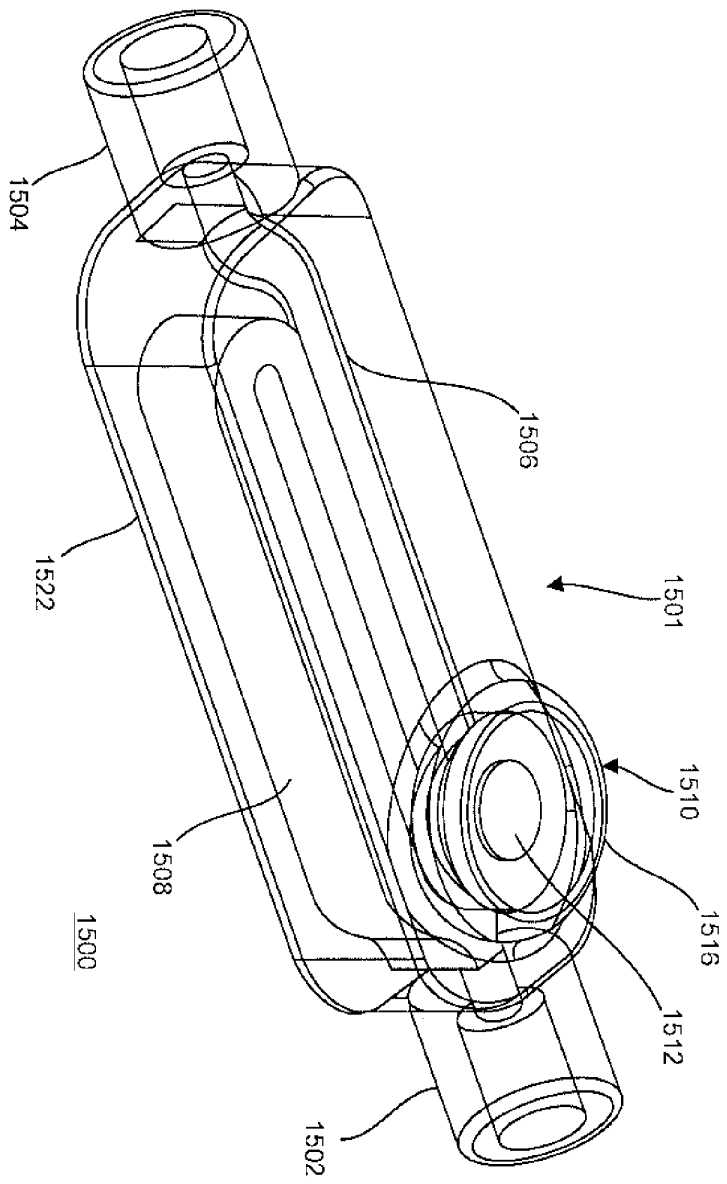


FIG. 15B

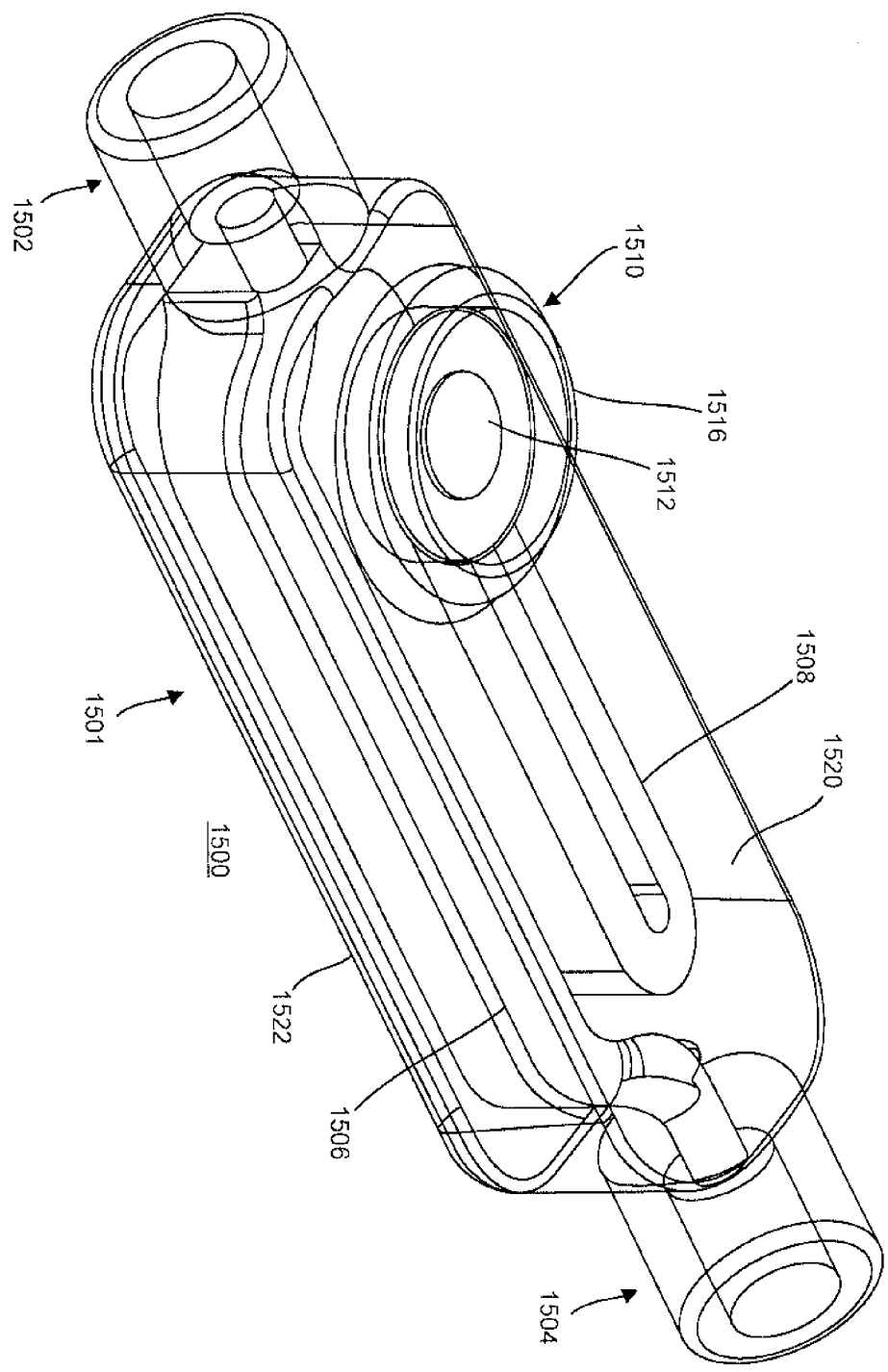


FIG. 15C

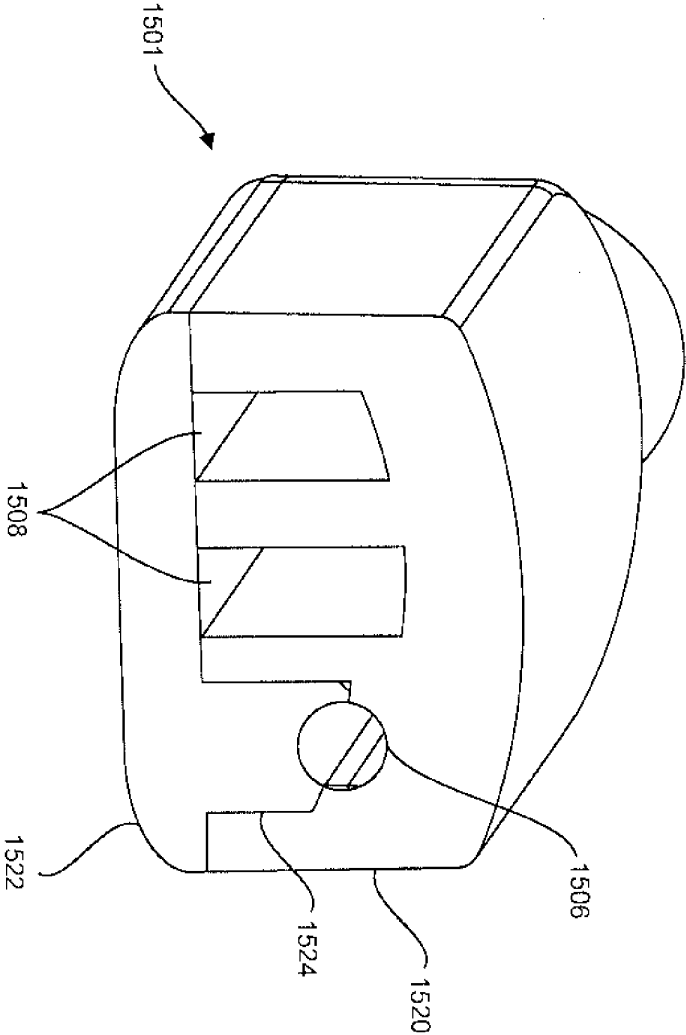


FIG. 15D

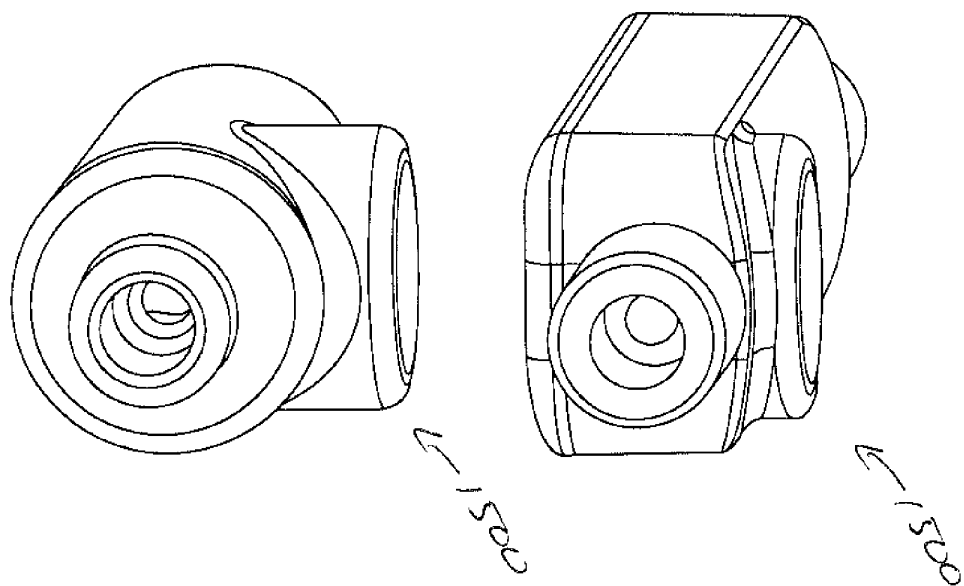


FIG. 15E

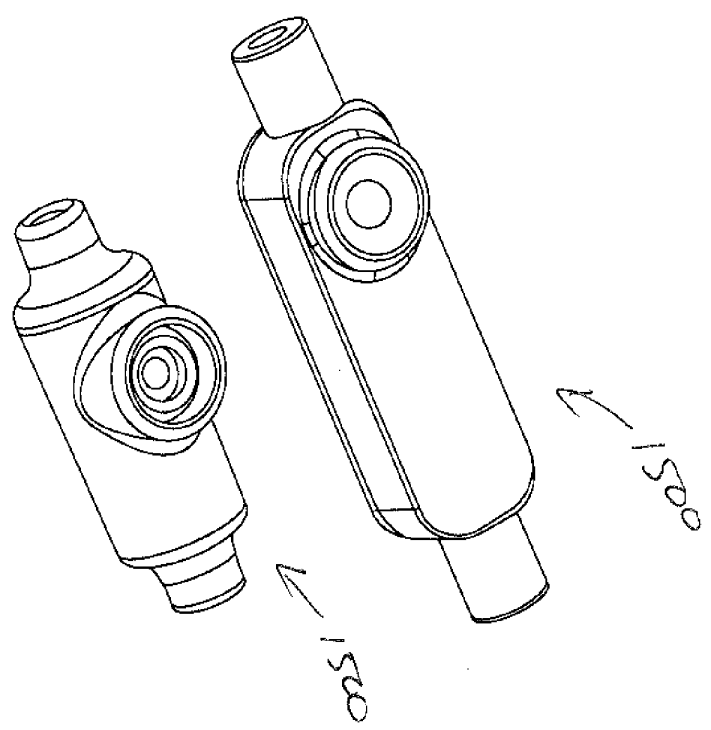


FIG. 15F

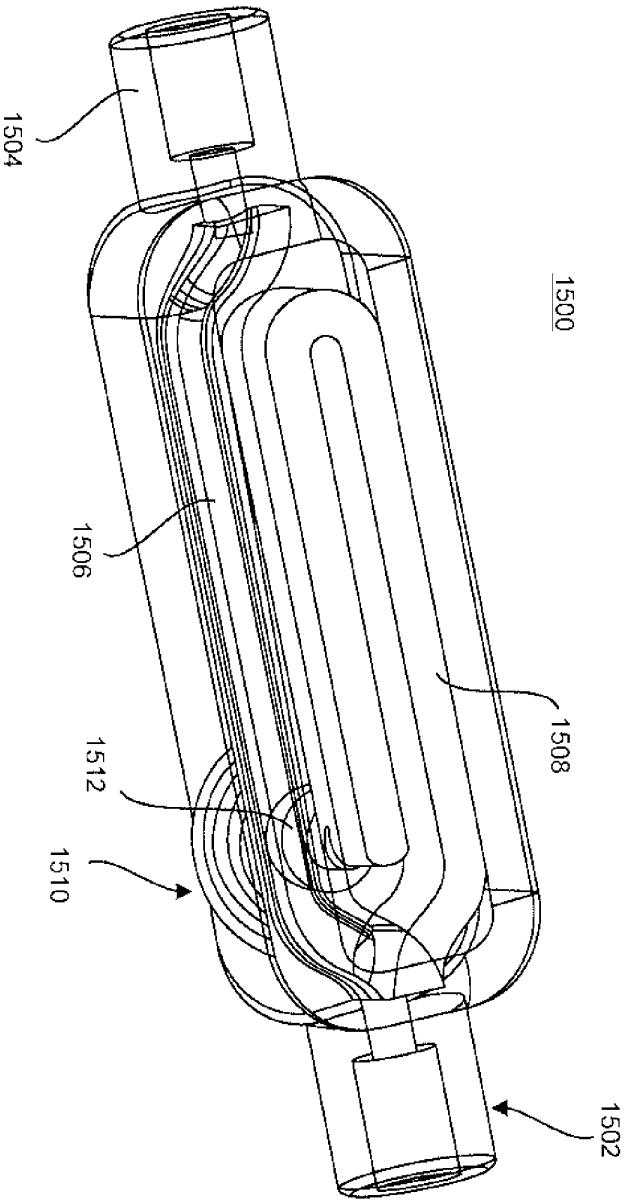


FIG. 15G

FIG. 16A

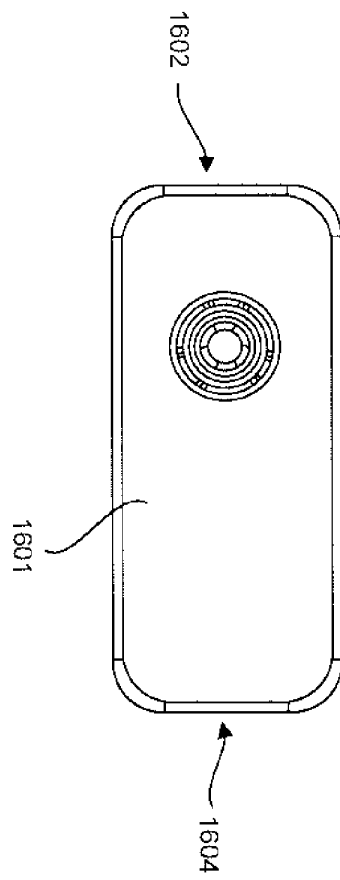
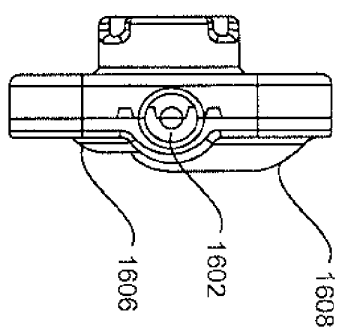


FIG. 16C

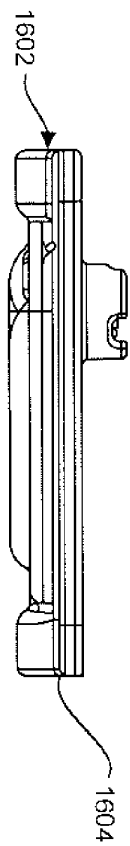
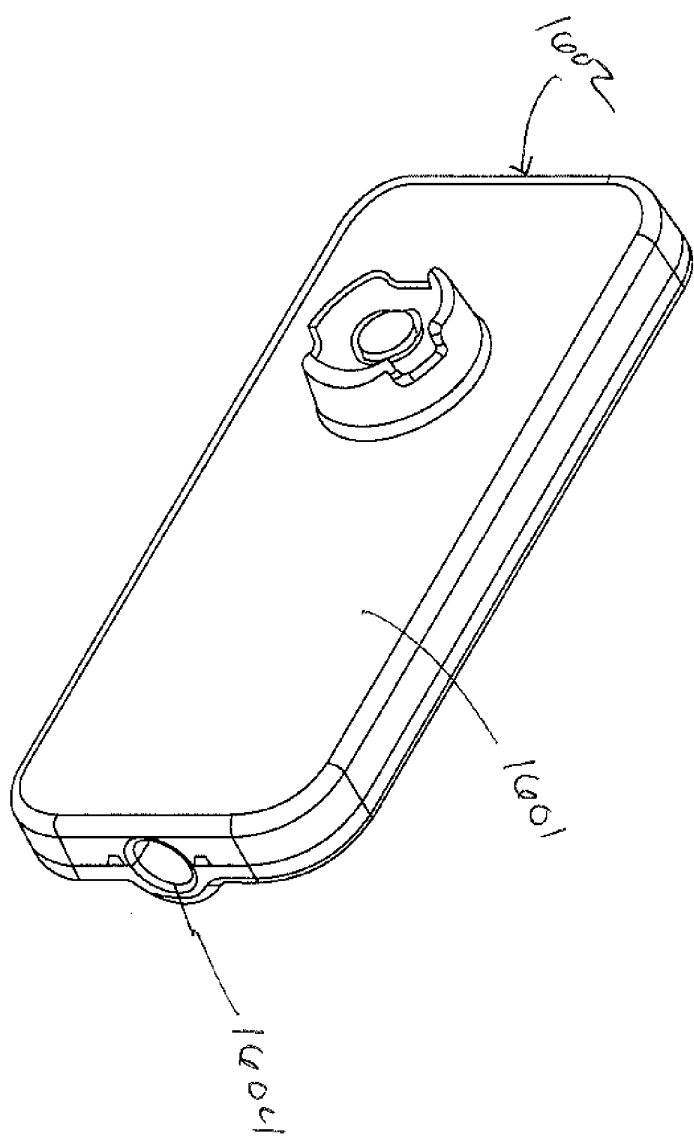


FIG. 16B

FIG. 16D



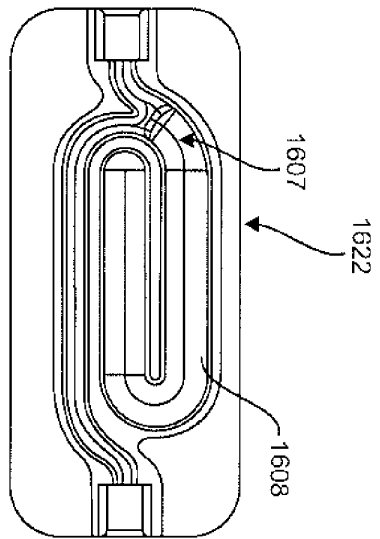


FIG. 17A

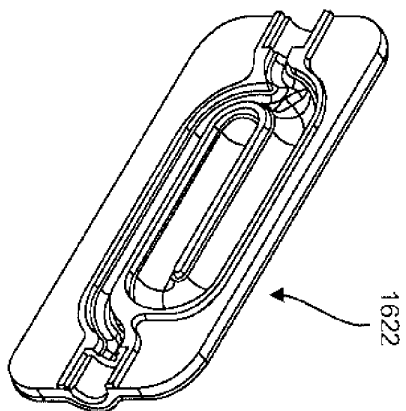


FIG. 17B

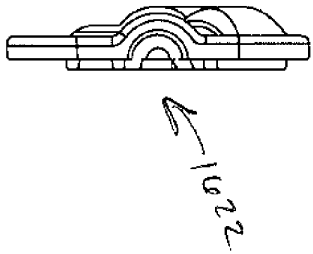


FIG. 17C

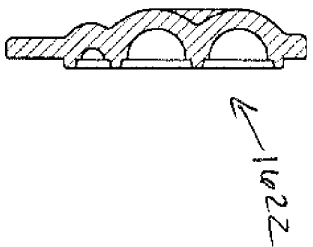


FIG. 17D

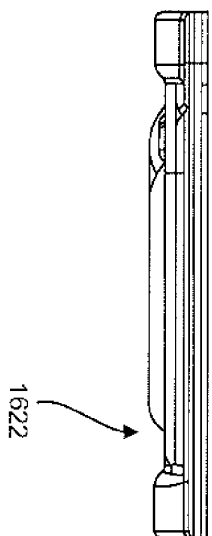


FIG. 17E

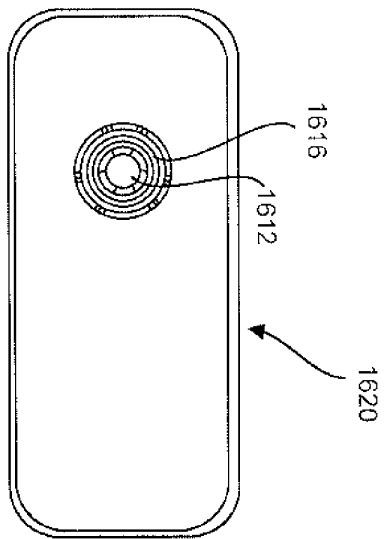


FIG. 18A

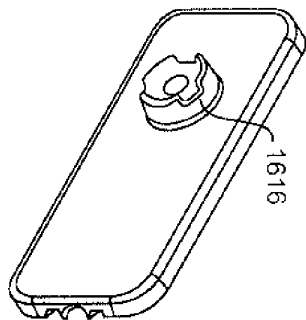


FIG. 18B

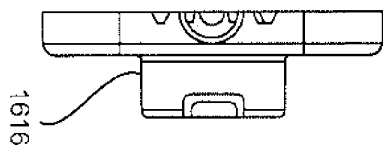


FIG. 18C

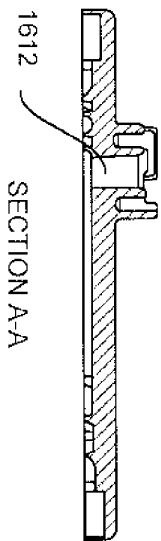


FIG. 18D

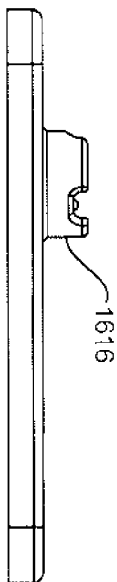


FIG. 18E

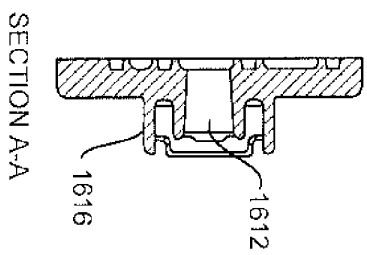


FIG. 18F

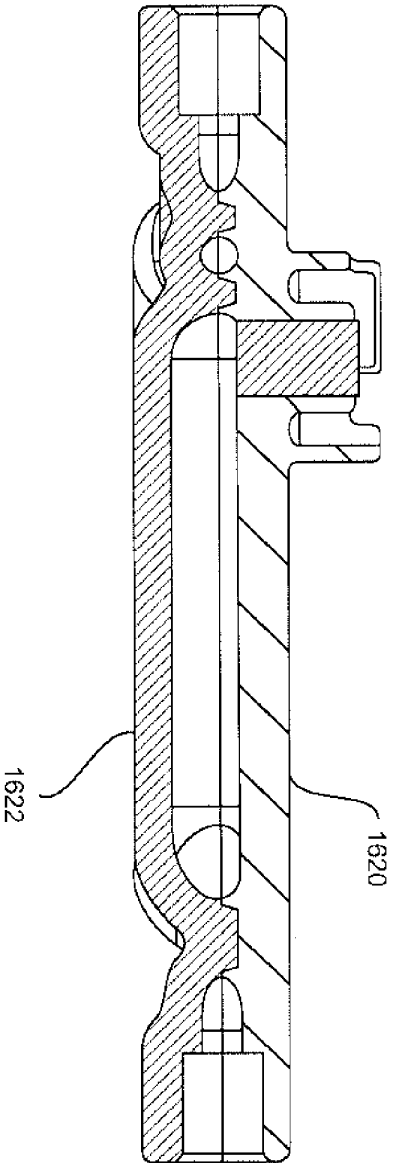


FIG. 19A

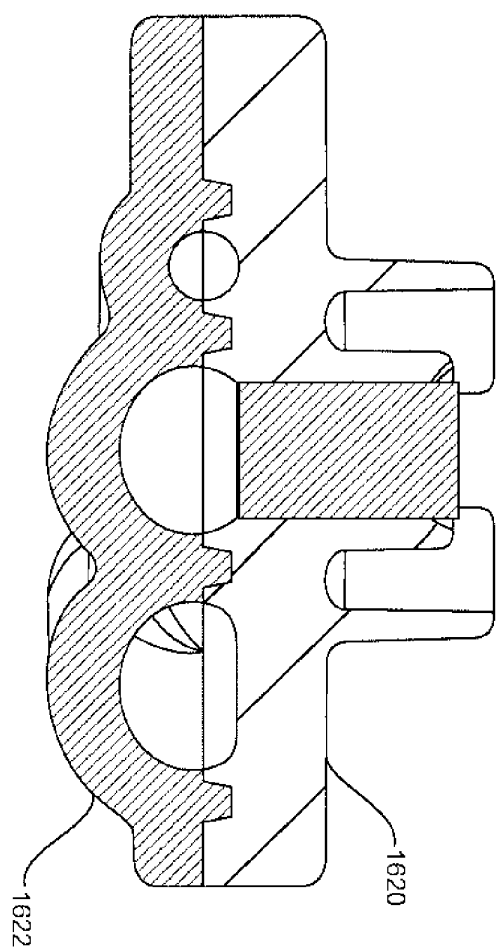
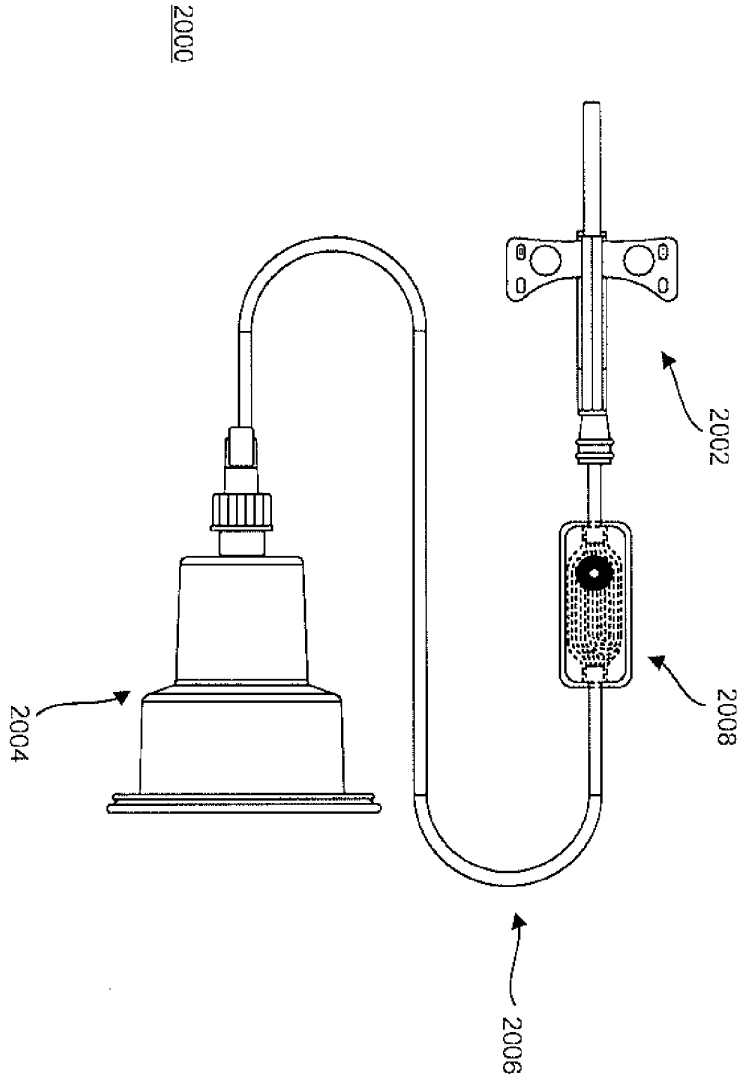


FIG. 19B

FIG. 20



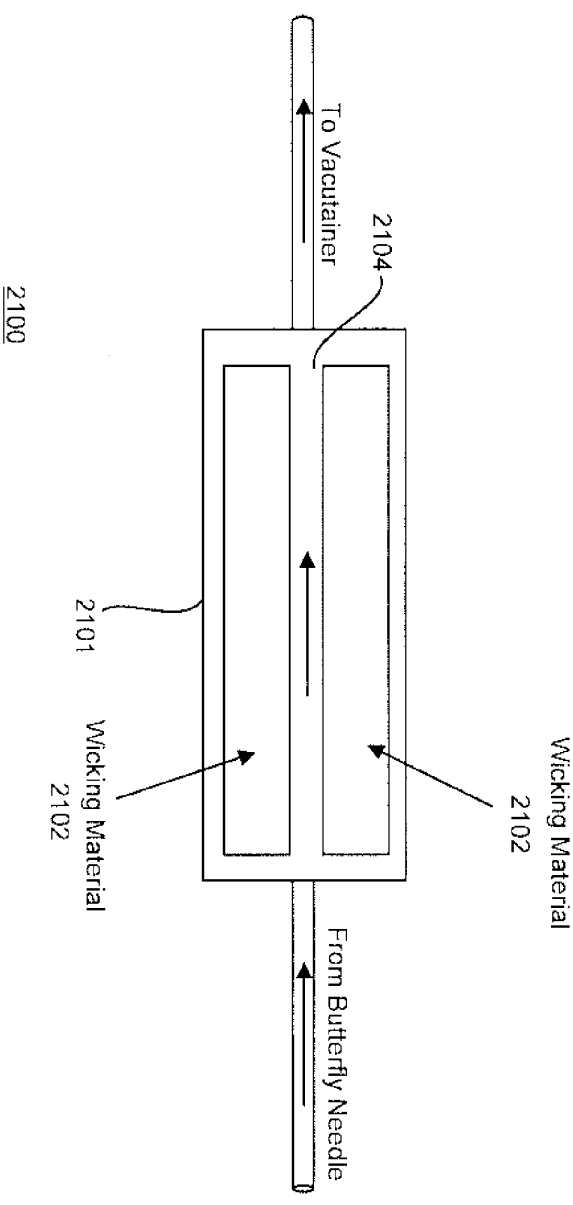
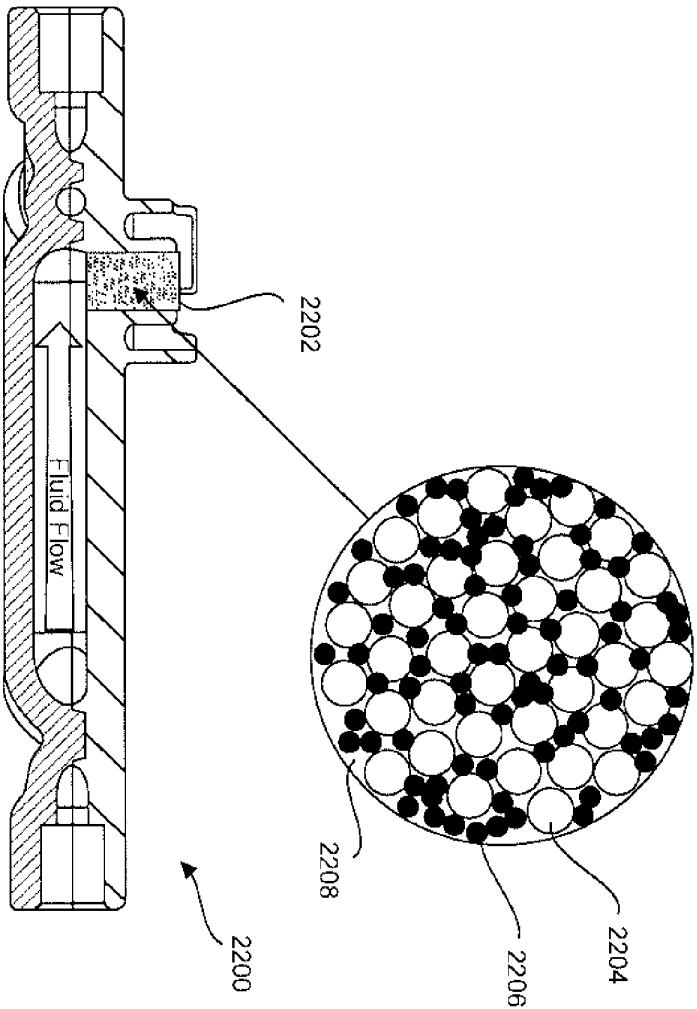


FIG. 21

FIG. 22A



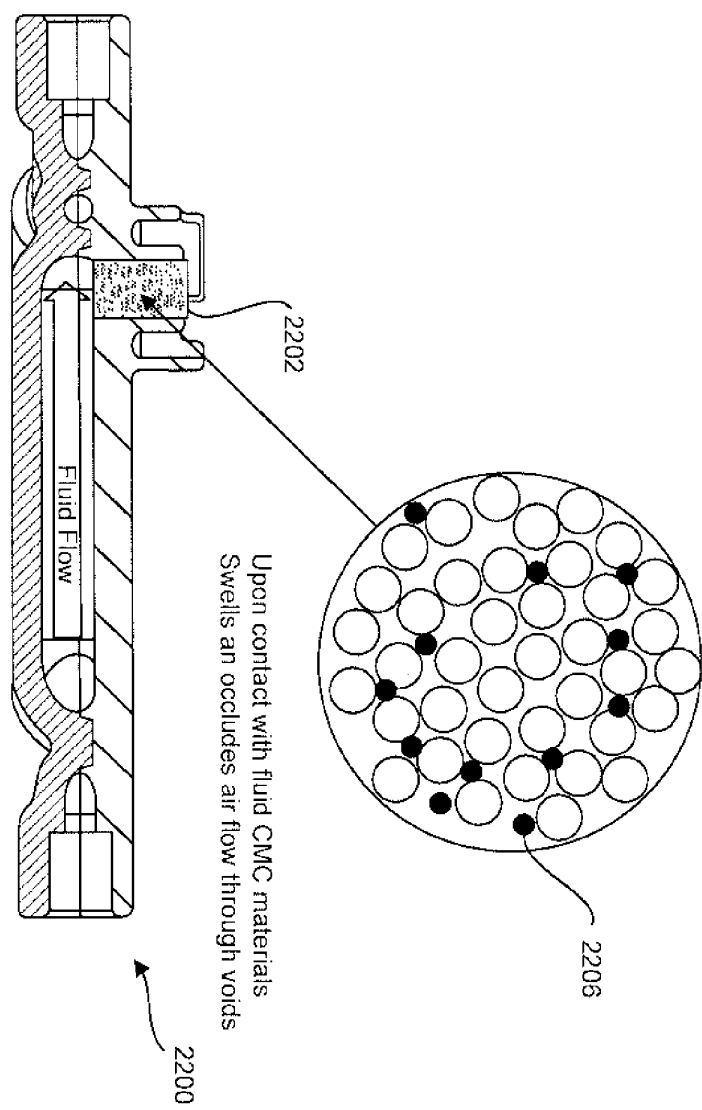


FIG. 22B

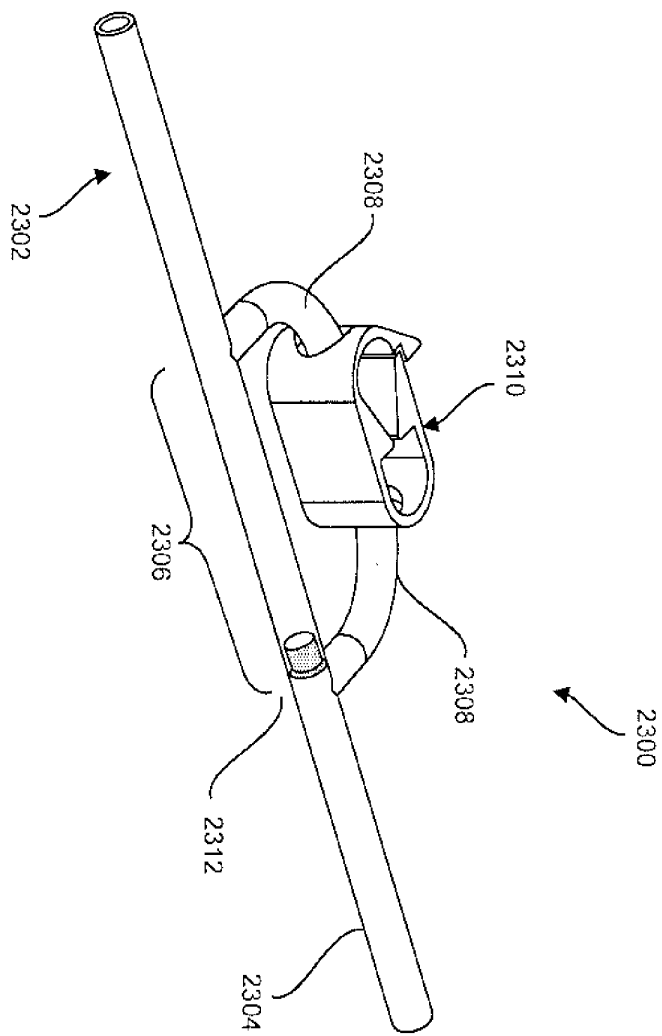


FIG. 23A

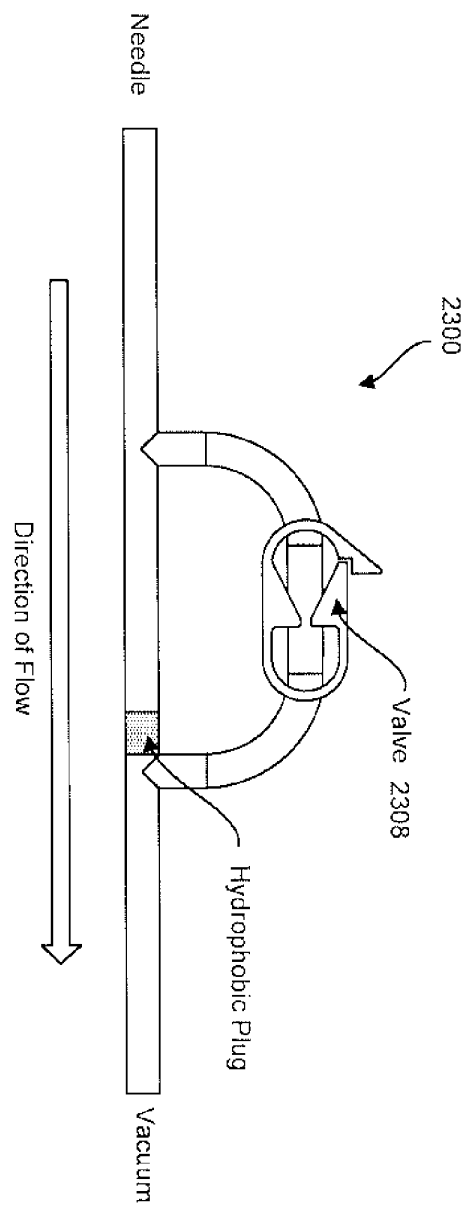


FIG. 23B

date of the parent application. And this in accordance with Section 24(3) of the law.

Attached for your kind attention are:

- The allowed Description
- The allowed Claims
- The allowed Drawings

Please review the attached documents, namely the allowed description, claims and drawings before authorizing us to pay the allowance fee. Of course, we will review the documents as well.

We additionally remind you of the continuing responsibility of the Applicant to update the ILPO with information of cited art and/or opposition procedure and/or cancellation procedures in corresponding Applications under Section 18 of the Israel Patent Law - until the payment of the allowance fee. When the Applicant becomes aware of publications or other citations that may be relevant information/material to the examination of this application, such information/material must be forwarded to us for reporting to the ILPO. Failure to disclose such information to the ILPO may result in cancellation of an issued IL patent.

2

Publications filed after this notice will not be reviewed but will be on record. Should the applicant wish to receive continued examination based on new publications, a request to file for re-examination must be filed along with an update of the list of publications.

Divisional Applications

Please be advised that pursuant to Art. 24(a) of the Act, divisional applications may be filed after the payment of the Allowance fee but before the publication. We highly recommend filing divisional applications before the payment of the allowance fee.

We look forward to receiving your instructions in due course.

Yours sincerely,



Ronen Presenti



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www.patents-il.com



Submitted herewith

- > The original notice in Hebrew.
- > The publication documents, namely, Description, Claims, Drawings.
- > Our invoice number 3264.



Reference No.: F1729JP01
Mailing No.: 662004
Mailing Date: January 16, 2024

Non-final Office Action
(Translation)

Application No.	Japanese Patent Application No. 2021-558648	
Drafting Date	January 5, 2024	
Examiner	Koji ISONO	3411 2Q00
Representative	Satoshi MURAKOSHI, et al.	
Applied Articles	Japanese Patent Act, Section 29, Paragraph 1, Item 3 (novelty)	
	Japanese Patent Act, Section 29, Paragraph 2 (inventive step)	

This application has been rejected for the grounds stated below. Applicant is invited to file a Response within three months from the mailing date of this notice.

Grounds

<Ground 1>

(Novelty) The claim(s) of this application set forth below was/were anticipated by the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are not entitled to obtain a patent under Section 29, Paragraph 1, Item 3 of the Japanese Patent Act.

<Ground 2>

(Inventive step) The claim(s) of this application set forth below would have been obvious to one ordinarily skilled in the art prior to the filing of this application, based on the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are unpatentable under Section 29, Paragraph 2 of the Japanese Patent Act.

Examiner Notes (the cited references are listed in Reference List below)

• Ground 1 (novelty) and Ground 2 (inventive step)

- As to Claims: 1 to 5, 6 to 10, and 14 to 18
- Reference cited: Reference 1
- Notes:

Reference 1 (see particularly paragraphs 0062 and 0140 to 0149 and Figs. 24A to 24B) discloses the following invention.

“A fluid sample optimization device (blood sample optimization system 2400) for optimizing a

fluid sample collected by a fluid collection device from a fluid source, a first portion of the fluid sample potentially having contaminants (see paragraphs 0062, 0141, etc.), the fluid sample optimization device comprising:

- an inlet (inlet port 2412) configured to connect with the fluid source;
- an outlet (outlet port 2414) configured to connect with the fluid collection device;
- a sample path (blood sample channel 2422) connected between the inlet and the outlet; and
- a contaminant containment reservoir (blood sequestration chamber 2418) connected between the inlet and the outlet, the contaminant containment reservoir having an air permeable fluid resistor (air permeable blood barrier 2420) proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet (see paragraph 0148 disclosing as follows: ‘As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position’ and ‘Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418’).”

Therefore, claims 1 and 14 are disclosed in Reference 1.

As for claim 2, Reference 1 discloses a housing (housing 2416) in paragraph 0146.

As for claim 3, see paragraph 0140 of Reference 1.

As for claim 4, see Figs. 29C and 30A to 30G of Reference 1.

As for claim 5, see paragraph 0144 of Reference 1.

As for claims 6 to 10, Reference 1 discloses in paragraph 0148 “a sample path (blood sample channel 2422) ..., the sample path further having a resistive plug (apertures 2424; see also the first sentence of paragraph 0148) that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path.”

Claims 14 to 18 correspond to the “sample optimization devices” of claims 1, 6, and 2 to 4, respectively, having the “fluid source” removed therefrom. Therefore, claims 14 to 18 are disclosed in Reference 1.

Accordingly, claims 1 to 5, 6 to 10, and 14 to 18 are disclosed in Reference 1.

< Allowable Subject Matters >

As to claims 11 to 13 and 19 to 20, no grounds for refusal have been found so far. Applicant would receive an additional Office Action upon finding of any other ground(s) for refusal.

<Reference List>

1. U.S. Patent Application Publication No. 2018/0271425

		Record of Search for Prior Art Literature
- Searched Field	IPC	A61B 5/15 – 5/157 G01N 1/00
- Prior Art Literature		International Publication No. WO 2019/055487

This record of search for prior art literatures does not constitute grounds for refusal.

拒絶理由通知書

特許出願の番号	特願 2 0 2 1 - 5 5 8 6 4 8
起案日	令和 6 年 1 月 5 日
特許庁審査官	磯野 光司 3 4 1 1 2 Q 0 0
特許出願人代理人	村越 智史 (ほか 4 名) 様
適用条文	第 2 9 条第 1 項第 3 号 (新規性) 第 2 9 条第 2 項 (進歩性)

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から 3 か月以内に意見書を提出してください。

理由

1. (新規性) この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記 of 刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明であるから、特許法第 2 9 条第 1 項第 3 号に該当し、特許を受けることができない。

2. (進歩性) この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記 of 刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第 2 9 条第 2 項の規定により特許を受けることができない。

記 (引用文献等については引用文献等一覧参照)

●理由 1 (新規性)、理由 2 (進歩性) について

- ・請求項 1 - 5, 6 - 1 0, 1 4 - 1 8
- ・引用文献等 1
- ・備考

引用文献 1 (特に、段落[0062], [0140]-[0149]、図24A-24B参照) には、以下の発明が記載されている。

「流体源から流体収集装置によって収集された流体サンプルを最適化するための流体サンプル最適化装置 (blood sample optimization system 2400) であって

、前記流体サンプルの第1の部分が汚染物質を潜在的に有しており（段落[0062]、[0141]等参照）、

前記流体源と接続するように構成される入口（inlet port 2412）と、

前記流体収集装置に接続するように構成される出口（outlet port 2414）と、

前記入口と前記出口との間に接続されるサンプル経路（blood sample channel 2422）と、

前記入口と前記出口との間に接続される汚染物質封じ込めリザーバ（blood sequestration chamber 2418）と

を備え、

前記汚染物質封じ込めリザーバは、前記出口に近接して空気透過性流体抵抗器（air permeable blood barrier 2420）を有し、

前記汚染物質封じ込めリザーバは、前記入口と前記出口との間に圧力差が印加されたとき、前記流体源から前記流体サンプルの第1の部分を受け取って、前記空気透過性流体抵抗器及び前記出口を通してその中の空気を移動させるように配置され、それによって、前記汚染物質封じ込めリザーバ内に、前記流体サンプルの前記第1の部分が受け取られ、かつ前記汚染物質が封じ込められると、前記流体サンプルの後続の部分は、前記入口と前記出口との間に後続の圧力差が印加されたときに、前記サンプル経路によって前記入口から前記出口へと搬送され得る（段落[0148]の“As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position.”、及び、“Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.”の記載を参照されたい。）

、流体サンプル最適化装置。」

よって、請求項1、14に係る発明は、引用文献1に記載されている。

請求項2について、引用文献1の段落[0146]には、ハウジング（housing 2416）が記載されている。

請求項3については、引用文献1の段落[0140]を参照されたい。

請求項4については、引用文献1の図29C, 30A-G等を参照されたい。

請求項5については、引用文献1の段落[0144]を参照されたい。

請求項6－10について、引用文献1の段落[0148]には、「流体サンプルの前記第1の部分の少なくとも一部及び前記汚染物質が前記サンプル経路に入ること阻止するように構成される抵抗プラグ（apertures 2424；段落[0148]冒頭の一文も参照されたい。）をさらに有するサンプル経路（blood sample channel 2422）」が記載されている。

請求項 1 4 - 1 8 について、これら請求項に係る発明は、それぞれ請求項 1 , 6 , 2 - 4 に係る「サンプル最適化装置」の発明から「流体源」を除いたものにあたり、そのため、引用文献 1 に記載されているといえる。

したがって、請求項 1－5，6－10，14－18に係る発明は、引用文献 1 に記載されている。

＜拒絶の理由を発見しない請求項＞

請求項（１１－１３，１９－２０）に係る発明については、現時点では、拒絶の理由を発見しない。拒絶の理由が新たに発見された場合には拒絶の理由が通知される。

<引用文献等一覽>

1. 米国特許出願公開第2018/0271425号明細書

＜先行技術文献調査結果の記録＞

・調査した分野 I P C A61B 5/15-5/157
G01N 1/10

・先行技術文献
国際公開第2019/055487号

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27500 7590 07/19/2023 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER NGUYEN, HUONG Q	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

DETAILED ACTION

This office action is responsive to the amendment filed 5/22/2023. Claims 1-4, 6-7, and 32-41 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "junction" in **Claims 3-4 and 40-41** must be shown *with element numbers* or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the

filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

- (A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;
- (B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g., “means for”) or another linking word or phrase, such as “configured to” or “so that”; and
- (C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step”) in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as

otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL. — The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 40-41 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims recite a junction connecting the inlet port, sampling channel, and the chamber. However, as the instant invention appears to be drawn to the embodiment in Figure 24 and said junction has not been identified in Figure 24 per the drawing objection above, it is unclear that applicant has proper support for the embodiment of Figure 24 with the moving part having a first and second position along with said junction as claimed. If support exists for said junction, applicant is requested to point out portions of the disclosure showing said support.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 1-4, 6-7, 32, 34-38, and 40-41 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al (US Pat No. 3848581) in view of Eldridge (US Pat No. 4207870).

In regard to Claim 1, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood, thus bypassing the first test tube/chamber as defined; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

2. Eldridge discloses the material is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

3. Cinqualbre et al disclose a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

4. Cinqualbre et al disclose wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

6. Cinqualbre et al disclose wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

7. Cinqualbre et al disclose the moving part 11 as defined further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled, the user can close the valve 11 to move it into the closed position so that the next test tube in the series can be

filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

32. Cinqualbre et al disclose wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

In regard to Claim 34, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

35. Eldridge discloses the device in accordance with claim 34, wherein the air permeable blood barrier is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

36. Cinqualbre et al disclose the device in accordance with claim 34, wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling

channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

37. Cinqualbre et al disclose the device in accordance with claim 36, the moving part further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled with blood, the user can close the valve 11 to move it into closed position so that the next test tube in the series can be filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

38. Cinqualbre et al disclose the device in accordance with claim 36, wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

40. Cinqualbre et al disclose the device in accordance with claim 34, further comprising a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

41. Cinqualbre et al disclose the device in accordance with claim 40, wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

Claim(s) 33 and 39 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al in view of Eldridge, further in view of Vaillancouert (US Pat No. 6126643).

Cinqualbre et al in view of Eldridge disclose the inventio above but do not expressly disclose a locking mechanism configured to maintain the moving part in the first position until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Vaillancouert teach that it is well-known in the art to provide an analogous blood sampling device comprising a locking mechanism 24 that enables plunger 21 to be releasably locked relative to barrel 11 so that blood is selectively introduced into the syringe, best seen in Figure 4-5 (Col.4: 63-Col.5: 53). Vaillancouert also teaches that other suitable releasable locking means may also be used to secure the plunger 21 relative to the barrel 11 (Col.5: 8-9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the invention of Cinqualbre et al in view of Eldridge such that there is a locking mechanism configured to selectively maintain the moving part in the first position until the chamber is filled, as taught by Vaillancouert, to effectively prevent the moving part (valve 11 of Cinqualbre et al) from prematurely closing the window 12 before blood sufficiently fills chamber 5 (defined as first test tube on left), which when combined with the user, would thus provide force to overcome the locking mechanism to enable movement of the moving part to the second position as desired. It is noted that the disclosure does not provide any detail into how force would overcome the locking mechanism other than as broadly as has been claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or impropertimewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used.

Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 3, and 20-21 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a

housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 and 8-9 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Response to Arguments

Applicant's arguments with respect to claim(s) above have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

The previous Drawing objections and 112 rejections are moot in light of applicant's amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.Q. NGUYEN
Examiner
Art Unit 3791

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791



Espacenet

Bibliographic data: WO9605875 (A1) — 1996-02-29

CLOSED SYSTEM BLOOD SAMPLING DEVICE

Inventor(s): DESECKI VINCENT C; BROWNE GLENNIE ± (DESECKI, VINCENT, C, ; BROWNE, GLENNIE)

Applicant(s): BAXTER INT [US] ± (BAXTER INTERNATIONAL INC)

Classification: - international: A61B5/15; (IPC1-7): A61M5/00
- cooperative: A61B5/15003 (EP, US); A61B5/150213 (EP, US);
A61B5/150259 (EP, US); A61B5/150992 (EP, US);
A61B5/155 (EP, US)

Application number: WO1995US10702 19950822 Global Dossier

Priority number(s): US19940296207 19940825

Also published as: ATE208640 (T1) AU3412795 (A) AU686450 (B2)
CA2173331 (A1) DE69523887 (T2) more

Abstract of WO9605875 (A1)

The invention comprises a closed system blood sampling device comprising a bifurcated capillary tube (10) which has a first branch (12) having a cannula shaped end (14) for withdrawing and conveying blood to a communicating blood collection zone. The second branch of the bifurcated capillary tube (32) is connected to and is in fluid communication with the blood collection zone. It terminates in an opening adapted to receive a blood withdrawal device.

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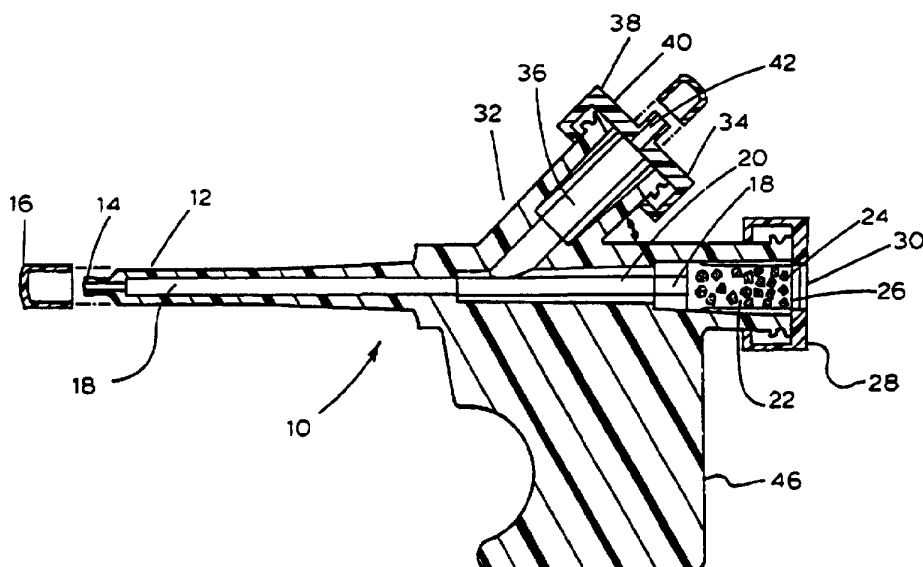


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<p>(21) International Application Number: PCT/US95/10702</p> <p>(22) International Filing Date: 22 August 1995 (22.08.95)</p> <p>(30) Priority Data: 08/296,207 25 August 1994 (25.08.94) US</p> <p>(71) Applicant: BAXTER INTERNATIONAL INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US).</p> <p>(72) Inventors: DESECKI, Vincent, C.; 28420 West Big Hollow Road, Ingleside, IL 60041 (US). BROWNE, Glennie; 944 Hidden Lake Drive, Buffalo Grove, IL 60089 (US).</p> <p>(74) Agents: NICHOLS, Jeffrey, C. et al.; One Baxter Parkway, Deerfield, IL 60015 (US).</p>		<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: CLOSED SYSTEM BLOOD SAMPLING DEVICE



(57) Abstract

The invention comprises a closed system blood sampling device comprising a bifurcated capillary tube (10) which has a first branch (12) having a cannula shaped end (14) for withdrawing and conveying blood to a communicating blood collection zone. The second branch of the bifurcated capillary tube (32) is connected to and is in fluid communication with the blood collection zone. It terminates in an opening adapted to receive a blood withdrawal device.

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CLOSED SYSTEM BLOOD SAMPLING DEVICE

FIELD OF THE INVENTION

The invention relates to closed system blood sampling devices.

5 BACKGROUND OF THE INVENTION

Arterial blood gas sampling is a standard procedure often used to help assess respiratory function in the critically ill. In some cases, samples can be drawn as many as 20 times a day.

For the typical neonatal patient weighing 1000 grams and
10 having approximately 85 cc of total body fluid capacity, the volume of blood samples becomes a critical factor.

A technique called the 3 drop method is gaining substantial clinical acceptance in neonatal units across the country. This method calls for inserting a blunt hypodermic
15 needle as far as possible into a standard sleeve stoppered T-Connector. Three drops of blood estimated to be approximately .06 cc are allowed to drip onto a gauge pad, thereby clearing the cannula of heparinized or non-circulating blood while providing a fresh arterial sample to the surface. 3 more drops
20 are then collected in a micro container followed by cannula withdrawal. Blood cannula contents within the cannula lumen and the previously collected micro container sample are then aspirated into a tuberculin type syringe for transport to the blood lab for testing. A flush of the T-Connector to eliminate residual
25 blood then ensues. This procedure provides the ability to withdraw a controlled blood volume; .06 cc as necessary

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discard and .12 cc to perhaps .20 cc for actual blood gas testing.

Several opportunities for procedural improvement exist. One challenge is the open environment method of collection which could foster blood contamination and/or the spread of infectious diseases. Secondly, the collection process in regard to volume accuracy is difficult to control and highly sensitive to variations in clinician technique, catheter positioning and arterial pressure. If a device can be designed for closed system collection which could also insure consistency of sample volume time after time, treatment of neonatal patients where blood volume levels are critical, accuracy improvements could be a major clinical benefit.

THE DRAWINGS

Fig. 1 is a horizontal cut away side view showing the closed system blood sampling device of the invention.

Fig. 2 is a vertical, partial schematic view showing the closed system blood sampling device connected to an injection site which, in turn, is fitted into a venipuncture device used to withdraw arterial blood.

In the drawings, like parts have like numbers.

THE INVENTION

The invention is a closed system blood sampling device comprising a bifurcated capillary tube which has a first branch having a cannula shaped end for withdrawing and conveying blood to a communicating blood collection zone. The blood

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collection zone is for storing a quantity of withdrawn blood. It also feeds an initial fraction of withdrawn blood to a communicating blood disposal chamber which has an air permeable liquid sealed end.

5 The second branch of the bifurcated capillary tube is connected to and is in fluid communication with the blood collection zone. It terminates in an opening adapted to receive a blood withdrawal device.

10 In preferred embodiments the closed system blood sampling device the cannula shaped end is blunt, the blood disposal chamber has its end fitted with a cap containing an air permeable hydrophobic membrane, and the blood disposal chamber contains a porous blood adsorbent. The second branch has an interior angle not greater than 90 degrees and preferably
15 the interior angle is 60 degrees. It is also desirable that the cannula shaped end be tapered so that it snugly fits into the preferred injection sites more fully described hereafter.

20 Preferably, the closed system blood sampling device is removed from the injection site before the blood sample is withdrawn therefrom by means such as a tuberculum syringe or aspirated directly into a blood gas analyzer.

 While the closed blood sampling device is particularly suited for obtaining neonatal blood samples it is readily adapted to obtain samples from a variety of patient types.

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DETAILED DESCRIPTION OF THE INVENTION

In Fig. 1 the closed system blood sampling device is designated generally by the numeral 10. It is preferably constructed of a clear chemically inert non-toxic plastic such as polycarbonate. It comprises a blood withdrawal cannula shaped end 12. The cannula tip 14 is blunt and necked down to prevent injection site from blood flash back during arterial sampling. To maintain sterility the cannula tip is fitted with a removable cap 16 which is removed just before the blood sampling device is to be used.

Fig. 1 shows the cannula shaped end 12 to be tapered. This particular configuration was selected so that the cannula may engage and generally mate with a particular injection site, the details of which will be more fully described hereafter. The interior bore 18 of the cannula shaped end is dimensioned to allow withdrawn blood to move along the bore by means of capillary action driven by normally positive arterial blood pressure.

The interior capillary bore 18 connects with and continues into a larger outer diameter lumen 20. The continuous bore 18 of the cannula 12 and the lumen 20 comprise a blood collection zone. Bore 18 as it exits the lumen 20 empties into blood disposal chamber 22. In a preferred embodiment of the invention, blood disposal chamber 22 contains a blood retaining means such as adsorbing material 24 which may be rayon or cellulosic wadding. The open end 26 of the blood disposal

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chamber 22 is closed with a cap 28 that has its top fitted with a liquid tight, air permeable hydrophobic membrane 30 which allows air to be evacuated from the blood sampling device 10 of the invention. A suitable membrane material is sheet
5 polytetrafluoroethylene having a thickness of about 0.8 microns.

Fitted to the lumen 20, and in fluid communication therewith, is the second branch or port 32. It is positioned so as to have an interior angle 34 not exceeding 90 degrees. The interior angle is preferably about 60 degrees. The bore 36
10 connects with and corresponds in dimension with bore 18. Port 32 terminates and is sealed by adapter cap 38 whose top 40 is fitted with a capillary luer 42. The capillary luer is protected from contamination by means of protective cap 44 which is removed just prior to blood being withdrawn from the closed
15 blood sampling device. The port 32 and its bore 36 form a part of the blood collection zone previously described. For convenience of use, the closed blood sampling device is fitted with pistol grip handle 46.

The blood collection zone has a larger liquid capacity than
20 the liquid capacity of the blood disposal chamber. If the closed blood sampling device described were to be used in neonatal blood sampling, the liquid capacity of the blood collection zone might be 0.12 cc and the liquid capacity of the blood disposal chamber 22 would be about 0.06 cc.

25 The use of the closed blood sampling device of the invention to withdraw and sample blood is illustrated in Fig. 2 which shows artery 48 in communication with a venipuncture

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device 50 which was inserted through subcutaneous tissue 52. The neck 54 of the venipuncture device 50 is adapted to receive an injection site 56. While conventional injection sites may be used as such or adapted to be used in the practice of the invention, it is preferred that the injection site be of the type having a resilient resealable septum which is preferably pre-slit. An injection site of this type is available from Baxter Healthcare Corporation and is a Neonatal T-Connector Luer sold under the brand name, InterLink, a registered trademark of Baxter Healthcare Corporation.

Such pre-slit, resilient, resealable injection sites and their method of fabrication are described in U.S. 5,188,620 the disclosure of which is incorporated herein by reference. The pre-slit resilient resealable injection sites described in this patent are designed to receive blunt cannulas. Another injection site related to the injection sites detailed in U.S. 5,188,620 is described in U.S. 5,300,034. This patent also details numerous publications and references which describe the preferred injection sites used in the practice of this invention. This patent and the publications listed therein also are incorporated herein by reference.

The injection site 56 is fitted with T-connector 58 which, in turn, is fitted with microbore tubing which, through female luer 62, is connected to IV line 64. The distal end 64 of the injection site 56 is connected to the neck 54 of the venipuncture device 50. The proximal end 66 of the injection site 56 is fitted with a pre-slit resilient resealing septum 68 adapted to receive

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the blood withdrawal cannula 12 which is dimensioned to fit snugly into the injection site. Inserted into the second branch or
160 port 32 is a conventional syringe 70, such as a tuberculum blood draw syringe, or an arterial blood gas loss of resistance syringe.

The device's cannula 12 would be inserted through the septum 68 of the injection site 56 and positioned so that the tip
165 14 of the cannula 12 was fully inserted into the injection site adjacent to the venipuncture device. In doing so, the residual volume of the actual T-Housing would be eliminated as a measurable factor in blood draw volume. Arterial pressure would cause blood flow to enter and flow up the device via
170 capillary action. As blood moved up the hydrophobic membrane 30 of the device, air would escape via the upstream hydrophobic membrane 30. Original blood first present in the catheter would be pushed beyond the luer bifurcation for retention in the device and eventual disposal. The device would
175 be withdrawn from the T-Connector as soon as visual confirmation of the blood filled lumen was made. The vented removal cap 44 would be removed from the bifurcated luer 42 and replaced by the syringe 70 which would be aspirated to remove the arterial blood sample. Residual blood volume
180 upstream of the bifurcation would remain in the device for subsequent disposal.

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WE CLAIM:

1. A closed system blood sampling device comprising a bifurcated capillary tube comprising:

- 5 a. a first branch having a cannula shaped end for withdrawing and conveying blood to a communicating;
- b. blood collection zone for storing a quantity of withdrawn blood and feeding an initial fraction of withdrawn blood to a communicating;
- 10 c. blood disposal chamber having an air permeable liquid sealed end; and,
- d. a second branch connected to and in fluid communication with the blood collection zone which terminates in an opening adapted to
15 receive a blood withdrawal device.

2. The closed system blood sampling device of Claim 1 where the cannula shaped end is blunt, the blood disposal chamber has its end fitted with a cap containing an air permeable hydrophobic membrane, and the blood disposal
5 chamber contains a porous blood adsorbent.

3. The closed system blood sampling device of Claim 1 where the second branch has an interior angle not greater than 90 degrees.

4. The closed system blood sampling device of Claim 3 where the second branch has an angle of about 60 degrees.

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5. The closed system blood sampling device of Claim 2 where the cannula shaped end is tapered.

6. The closed system blood sampling device of Claim 2 where the blunt cannula shaped end is adapted to be received by a injection site which contains a resilient resealing means.

7. The closed system blood sampling device of Claim 6 where the injection site is a pre-slit injection site.

8. The closed system blood sampling device of Claim 2 where the blood collection zone has a volume greater than the volume of the blood disposal chamber.

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9. A method of sampling blood from a patient having an artery fitted with a venipuncture device which is attached to an injection site containing the closed blood sampling device of Claim 1 which comprises the steps of:

- 5 a. withdrawing blood through the cannula shaped end of the closed blood sampling device thereby sequentially filling the blood disposal chamber and then the blood collection zone;
- 10 b. withdrawing through the opening in the second branch the blood contained in the blood collection zone for subsequent processing; and, then,
- c. discarding the closed system blood sampling device

10. The method of Claim 9 where the cannula is blunt, the blood disposal chamber has its end fitted with a cap containing an air permeable hydrophobic membrane, and contains a porous blood adsorbent.

11. The method of Claim 9 where the second branch has an interior angle not greater than 90 degrees.

12. The method Claim 11 where the second branch has an angle of about 60 degrees.

13. The method of Claim 10 where the cannula shaped end is tapered.

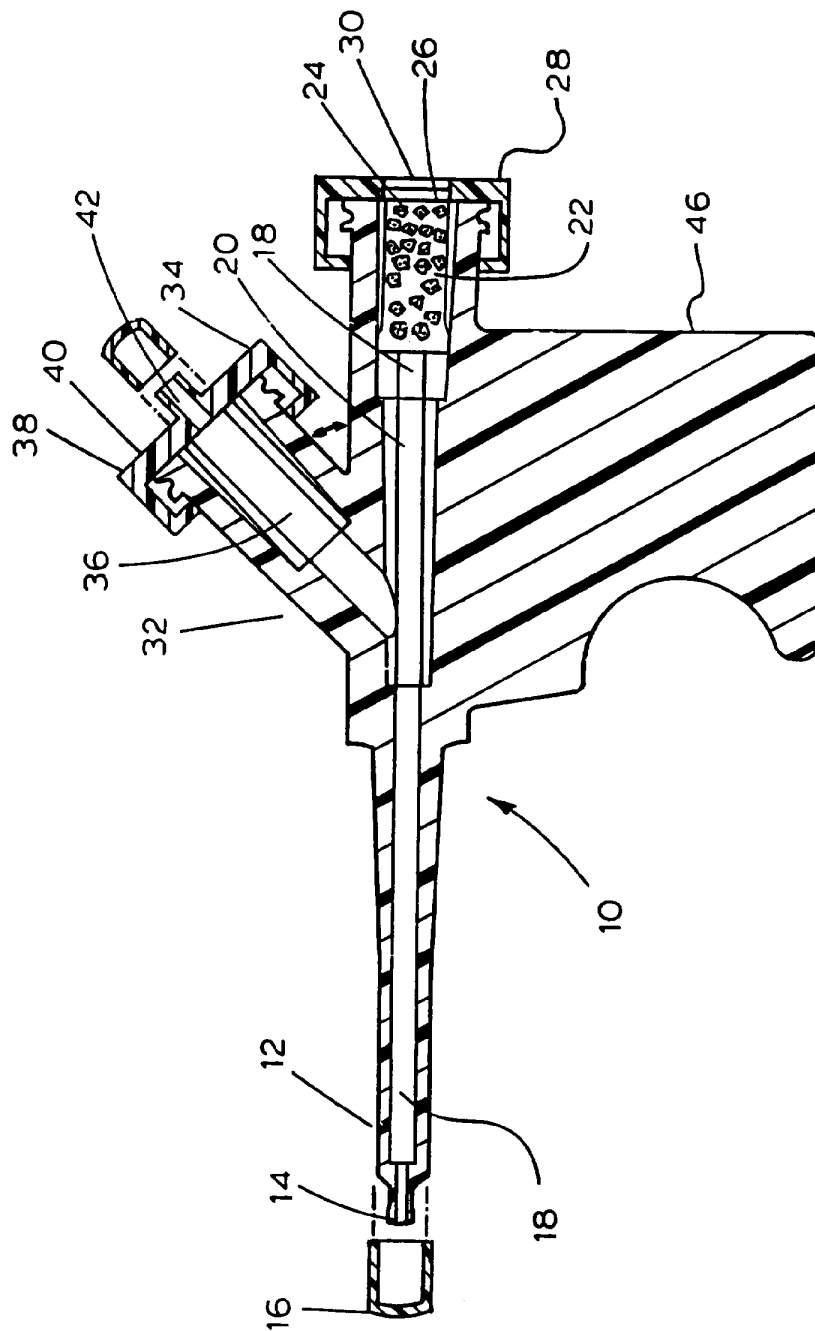
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14. The method of Claim 10 where the blunt cannula shaped end is adapted to be received by a injection site which contains a resilient resealing means.

15. The method of Claim 14 where the injection site is a pre-slit injection site.

16. The method of Claim 10 where the blood collection zone has a volume greater than the volume of the blood disposal chamber.

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SUBSTITUTE SHEET (RULE 26)

FIG. 1

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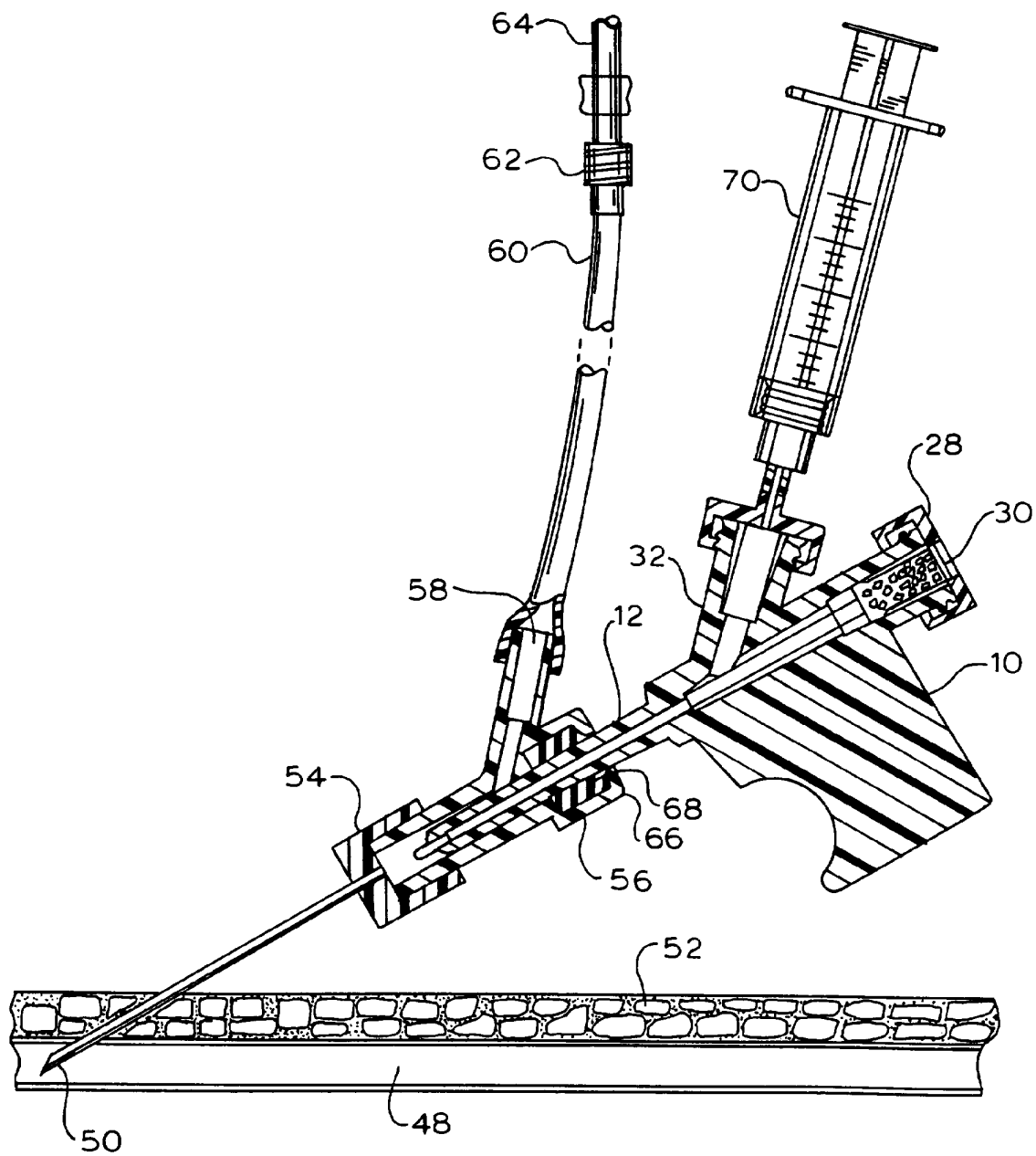


FIG. 2
SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/10702**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) : A 61M 5/00

US CL : 604/122

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/122, 35, 125, 126, 128, 256, 258, 283, 284
128/ 760, 762, 767, 768

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US, A, 4,531,937 (Yates) 30 July 1985, See Entire Reference	1-7,9-15 ----- 8,16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 08 DECEMBER 1995	Date of mailing of the international search report 04 JAN 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer SAM RIMELL
Facsimile No.	Telephone No. (703) 308-0858

Reference No.: 0575273
Mailing No.: 092516
Mailing Date: February 27, 2024

Non-final Office Action
(Translation)

Application No.	Japanese Patent Application No. 2023-076490	
Drafting Date	February 26, 2024	
Examiner	Yoshinori TAKA	9813 2Q00
Representative	Satoshi MURAKOSHI	
Applied Articles	Japanese Patent Act, Section 36, Paragraph 6, Item 2 (clearness) Japanese Patent Act, Section 36, Paragraph 6, Item 1 (support requirement) Japanese Patent Act, Section 29, Paragraph 1, Item 3 (novelty) Japanese Patent Act, Section 29, Paragraph 2 (inventive step)	

This application has been rejected for the grounds stated below. Applicant is invited to file a Response within three months from the mailing date of this notice.

Grounds

<Ground 1>

(Clearness) This application does not conform to Section 36, Paragraph 6, Item 2 of the Japanese Patent Act in the following points.

<Ground 2>

(Support requirement) This application does not conform to Section 36, Paragraph 6, Item 1 of the Japanese Patent Act in the following points.

<Ground 3>

(Novelty) The claim(s) of this application set forth below was/were anticipated by the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are not entitled to obtain a patent under Section 29, Paragraph 1, Item 3 of the Japanese Patent Act.

<Ground 4>

(Inventive step) The claim(s) of this application set forth below would have been obvious to one ordinarily skilled in the art prior to the filing of this application, based on the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are unpatentable under Section 29, Paragraph 2 of the Japanese Patent Act.

Examiner Notes (the cited references are listed in Reference List below)

- As to Ground 1 (clearness) and Ground 2 (support requirement)

(1) Claims 1 to 15

In claims 1 to 15, the following points are not clear.

(A) The device includes a first junction that connects the inlet port with the sampling channel and the chamber.

(B) The device includes a second junction, different from the first junction, that connects the outlet port with the sampling channel and the chamber.

Thus, the technical relationship is unclear among the inlet port, the outlet port, the sampling channel, and the chamber.

Claim 1 recites that the chamber is “connected with the inlet port and the outlet port.” This recitation could only specify that the chamber fluidically communicates with the inlet port and the outlet port (therefore, as in Reference 2 cited below, this recitation encompasses the case where the chamber is connected at only one location with a channel connecting between the inlet port and the outlet port).

Claim 1 also recites that the sampling channel is “connected with the inlet port.” This recitation does not indicate that the sampling channel is “connected with the inlet port and the outlet port.”

Further, a device lacking in the above features (A) and (B) is not at all described in the Detailed Description of the Invention.

Accordingly, claims 1 to 15 lacking in the above features (A) and (B) are unclear (Ground 1) and are not described in the Detailed Description of the Invention (Ground 2).

If the above features (A) and (B) are clearly recited, “the junction” recited in claim 11 should rightly be “the first junction and the second junction.”

(2) Claims 1 to 15

Claim 1 recites that the chamber is “connected with the inlet port and the outlet port.” This recitation specifies that the chamber is connected with the outlet port as well as with the inlet port.

According to the Detailed Description of the Invention, the chamber is connected with the outlet port as well as with the inlet port for the purpose that the device is configured such that,

(C) “when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber.”

The technical significance of the chamber being connected with the outlet port as well as with the inlet port is clear only when it is specified that the device achieves the above operation (C). The Detailed Description of the Invention does not at all describe a device having a chamber “connected with the inlet port and the outlet port” but not achieving the above operation (C).

The Detailed Description of the Invention describes the following feature for the device to achieve the above operation (C).

(D) “A material that is air permeable and blood impermeable is located at a distal end of the chamber.” The Detailed Description of the Invention does not at all describe a device achieving the above operation (C) but lacking in the above feature (D).

However, claim 1 and claims 2 to 15 depending on claim 1 do not specify that the device achieves the above operation (C) and satisfies the above feature (D). Thus, these claims are unclear (Ground 1) and are not described in the Detailed Description of the Invention (Ground 2).

(3) Claim 14

Claim 14 recites “the housing comprises a bottom member mated with a top member.” This recitation does not indicate that the housing comprises the top member. If the housing does not comprise the top member, claim 14 is not described in the Detailed Description of the Invention. It is unclear whether this recitation is intended to mean “the housing comprises a top member and a bottom member mated therewith.”

Accordingly, claim 14 is unclear (Ground 1) and is not described in the Detailed Description of the Invention (Ground 2).

• As to Ground 3 (novelty) and Ground 4 (inventive step)

- As to Claims: 1, 4, 8, 10, 11, and 15

- Reference cited: Reference 1

- Notes:

Reference 1 (page 3, lower left column, line 15 to page 7, upper left column, line 20 and Figs. 1 to 9) discloses the following.

A device comprising:

an inlet port (an inner end (inner opening 30) of a first puncture needle 14 that communicates with a chamber 28, or an inner end 39 of a second puncture needle 15 protruding into the chamber 28) for receiving a blood sample;

an outlet port (a tip end of an outer extension portion of the second puncture needle 15);

a chamber (the space containing the porous plug (porous member that is gas permeable and liquid impermeable) 52 and the space between the hole 48 and the porous plug 52, in the inner cavity 51 of the second puncture needle 15) connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable (the porous plug (porous member that is gas permeable and liquid impermeable) 52); and

a sampling channel (cavity 46) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

As to claim 8, the sleeve valve 41 of Reference 1 corresponds to the “valve” of claim 8.

As to claims 10 and 11, the location of the hole 48 of the inner cavity 51 corresponds to the “junction” of claims 10 and 11.

As to claim 15, the first puncture needle 14 of Reference 1 corresponds to the “patient needle” of claim 15, and the vessel holder 19 and the vacuum blood collection vessel 16 of Reference 1 correspond to the “sample collection device” of claim 15.

Accordingly, claims 1, 4, 8, 10, 11, and 15 are disclosed in Reference 1.

Also, claims 1, 4, 8, 10, 11, and 15 could have been readily devised by those skilled in the art

bead on Reference 1.

- As to Claims: 1, 4 to 6, 8, 13, and 15

- Reference cited: Reference 2

- Notes:

Reference 2 (paragraphs 0004 to 0015, Figs. 1 to 4, and the claims) discloses the following.

A device comprising:

an inlet port (one end 1a of the needle tube 1) for receiving a blood sample;

an outlet port (the other end 1b of the needle tube 1);

a chamber (the passage 21 in the needle tube support 2) connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable (air permeable and blood impermeable member 23); and

a sampling channel (the needle tube 1) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

For the features recited in claims 5 and 6, see Reference 2 (in particular, paragraph 0011).

As to claim 8, the rubber cap 4 or (D) that covers and seals the edge surface of the other end 1b of the needle tube 1 in Reference 2 (paragraphs 0014 and 0006) corresponds to the “valve” of claim 8.

As to claim 13, the needle tube support 2 of Reference 2 corresponds to the “housing” of claim 13.

As to claim 15, the needle tube 1 of Reference 2 corresponds to the “patient needle” of claim 15, and the vacuum blood collection tube of Reference 2 (paragraphs 0004, 0005, and 0012) corresponds to the “sample collection device” of claim 15.

Accordingly, claims 1, 4 to 6, 8, 13, and 15 are disclosed in Reference 2.

Also, claims 1, 4 to 6, 8, 13, and 15 could have been readily devised by those skilled in the art based on Reference 2.

• As to Ground 4 (inventive step)

- As to Claims: 9 and 12 to 14

- Reference cited: Reference 1

- Notes:

The features of claims 9 and 12 to 14 could have been devised as necessary by those skilled in the art, and thus claims 9 and 12 to 14 could have been readily devised by those skilled in the art based on Reference 1.

- As to Claims: 5 to 7

- References cited: References 1 to 3

- Notes:

In a blood sample collection device, use of an air permeable and blood impermeable material that is hydrophobic or hydrophilic is conventional. See Reference 2 (disclosing the hydrophobic material

in paragraph 0011 and a hydrophilic material in paragraph 0013) and Reference 3 (paragraph 0023 and Fig. 3). Claims 5 to 7 could have been readily devised by those skilled in the art based on References 1 to 3.

- As to Claims: 9, 12, and 14
- Reference cited: Reference 2
- Notes:

The features of claims 9, 12, and 14 could have been devised as necessary by those skilled in the art, and thus claims 9, 12, and 14 could have been readily devised by those skilled in the art based on Reference 2.

- As to Claim: 7
- References cited: References 2 and 3
- Notes:

In a blood sample collection device, use of an air permeable and blood impermeable material that is hydrophilic is conventional. See Reference 2 (disclosing a hydrophilic material in paragraph 0013) and Reference 3 (paragraph 0023 and Fig. 3). Claim 7 could have been readily devised by those skilled in the art based on References 2 and 3.

<Reference List>

1. Japanese Patent Application Publication No. Sho 58-25146
2. Japanese Patent Application Publication No. 2001-424
3. Japanese Patent Application Publication No. 2013-240628

Record of Search for Prior Art Literature

- Searched Field IPC A61B 5/06 – 5/22

- Prior Art Literature

U.S. Patent Application Publication No. 2008/0145933

This record of search for prior art literatures does not constitute grounds for refusal.

拒絶理由通知書

特許出願の番号	特願 2 0 2 3 - 0 7 6 4 9 0
起案日	令和 6 年 2 月 2 6 日
特許庁審査官	▲高▼ 芳徳 9 8 1 3 2 Q 0 0
特許出願人代理人	村越 智史 様
適用条文	第 3 6 条第 6 項第 2 号 (明確性) 第 3 6 条第 6 項第 1 号 (サポート要件) 第 2 9 条第 1 項第 3 号 (新規性) 第 2 9 条第 2 項 (進歩性)

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から 3 か月以内に意見書を提出してください。

理由

1. (明確性) この出願は、特許請求の範囲の記載が下記の点で、特許法第 3 6 条第 6 項第 2 号に規定する要件を満たしていない。
2. (サポート要件) この出願は、特許請求の範囲の記載が下記の点で、特許法第 3 6 条第 6 項第 1 号に規定する要件を満たしていない。
3. (新規性) この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明であるから、特許法第 2 9 条第 1 項第 3 号に該当し、特許を受けることができない。
4. (進歩性) この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第 2 9 条第 2 項の規定により特許を受けることができない。

記 (引用文献等については引用文献等一覧参照)

●理由 1 (明確性) および理由 2 (サポート要件) について

(1) 請求項 1 ～ 1 5

請求項 1 ～ 1 5 において、

(A) 装置が、入口ポートとサンプリング流路とチャンバとを接続する第1の分岐点を備えること

(B) 装置が、出口ポートとサンプリング流路とチャンバとを接続する、前記第1の分岐点とは異なる第2の分岐点を備えること

が明らかでなく、入口ポート、出口ポート、サンプリング流路、チャンバの間の技術的な関係が明らかでない。

請求項1における、チャンバに関する「前記入口ポートと前記出口ポートとに接続され」との記載は、チャンバが、前記入口ポートと前記出口ポートとに流体的に連通していれば足りる（したがって、後出の引用文献2のように、入口ポートと出口ポートとを結ぶ流路上に、チャンバが、1箇所のみで接続される場合を含む）との疑義を生じている。

また、請求項1における、サンプリング流路に関する「前記入口ポートと接続されており」との記載からは、そもそも、サンプリング流路が「前記入口ポートと前記出口ポートとに接続されて」いることが明らかでない。

また、上記(A)および(B)の事項を欠く装置は、発明の詳細な説明に何ら記載されていない。

したがって、上記(A)および(B)の事項を欠く請求項1～15に係る発明は、明確でない(理由1)と共に、発明の詳細な説明に記載されたものとはいえない(理由2)。

尚、上記(A)および(B)の点を明確化した場合、請求項11における「前記分岐点」は、正しくは、「前記第1の分岐点および前記第2の分岐点」であるものと認められる。

(2) 請求項1～15

請求項1には、チャンバに関して、「前記入口ポートと前記出口ポートとに接続され」と記載されており、チャンバが、前記入口ポートのみならず、前記出口ポートにも接続されていることが特定されている。

発明の詳細な説明によれば、チャンバが入口ポートのみならず出口ポートにも接続されているのは、装置が、

(C) 「出口ポートで吸引力が加えられると、血液が入口ポートに吸い込まれ、チャンバ内に流入する」

という動作を実現するためであり、装置が上記(C)の動作を実現することを特定することにより、はじめて、チャンバが入口ポートのみならず出口ポートにも接続されていることの技術的意味が明らかになる。また、発明の詳細な説明には、チャンバが「前記入口ポートと前記出口ポートとに接続され」る装置として、上記(C)の動作を実現しないものは、何ら記載されていない。

また、装置が上記(C)の動作を実現するための構成として、発明の詳細な説明には、

(D) 「空気透過性であり血液不透過性である材料が、チャンバの遠位端に配置

されること」

が記載されており、上記（C）の動作を実現する装置として、上記（D）の事項を欠くものは、発明の詳細な説明に何ら記載されていない。

しかしながら、請求項 1 とこれに従属する請求項 2 ～ 1 5 に係る発明は、装置が上記（C）の動作を実現すること、および、上記（D）の事項を満足することが特定されておらず、明確でない（理由 1）と共に、発明の詳細な説明に記載されたものとはいえない（理由 2）。

（3）請求項 1 4

請求項 1 4 における、「前記ハウジングは、上部部材と嵌合する下部部材を備え・・・」との記載からは、ハウジングが上部部材を備えることが明らかでない。また、ハウジングが上部部材を備えない場合の請求項 1 4 に係る発明は、発明の詳細な説明に記載されたものとはいえない。「前記ハウジングは、上部部材とこれに嵌合する下部部材とを備え・・・」ということなのか。

したがって、請求項 1 4 に係る発明は、明確でない（理由 1）と共に、発明の詳細な説明に記載されたものとはいえない（理由 2）。

●理由 3（新規性）および理由 4（進歩性）について

- ・請求項：1， 4， 8， 1 0， 1 1， 1 5
- ・引用文献等：1
- ・備考：

引用文献 1（第 3 頁左下欄第 1 5 行～第 7 頁左上欄第 2 0 行、第 1 ～ 9 図）には、

血液サンプルを受け入れるための入口ポート（室 2 8 に連通する第 1 の穿刺針 1 4 の内方端（内部開口 3 0）、または、室 2 8 に突出する第 2 の穿刺針 1 5 の内方端 3 9）と、

出口ポート（第 2 の穿刺針 1 5 の外方延長部の先端）と、

前記入口ポートと前記出口ポートとに接続され、前記血液サンプルの第 1 の部分を集めるように構成されたチャンバ（第 2 の穿刺針 1 5 の内腔 5 1 のうち、多孔性プラグ（ガス透過性液不透過性の多孔性部材） 5 2 が置かれたスペース、および、孔 4 8 と多孔性プラグ 5 2 との間のスペース）であって、空気透過性であり血液不透過性である材料（多孔性プラグ（ガス透過性液不透過性の多孔性部材） 5 2）を含む、チャンバと、

前記入口ポートと接続されており、前記チャンバを迂回しながら前記出口ポートに前記血液サンプルの後続の部分を運ぶように構成されたサンプリング流路（キャビティー 4 6）と、

を備える装置

が記載されている。

請求項8に関して、引用文献1におけるスリーブ弁41が、請求項8でいう「弁」に相当する。

請求項10, 11に関して、引用文献1における、内腔51の孔48がある位置が、請求項10, 11でいう「分岐点」に相当する。

請求項15に関して、引用文献1における第1の穿刺針14が、請求項15でいう「患者針」に相当し、引用文献1における容器ホルダー19および真空血液収集容器16が、請求項15でいう「サンプル採取装置」に相当する。

したがって、請求項1, 4, 8, 10, 11, 15に係る発明は、引用文献1に記載された発明である。

また、請求項1, 4, 8, 10, 11, 15に係る発明は、引用文献1に基づき、当業者が容易に想到し得るものである。

・請求項：1, 4～6, 8, 13, 15

・引用文献等：2

・備考：

引用文献2（[0004]～[0015]、図1～4、特許請求の範囲）には

、

血液サンプルを受け入れるための入口ポート（針管1の一端1a）と、

出口ポート（針管1の他端1b）と、

前記入口ポートと前記出口ポートとに接続され、前記血液サンプルの第1の部分を集めるように構成されたチャンバ（針管支持体2内の通路21）であって、空気透過性であり血液不透過性である材料（空気透過性血液不透過性部材23）を含む、チャンバと、

前記入口ポートと接続されており、前記チャンバを迂回しながら前記出口ポートに前記血液サンプルの後続の部分を運ぶように構成されたサンプリング流路（針管1）と、

を備える装置

が記載されている。

請求項5, 6の限定事項については、引用文献2の特に[0011]を参照のこと。

請求項8に関して、引用文献2における、針管1の他端1bの刃面を密封的に覆うゴム状キャップ4または(D)（[0014]、[0006]）が、請求項8でいう「弁」に相当する。

請求項13に関して、引用文献2における針管支持体2が、請求項13でいう「ハウジング」に相当する。

請求項15に関して、引用文献2における針管1が、請求項15でいう「患者針」に相当し、引用文献2における真空採血管（[0004]、[0005]、[0012]）が、請求項15でいう「サンプル採取装置」に相当する。

したがって、請求項 1, 4～6, 8, 13, 15に係る発明は、引用文献 2 に記載された発明である。

また、請求項 1, 4～6, 8, 13, 15に係る発明は、引用文献 2 に基づき、当業者が容易に想到し得るものである。

●理由 4（進歩性）について

- ・請求項：9, 12～14
- ・引用文献等：1
- ・備考：

請求項 9, 12～14の限定事項は、いずれも、当業者が適宜なし得ることであり、請求項 9, 12～14に係る発明は、引用文献 1 に基づき、当業者が容易に想到し得るものである。

- ・請求項：5～7
- ・引用文献等：1～3
- ・備考：

血液サンプル収集装置において、空気透過性かつ血液不透過性の材料を、疎水性または親水性とすることは、引用文献 2（[0011]には、前記材料を疎水性とすることが記載されており、[0013]に記載された材料は、親水性である。）、引用文献 3（[0023]、図 3）に記載のとおり、通常のことであり、請求項 5～7に係る発明は、引用文献 1～3 に基づき、当業者が容易に想到し得るものである。

- ・請求項：9, 12, 14
- ・引用文献等：2
- ・備考：

請求項 9, 12, 14の限定事項は、いずれも、当業者が適宜なし得ることであり、請求項 9, 12, 14に係る発明は、引用文献 2 に基づき、当業者が容易に想到し得るものである。

- ・請求項：7
- ・引用文献等：2, 3
- ・備考：

血液サンプル収集装置において、空気透過性かつ血液不透過性の材料を、親水性とすることは、引用文献 2（[0013]に記載された材料は、親水性である。）、引用文献 3（[0023]、図 3）に記載のとおり、通常のことであり、請求項 7に係る発明は、引用文献 2, 3 に基づき、当業者が容易に想到し得るも

<引用文献等一覧>

1. 特開昭58-25146号公報
 2. 特開2001-424号公報
 3. 特開2013-240628号公報
-

<先行技術文献調査結果の記録>

- ・調査した分野 I P C A 6 1 B 5 / 0 6 - 5 / 2 2
- ・先行技術文献 米国特許出願公開第2008/0145933号明細書

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません。

この拒絶理由通知の内容に関する問い合わせ先は以下のとおりです。補正案等の送付を希望される際は、その旨を事前にご連絡ください。

電子メールにて連絡する際は、氏名、所属、出願番号、電話番号、下記審査官名を記載していただき、下記メールアドレス（※）までご連絡ください。電子メールの連絡内容について不明な点等がある場合、電話で確認させていただく場合があります。

審査第一部 分析診断（医学診断）高 芳徳 （たか よしのり）

T E L . 0 3 - 3 5 8 1 - 1 1 0 1 内線 3 2 9 1

※ ●●●●@jpo.go.jp （上記「●●●●」に置き換えて、「PA2J」と入力ください。）



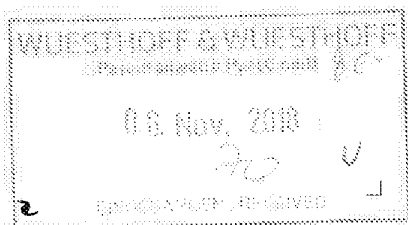
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Application No. 16 747 682.9 - 1132	Ref. EPA-142 451	Date 31.10.2018
Applicant KURIN, INC.		

Basel 28.02.1940/160

*WL 06.12.18 ✓
WV 28.01.19 ✓ not
103*

Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC. One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the Examining Division requesting that you correct this deficiency (R. 137(4) EPC).

In case you withdraw the application within the above-mentioned period, the examination fee will be refunded at a rate of 50% (Art. 11 (b) RFees).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).



Schultz, Ottmar
Primary Examiner
For the Examining Division

Enclosure(s): 1 page/s reasons (Form 2906)

Datum
Date 31.10.2018
Date

Blatt
Sheet 1
Feuille

Anmelde-Nr:
Application No: 16 747 682.9
Demande n°:

The examination is being carried out on the following application documents

Description, Pages

1-33 as published

Claims, Numbers

1-20 as published

Drawings, Sheets

1/50-50/50 as published

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An International Preliminary Report on Patentability has already been drawn up for the present application in accordance with the PCT. The deficiencies mentioned in that report give rise to objections under the corresponding provisions of the EPC.

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 50828-501001WO	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2016/043709	International filing date (<i>day/month/year</i>) 22 July 2016 (22.07.2016)	Priority date (<i>day/month/year</i>) 24 July 2015 (24.07.2015)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant KURIN, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| ☒ | Box No. I | Basis of the report |
| ☐ | Box No. II | Priority |
| ☐ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ | Box No. VI | Certain documents cited |
| ☒ | Box No. VII | Certain defects in the international application |
| ☒ | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Date of issuance of this report 30 January 2018 (30.01.2018)</p> <p>Authorized officer Lingfei Bai</p> <p>e-mail: pct.team2@wipo.int</p>
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Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2016/043709

International filing date (day/month/year)
22.07.2016

Priority date (day/month/year)
24.07.2015

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/15 A61B5/153 A61B5/154

Applicant
CALLIOPE SOLUTIONS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
Gitschiner Str. 103
D-10958 Berlin
Tel. +49 30 25901 - 0
Fax: +49 30 25901 - 840

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Schultz, Ottmar

Telephone No. +49 30 25901-0



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2016/043709

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed:
 - ☐ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2016/043709

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>2, 6, 7, 11, 14</u>
	No: Claims	<u>1, 3-5, 8-10, 12, 13, 15-20</u>
Inventive step (IS)	Yes: Claims	<u>6, 14</u>
	No: Claims	<u>1-5, 7-13, 15-20</u>
Industrial applicability (IA)	Yes: Claims	<u>1-20</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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Reference is made to the following document:

D1: WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES
LLC [US]; FISCHER LLOYD [US]; BR) 29 December 2011.

+++++

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial
applicability; citations and explanations supporting such statement**

+++++

1 INDEPENDENT CLAIMS 1, 8, 17

- 1.1 Claims 8 seeks to define a blood sequestration device by being connected with a blood sampling pathway having a patient needle and a sample collection device whereby said blood sampling pathway does not form part of the claimed blood sequestration device.

This would only be the case if e.g. claim 8 defined e.g. "A system of a blood sequestration device and a blood sampling pathway having a patient needle and a sample collection device, whereby the blood sequestration device is connected with the blood sampling pathway, said blood sequestration device comprising...".

The technical features and the related definitions of the blood sampling pathway can therefore not be used to render the subject-matter of claim 8 either novel or inventive.

Since the intended limitation does not belong to the subject-matter claimed, namely the blood sequestration device, this said limitation leads to uncertainty with regard to the actual protection sought, contrary to the requirements of Article 6 PCT.

The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 17, which therefore is also considered not meeting the requirements of Article 6 PCT.

- 1.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. The reason is the following:

Document D1 discloses (the references in parenthesis applying to this document) in figure 15 all the features of independent claim 1, namely:

"A blood sequestration device (see figure 15) comprising;

an inlet port (see ref. sign 117 "well");

an outlet port (see ref. sign 330 "sleeve connector");

a sequestration chamber (see ref. sign 117 "guide tube aperture") connected with the inlet port, the sequestration chamber having a vent (see ref. sign 117 "venting member") comprising an air permeable blood barrier;

a sampling channel (see the channel formed in the sleeve connector 330) having a proximal end connected with the inlet port and a distal end connected with the outlet port; and

a housing (see ref. sign 116 "guide tube") that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel".

- 1.3 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claims 8 and 17, which therefore are also considered not new (Article 33(1) and (2) PCT).

2 DEPENDENT CLAIMS 2-7, 9-16, 18-20

- 2.1 Dependent claims 2 to 5, 7, 9 to 13, 15, 16 and 18 to 20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT) and/or inventive step (Article 33(3) PCT), the reasons being as follows:

As far as the features of these said dependent claims are not already explicitly anticipated by document D1 (for further details, see the relevant passages as cited in the International Search Report and in the above-mentioned paragraph 1), these features would be chosen by a person skilled in the art simply by routine trial and error or these said features are at least generally known by a person skilled in the art either to be one of several straightforward possibilities from which this said person would select or to be regarded by this said person as a normal design option and thus would not add any inventive merit to the subject-matter of the these said dependent claims.

- 2.2 The features of dependent claims 6 and 14 in combination with the features of any claim to which these said claims refer, seem neither to be known from, nor rendered obvious by, the available prior art.

+++++

Re Item VII

Certain defects in the international application

+++++

- 1 The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT with those features known in combination from the prior art (e.g. one of the documents cited in the International Search Report) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents cited in the International Search Report is not mentioned in the description, nor are at least some of these documents identified therein.
- 3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

+++++

Re Item VIII

Certain observations on the international application

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Claims 8 seeks to define a blood sequestration device by being connected with a blood sampling pathway having a patient needle and a sample collection device whereby said blood sampling pathway does not form part of the claimed blood sequestration device.

This would only be the case if e.g. claim 8 defined e.g. "A system of a blood sequestration device and a blood sampling pathway having a patient needle and a sample collection device, whereby the blood sequestration device is connected with the blood sampling pathway, said blood sequestration device comprising...".

The technical features and the related definitions of the blood sampling pathway can therefore not be used to render the subject-matter of claim 8 either novel or inventive.

Since the intended limitation does not belong to the subject-matter claimed, namely the blood sequestration device, this said limitation leads to uncertainty with regard to the actual protection sought, contrary to the requirements of Article 6 PCT.

The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 17, which therefore is also considered not meeting the requirements of Article 6 PCT.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715
27500 7590 08/25/2023 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER ABOUELELA, MAY A	
			ART UNIT 3791	PAPER NUMBER
			NOTIFICATION DATE 08/25/2023	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 08/09/2023, and 05/10/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1, 5, 8-13 and 16 is/are rejected under 35 U.S.C. 102(1)(a) as being anticipated by Christensen et al (US 20100057004).

As to claim 1, Christensen discloses a device comprising:

an inlet port (catheter 14 and the frontal inlet port of device 10 where catheter 14 is connected/inserted therein, par.41-43 and par.47, fig.1-4);

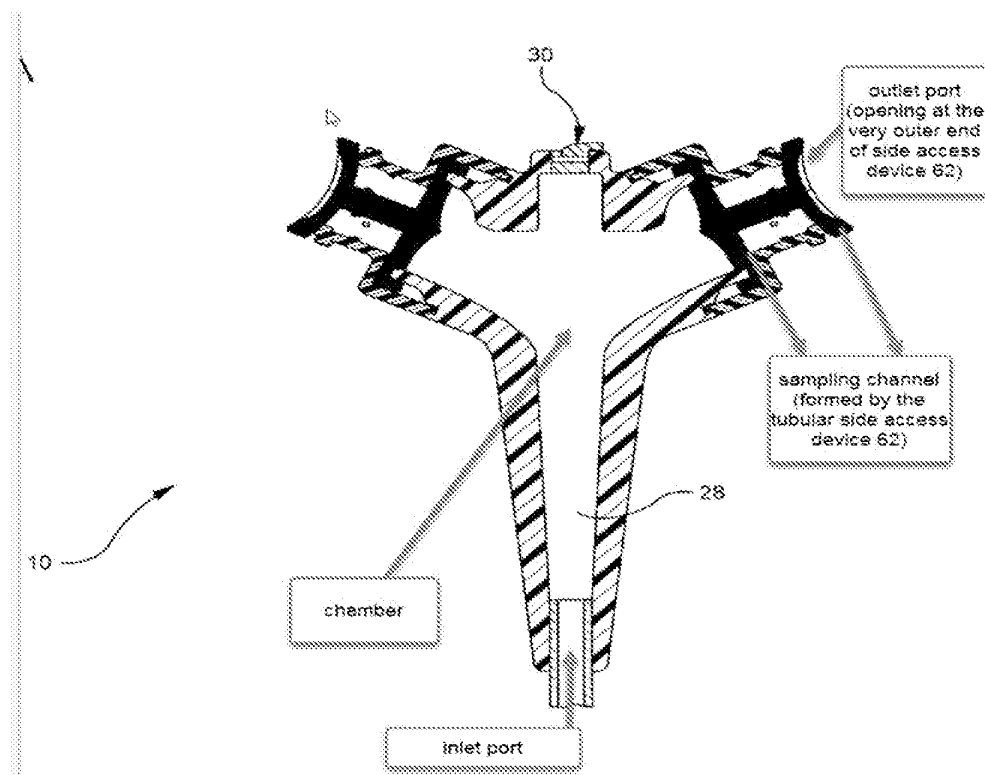
an outlet port (outlet opening at the very outer end of side access device 62 of device 10 where tube 16 is connected to and/or outlet port at the end of tube 16 connected to Y-adapter 18, par.41-43, par.53, fig.1-5);

a chamber (a fluid path 28 filling the interior of the extravascular system 10, par.47, fig.1-4) connected with the inlet port (fluid path 28 within the interior of device 10 is connected to catheter 14 and the frontal inlet port of device 10, fig.1-5) and configured to receive a first portion of blood (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into the system 10 to confirm that the needle 12 is properly located within the vasculature of the patient, par.7, par.42, and blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43)(The Examiner respectfully notes that flashback of blood, is considered the initial portion of blood),

the chamber including an air permeable material (venting material in vent 30, par.48-50, a removable filter plug 50 and a re-seal elastomer 52 in vent 30, par.51-53, or 114 that expands when exposed to liquid from bath 28, and thus seals the vent, par.71-72, fig.1-16, and/or curing material 108 of the vent 30 described with reference to FIGS. 13 and 14 provides a vent capable of venting gas from the system 10 without permitting the escape of liquid after the liquid has come into contact with the material 108, par.69, a porous membrane 110, par.70) that seals at least partially upon contact with a portion of the first portion of blood (par.48-53); and

a sampling channel (tubular channel formed by side access device 62 of device 10 and integrated extension tube 16, par.41-42, fig.1-6) having a proximal end connected with

the inlet port and a distal end connected with the outlet port (tubular channel formed by side access device 62 of device 10 having proximal end connected to frontal inlet port of device 10 at catheter 14, and having a distal end connected to the outlet opening at the very outer end of side access device 62 of device 10, as best seen in fig.1-6)(Examiner respectfully notes that since blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43, so tubular channel formed by side access device 62 is configured to sample and convey blood to tubing 16).



As to claim 5, Christensen discloses the device, wherein the air permeable material is located at a distal end of the chamber (a vent may be placed at or near the start of the fluid path, or the vent may be placed at any point in between the start or end of the fluid path of the extravascular system, par.45, as best seen in fig.1-3).

As to claim 8, Christensen discloses the device, wherein the air permeable material is a hydrophilic membrane (vent 30 includes an expandable vent material 114 that is hydrophilic, par.71, fig.16).

As to claim 9, Christensen discloses the device, wherein the sampling channel further comprises a valve configured to close off the sampling channel (side clamp 20, par.41, slide clamp 20 on the integrated extension tubing 16 is provided to eliminate blood exposure when the vent plug 22 is replaced with another vascular access device, par.42, fig.1).

As to claim 10, Christensen discloses the device, wherein the valve is a clip (clamp 20, par.41, fig.1)

As to claim 11, Christensen discloses the device, further comprising a junction configured to direct an initial blood flow into the chamber (the longitudinal shape at the beginning of fluid path 28 formed in the interior of device 10 forces the flashback blood to enter the interior of device 10, par.43-48, and/or vent 30, vent 30 may be placed at or near the terminus of the system 10 in order to allow fluid, including gas, blood, saline,

and water, to fill the internal chamber of the fluid path directly adjacent any vascular access devices of the system 10, par.51-52, fig.1-6).

As to claim 12, Christensen discloses the device, further comprising a junction configured such that flow out of the inlet port is preferentially directed toward the chamber (the longitudinal shape at the beginning of fluid path 28 formed in the interior of device 10 forces the flashback blood to enter the interior of device 10, par.43-48, and/or vent 30, vent 30 may be placed at or near the terminus of the system 10 in order to allow fluid, including gas, blood, saline, and water, to fill the internal chamber of the fluid path directly adjacent any vascular access devices of the system 10, par.51-52, fig.1-6).

As to claim 13, Christensen discloses the device, wherein the chamber has a larger cross-sectional area than the sampling channel (the cross-sectional area of fluid path 28 of the interior of device 10 is larger than the side tubular channel and tube 16, as best seen in fig.1-3).

As to claim 16, Christensen discloses the device, further comprising a patient needle (needle 12, par.41-43, fig.1) and a sample collection device (Luer access device or port 24, par.41)(Examiner respectfully notes that the luer access device is a device that is connected to obtain blood sample in a sampling container, see link:

<https://www.medline.com/product/Blood-Transfer-and-Luer-Lock-Access-Device/Z05-PF253812#:~:text=Luer%20lock%20access%20devices%20%28LLAD%20and%20AC>

SD%29%20are,reduce%20the%20risk%20of%20transfer-related%20injuries%20and%20infections).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 2-4, 6 and 7 is/are rejected under 35 U.S.C. 103 as being obvious over Christensen et al (US 20100057004), in view of Weilbacher et al (US 2008/0167577).

As to claims 2-4, 6 and 7, Christensen discloses the device, wherein the device is further configured such that an initial aliquot of blood will contact the air permeable material and back up into the chamber (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into the system 10 to confirm that the needle 12 is properly located within the vasculature of the patient. The blood travels into and along the catheter 14 and extension tubing The fluid path 28 is in communication with a vent 30, and the vent 30 is capable of venting gas from the fluid path 28 of the system 10, par.47 and par.53), wherein the device is further configured such that follow-on amounts of blood will flow through the sampling channel towards the outlet port (blood travels into and along the catheter 14 and extension tubing 16

because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43).

Christensen discloses the invention substantially as above, but failed to explicitly teach wherein the device is configured such that, when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber, and wherein the air permeable material is a hydrophobic plug/membrane.

However Weilbacher discloses an analogous vascular access needle assembly (abstract, fig.1-3), when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber (collection tube 17 is maintained at a vacuum such that when distal needle portion 20 is properly positioned in a vein 38 of a patient and collection tube 17 is positioned within cavity 34 OF BODY 30, blood will flow through needle 10 into blood collection tube 17, par.33, fig.1)(the Examiner respectfully notes the vacuum applies blood drawing force), and wherein the air permeable material is a hydrophobic plug/membrane (filter material 116 disposed in chamber 112, wherein material includes a hydrophobic material. In an alternate embodiment, the material includes a hydrophilic wicking material. In yet another embodiment, the material includes a hydrophobic plug, par.11 and par.35, fig.2).

As these types of blood drawing force are well-known in the art, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to maintain blood collection devices and/or luer accesses devices connected to port 24 taught by Christensen's invention under vacuum, as tube 17 taught by

Weilbacher's invention, to facilitated blood sampling and prevent unwanted blood exposure/spilling, as taught by Weilbacher's invention (par.33).

Still, as the hydrophobic air permeable filter/material are well known in the art to vent air, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to substitute the hydrophilic material taught by Christensen's invention, with the hydrophobic material taught by Weilbacher's invention, for the same reason of venting air from sampling chamber, as taught by Weilbacher's invention (par.11 and par.35-36).

Allowable Subject Matter

5. Claims 17-31 are allowed.

6. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Christensen et al (US 2010/0057004) teaches a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable.

The prior art does not teach, disclose and/or fairly suggest a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

7. Applicant's arguments claim objections/rejections and double patenting have been fully considered and are persuasive. The claim objections/rejections and double patenting have been withdrawn.

8. Applicant's arguments regarding Christensen's invention does not teach the claimed subject matter "an air permeable material that seals at least partially upon contact with a portion of the first portion of blood" in claim 1 have been fully considered but they are not persuasive, because Christensen's invention explicitly teaches hydrophilic air permeable material 114 that allows air to pass through vent 30, and then expands when exposed to liquid from fluid path 28, and thus seals the vent (par.71-72), similarly materials 108 and 110, par.69-70.

So, Christensen's invention explicitly teaches the claimed subject matter "an air permeable material that seals at least partially upon contact with a portion of the first portion of blood" in claim 1.

9. Still, regarding the Applicant's arguments that Christensen's invention does not teach "a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port" in claim 1 because Christensen's invention is not taking samples. Instead Christensen's invention is used for infusion therapy (see arguments page 5) have been fully considered but are not persuasive, because claim 1 broadly claims "A device comprising" in the preamble, and does not claim a blood sampling/collecting device. Under the broadest reasonable interpretation the claimed

subject matter "sampling channel" may be interpreted as sampling any type of tissue, fluid and/or infusion agents, and does not necessarily means sampling blood.

Device 10 taught by Christensen's invention comprises a fluid path 28 filling the interior of the extravascular system 10 (par.47) configured to receive a portion of blood (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into fluid path 28 to confirm that the needle 12 is properly located within the vasculature of the patient (par.7, par.42), and blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10 (par.43).

Examiner respectfully notes that since blood travels into and along the catheter 14 and extension tubing 16, so tubular channel formed by side access device 62 is configured to sample and convey blood to tubing 16.

So, it can be fairly interpreted that the tubular channel is a sampling channel that samples blood to and from tubing 16, as claimed in claim 1.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure Burkholz et al (US 20120/016266).

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For

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Art Unit: 3791

Page 13

additional questions, contact the Electronic Business Center (EBC) at 866-217-9197
(toll-free). If you would like assistance from a USPTO Customer Service
Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

<i>Notice of References Cited</i>	Application/Control No. 18/113,710	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20160325085-A1	11-2016	Chelak; Todd	F16K7/20	1/1
*	B	US-20160262677-A1	09-2016	EBETSBERGER; Franz	A61B5/150251	1/1
	C					
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		18113710	
	Filing Date		2023-02-24	
	First Named Inventor	Bobby E. ROGERS		
	Art Unit	-		
	Examiner Name			
	Attorney Docket Number	069366-0574153_KUR2C04US		

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	18113710
Filing Date	2023-02-24
First Named Inventor	Bobby E. ROGERS
Art Unit	-
Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

1		☐
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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	08/22/2023
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	18113710
Filing Date	2023-02-24
First Named Inventor	Bobby E. ROGERS
Art Unit	-
Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-08-09
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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	Filing Date	2023-02-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
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	1	2593169A1	EP		2013-05-22	BECTON DICKINSON CO		
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	1	International Search Report and Written Opinion dated Nov. 5, 2015, for PCT application No. PCT/US2015/035870. 6 pages.	
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Examiner Signature	/MAY A ABOUELELA/	Date Considered	08/22/2023
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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Date	28.10.2022
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Reference KUR-18996-P-EP	Application No./Patent No. 20781928.5 - 1122 / 3948211 PCT/US2020026276
Applicant/Proprietor Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the supplementary European search report (Art. 153(7) EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

Refund of the search fee

If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued shortly (R. 70(2) EPC).



The examination is being carried out on the **following application documents**

Description, Pages

1-28 as published

Claims, Numbers

1-20 as published

Drawings, Sheets

1/16-16/16 as published

Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

- D1 US 2018/271425 A1 (ROGERS BOBBY E [US] ET AL) 27 September 2018 (2018-09-27)
- D2 EP 3 324 845 A1 (KURIN INC [US]) 30 May 2018 (2018-05-30)
- D3 WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05)
- D4 WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 21 March 2019 (2019-03-21)

1. The application does not meet the requirements of Article 84 EPC, because claims 1, 6 and 14 are not clear.

Claims 1, 6 and 14 have been drafted as separate independent claims.

Under Article 84 in combination with Rule 43(2) EPC, an application may contain more than one independent claim in a particular category only if the subject-matter claimed falls within one or more of the exceptional situations set out in paragraph (a), (b) or (c) of Rule 43(2) EPC. However, this is not the case in the present application.

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claims 1, 6 and 14 is not new within the meaning of Article 54(1) and (2) EPC.

2.1 D1 discloses a **fluid sample optimization device** (see fig.23,24, par. [0141]-[0149]:"blood sample optimization system 2400") **for optimizing a fluid sample collected by a fluid collection device from a fluid source, a first portion of the fluid sample potentially having contaminants** (see par. [0141]:" a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered"), **the fluid sample optimization device comprising:**

an inlet ("inlet port 2412") configured to connect with the fluid source;

an outlet ("outlet port 2414") configured to connect with the fluid collection device;

a sample path ("blood sample channel 2422") connected between the inlet and the outlet; and

a contaminant containment reservoir ("blood sequestration chamber 2418 ") connected between the inlet and the outlet, the contaminant containment reservoir having an air permeable fluid resistor ("air permeable blood barrier 2420") proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet (see par. [0148]:"As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position.", "Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.").

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

2.2 D1 discloses a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source (see fig.23,24, par. [0141]-[0149]:"blood sample optimization system 2400"), a first portion of the fluid sample potentially having contaminants (see par. [0141]:" a sampling channel 2308 that

bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered"), the fluid sample optimization device comprising:

an inlet ("inlet port 2412") configured to connect with the fluid source;

an outlet ("outlet port 2414") configured to connect with the fluid collection device;

a sample path ("blood sample channel 2422") connected between the inlet and the outlet, the sample path further having a resistive plug ("apertures 2424") that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path (see par.[0141]: "the inner chamber housing 2419 is in the first position toward the inlet port 2412, such that the one or more apertures 2424 are closed, and the blood sequestration chamber 2418 is in a direct path from the patient needle."); and

a contaminant containment reservoir ("blood sequestration chamber 2418 ") connected between the inlet and the outlet, the contaminant containment reservoir further having an air permeable fluid resistor ("air permeable blood barrier 2420") proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet (see par.[0148]: "As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position.", "Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.").

The subject-matter of claim 6 is therefore not new (Article 54(1) and (2) EPC).

2.3 The subject-matter of claim 14, which comprises for essentially the same features as the subject matter of claim 1, is for essentially the same reasons as those given above (see point 2.1) also not new (Article 54(1) and (2) EPC).

2.4 Furthermore, the documents D2-D3 also disclose all the features of claim 1, 6 and 14. For further details, see the relevant parts thereof as cited in the Search Report.

3. The dependent claims 2 to 5, 7 to 13 and 15 to 20 and seem not to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC in respect of novelty and/or inventive step, defining either features already known from any of D1-D3 or straightforward possibilities from which the person skilled in the art would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

4. Independent claims are not in the two-part form in accordance with Rule 43(1) EPC, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 43(1)(a) EPC) and the remaining features being included in the characterising part (Rule 43(1)(b) EPC).

5. The features of the claims should be provided with reference signs placed in parentheses to increase the intelligibility of the claims (Rule 43(7) EPC). This applies to both the preamble and characterising portion (see Guidelines F-IV, 4.18).

6. The applicant is invited to file new claims which take account of the above comments.

In order to comply with the requirements of Rule 137(4) EPC, the applicant should clearly identify the amendments made, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (see Guidelines H III, 2.1).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed or in documents with tracked changes.

When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and of any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

Datum
Date cf Form 1507
Date

Blatt
Sheet 5
Feuille

Anmelde-Nr:
Application No: 20 781 928.5
Demande n°:

Information on Search Strategy - Pilot phase (see OJ 2015, A86)

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

EP 20 78 1928

TITLE: NON-VENTING BODILY FLUID SAMPLE OPTIMIZATION DEVICE AND SYSTEM**APPLICANT: Kurin, Inc.****IPC CLASSIFICATION: G01N1/10, G01N1/02, A61B5/15, A61B5/154****EXAMINER: Coja, Michael****CONSULTED DATABASES: EPODOC, WPI****CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:****IPC:****CPC: A61B5/15003, A61B5/150213, A61B5/150221, A61B5/150251****FI/F-TERMS:****KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:**



**SUPPLEMENTARY
EUROPEAN SEARCH REPORT**

Application Number
EP 20 78 1928

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2018/271425 A1 (ROGERS BOBBY E [US] ET AL) 27 September 2018 (2018-09-27) * the whole document *	1-20	INV. G01N1/10 G01N1/02 A61B5/15 A61B5/154
X	EP 3 324 845 A1 (KURIN INC [US]) 30 May 2018 (2018-05-30) * paragraph [0104]; figure 23 *	1-20	
X,P	WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05) * paragraphs [0074], [0099], [0120], [0141]; figures 1-14 *	1, 6, 14	
A	WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 21 March 2019 (2019-03-21) * paragraph [1179]; figures 35-37 *	1-20	
			TECHNICAL FIELDS SEARCHED (IPC)
			A61B
The supplementary search report has been based on the last set of claims valid and available at the start of the search.			
Place of search The Hague		Date of completion of the search 20 October 2022	Examiner Coja, Michael
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			
T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

1
EPO FORM 1503 03.82 (F04C04)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 20 78 1928

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

20-10-2022

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2018271425 A1	27-09-2018	US 2018271425 A1	27-09-2018
		US 2021145336 A1	20-05-2021
EP 3324845 A1	30-05-2018	AU 2016297849 A1	22-02-2018
		AU 2021202622 A1	27-05-2021
		CA 2993646 A1	02-02-2017
		EP 3324845 A1	30-05-2018
		EP 3622890 A1	18-03-2020
		IL 257137 A	29-03-2018
		IL 286030 A	31-10-2021
		JP 6643474 B2	12-02-2020
		JP 6734490 B2	05-08-2020
		JP 2018525191 A	06-09-2018
		JP 2020096843 A	25-06-2020
		JP 2020192333 A	03-12-2020
		US 2017020427 A1	26-01-2017
		US 2017020428 A1	26-01-2017
		US 2018289304 A1	11-10-2018
		US 2019159711 A1	30-05-2019
		US 2022079483 A1	17-03-2022
		WO 2017019552 A1	02-02-2017
WO 2019232196 A1	05-12-2019	CA 3101972 A1	05-12-2019
		EP 3801258 A1	14-04-2021
		JP 2021525862 A	27-09-2021
		US 2019365303 A1	05-12-2019
		US 2022151526 A1	19-05-2022
		US 2022151527 A1	19-05-2022
		US 2022304601 A1	29-09-2022
		WO 2019232196 A1	05-12-2019
WO 2019055487 A1	21-03-2019	AU 2018334138 A1	12-03-2020
		CA 3074105 A1	21-03-2019
		CN 111212597 A	29-05-2020
		EP 3681384 A1	22-07-2020
		IL 273025 A	30-04-2020
		JP 2020533045 A	19-11-2020
		US 2019076074 A1	14-03-2019
		US 2022175284 A1	09-06-2022
		WO 2019055487 A1	21-03-2019



Application No.: 20781928.5

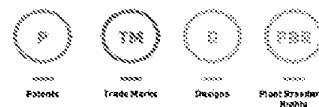
The search has started on 19.10.22 (see Notice from the European Patent Office dated 03/2013, OJ EPO 2013, 153).

Receiving Section



Australian Government
IP Australia

29 April 2020



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ABN: 38 113 072 755

Examination report No. 1 for standard patent application

Griffith Hack
GPO Box 4164
Sydney NSW 2001
Australia

Your reference	P108089.AU
Application number	2016297849
Applicant name	Kurin, Inc.
Earliest priority date	24 July 2015

Final date for acceptance: 29 April 2021
Date of this report: 29 April 2020
Examination request date: 11 December 2019

Dear Griffith Hack,

Your application has been examined under section 45 of the Patents Act 1990. I consider that this application does not meet the requirements of the Act because there are issues with the application that are explained in the report details.

You have **12 months** from the date of this report to overcome all my objection(s) otherwise this application will lapse.

You will also need to pay any annual continuation fees that apply. Your next continuation fee is due on **22 July 2020**.

NOTE: There is a current postponement of acceptance in place. If you overcome all other objections before the expiration of that postponement, the Commissioner will only accept the application at that time if you have filed a clear and unambiguous statement requesting the withdrawal of that postponement. Otherwise, a further adverse report will be issued.

Details of this patent application can be viewed on [AusPat](#), our Australian patent search database.

Yours sincerely,

Morris Ark
Section: MXT - MIXED TECHNOLOGY
Phone: (612) 6210 8487



Report details

Basis of the report

In examining this application I have considered:

- the PCT pamphlet as originally filed

Summary of novelty, inventive step and patentable subject matter

	<i>Satisfy requirements?</i>	<i>Claim numbers</i>
Novelty/inventive step	Yes	NONE
	No	1-20
Patentable subject matter	Yes	1-20
	No	NONE

Detailed objections on issues that have been identified

Documents cited or considered relevant

D1 : WO 2011162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES, LLC et al.) 29 December 2011 ^[1]
Category: **X** Claims: 1-20

[1] Cited in WO 2017019552

Special categories of cited documents:

X: The claimed invention cannot be considered novel under subsection 7(1) in light of the document and/or cannot be considered to involve an inventive step under subsection 7(2) of the Act in light of the common general knowledge considered together with the document.

Novelty and inventive step

- 1 The invention defined in **claims 1, 8 and 17** are not novel (and do not involve an inventive step) when compared with the following prior art document **D1**.

Regarding **claim 1**, **D1** discloses a blood sequestration device (Fig. 15; item 10) comprising;

an inlet port (100); an outlet port (330); a sequestration chamber connected with the inlet port (117), the sequestration chamber having a vent (160) comprising an air permeable blood barrier (Para [0042]); a sampling channel (130) having a proximal end connected with the inlet port and a distal end connected with the outlet port; and a housing (116) that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

Claims **8 and 17** define a blood sequestration device with a similar scope to claim 1, only differing by the additional features of a blood sampling pathway or blood sampling system

connected to said device. **D1** also discloses a blood sampling pathway or system connected to the blood sequestration device (Fig. 23; patient needle 184, connected to inlet 100).

Furthermore, appended **claims 2-7, 9-16, 18-20** are not considered to make any patentable contribution over the teachings of the cited document **D1** or are common general knowledge in the art or workshop improvements and which therefore cannot contribute to providing novelty or an inventive step. For example, **D1** discloses features of **claims 2, 11, 20** of the air permeable blood barrier sealing upon contact with blood (Para [0081], [0085]). Features of dependent **claim 3** are considered matters of workshop improvement over **D1**. It would be obvious to the person skilled in the art that a sequestration channel be implemented to improve transport of blood to the sequestration chamber.

END OF REPORT



רשות המכס



מדינת ישראל
משרד הביטחון

פ.ק. 26

תאריך: י"ג שבט תשפ"ד
23/01/2024
מספרם: 1000-018-02

לכבוד
כץ, פרזנט ושות'
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.

הנדון: הודעה על ליקויים בבקשת פטנט מספר 302893

סימוכין: מכתבם מיום 08/09/2023, 10/09/2023

לתשומת לבכם: מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ"ז – 1967. מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ"ח – 1968. עליכם להשיב על הודעה זו תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה, עם בקשת הארכה שתוגש יש לשלם אגרה בסך 226.00 ש"ח בעד כל חודש או חלק ממנו. לא יינתנו יותר מארבעה חודשי ארכה בגין כל הודעה על ליקויים וסך כל תקופות הארכה במהלך הבחינה לא יעלה על 12 חודשים בהתאם לכללים שנקבעו בחוזר הרשם 035/2017-פטנטים.

הודעה זו מבוססת על המסמכים הבאים:

שרטוטים מתאריך: 13/05/2023
פרטי הבקשה מתאריך: 20/08/2023
תביעות מתאריך: 20/08/2023

ההפניות בהודעה זו מתייחסות לפרסומים הבאים:

D1: US 3848581 A [CINQUALBRE L] - 19/11/1974
D2: US 4207870 A [BECTON DICKINSON CO] - 17/06/1980

בהתאם למפורט בהמשך הודעה זו להלן סיכום עמדתי לעניין כשירות התביעות לפטנט:

תביעה/ות מס' 14-12, 9-2 הינן כשירות לפטנט בהתאם לסעיף 17(א) לחוק.
בתביעה/ות מס' 18-15, 11-10, נמצאו ליקויים.
ראה הנימוקים בהמשך הודעה זו.

בהתאם להוראות תקנה 41 הנני להודיעכם כי נמצאו בבקשה הנ"ל הליקויים המפורטים להלן:

1. בחינת הבקשה מבוססת על ההודעות הבאות:

1.1 הריני להודיעכם כי:

תאריך הבקשה הנוכחית, שהינה בקשת חלוקה מן הבקשה מס' 267684, הוקדם לתאריך 27/12/2017, שהוא תאריך הבקשה ההורה, וזאת בהתאם לסעיף 24(ג) לחוק.

רחוב אגודת ספורט הפועל מס' 1,
הגן הטכנולוגי מלחה בנין מס' 5
ירושלים, מיקוד 9695101
טל: 972-73-3927100 פקס: 972-2-6467774
<https://www.gov.il/he/departments/ilpo>



2. חידוש והתקדמות המצאתית

2.1 תביעות 1,10-11,15-18 אינן מגדירות אמצאה שיש בה התקדמות המצאתית כהגדרתה בסעיף 5 לחוק, לאור פרסומים: D1, D2.

תביעות 1,10-11,15-18 בבקשה שבפניי תואמות לתביעות 1,3-4,6-7,23,34 בבקשה 17/893,079 שנבחנה על ידי ה-USPTO והופק עבורה דוח בחינה בתאריך 22/08/2023. לאחר עיון בדוח הבחינה האמור ולאור תאימות התביעות, מצאתי כי הליקוי שפורט בנוגע לחוסר התקדמות המצאתית חל גם על התביעות שבפניי לפי חוק הפטנטים הישראלי.

2.2 תביעות 2-9,12-14 עונות על דרישות **סעיפים 4 ו-5 לחוק**, מאחר שהאמצאה המוגדרת בתביעות אלה לא נתפרסמה בפומבי לפני תאריך הבקשה ויש בה התקדמות המצאתית.

חובת המבקש לעדכן את הרשות

תשומת לבכם **לסעיף 18 לחוק** לעניין חובת המבקשת לעדכן את הרשות על כל שינוי שחל ברשימת האסמכתאות או הפרסומים כאמור בסעיף 18(א) **לחוק ולסעיף 18ג לחוק** בדבר אמצעי האכיפה.

הגשת תיקונים לפירוט במהלך בחינת הבקשה

באם יבוצעו תיקונים בבקשת הפטנט, תשומת לבכם מופנית **לתקנה 22(א)**. יש לשלוח לרשות עותק מלא של חלק הבקשה שבו הוכנסו התיקונים תוך סימונם באופן ברור. יש לסמן תוספות בקו תחתי (כך: דוגמה) והשמטות בקו חוצה (כך: דוגמה). אין להגיש מחדש קבצים שלא תוקנו.

לתשומת לבכם:

(א) **בהתאם לתקנות 22(ב) ו-42 במידה שהנכם מתקנים את הפירוט כדי להתגבר על הליקויים בהדעה זו, עליכם לפרט את הליקויים שהתיקונים באים לסלק, לנמק כיצד תיקון הפירוט מתקן את הליקוי ולגבי תיקון בתביעות, כיצד עומד התיקון בתנאי סעיף 13 לחוק.**

(ב) **בהתאם להוראות חוזר רשם 034/2017-פטנטים, במידה שבחינת הבקשה החלה לאחר 27.03.2017, תיקון פירוט בדרך של החלפת האמצאה שנבחנה ואשר לגביה הועלה ליקוי, באמצאה אחרת, בין אם היא הופיעה בתביעות מלכתחילה ובין אם תוארה בלבד, גם אם היא נובעת מהתיאור, אינו מהווה תיקון הליקוי ויביא לשליחת הדעה לפני סירוב.**

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

<https://israelpatents.justice.gov.il/#/en/patent-file/details/302893>

ראיון עם בוחן

בהתאם לה.ע. 23.3, המפורסמת באתר הרשות, ניתן לקיים ראיון עם הבוחן באמצעות פגישה במשרדי הרשות, בשיחה טלפונית או בהיוועדות חזותית.



רשות הפטנטים



מדינת ישראל
משרד המשפטים

רשות הפטנטים מעודדת קיום של קשר ישיר בין הבוחן למבקש או בא-כוחו באמצעות שירות זה. קיום ראיון עם בוחן מאפשר לרוב את ייעול וקיצור זמן הבחינה ואף לחיסכון בעלויות בתהליך הבחינה והאישור של בקשה לפטנט. במסגרת הראיון ניתן לדון עם הבוחן בנושאים הקשורים לתיאור האמצאה והגדרתה, בליקויים שהועלו במהלך הבחינה ואף בתיקונים אפשריים לליקויים אלה. תיאום הראיון יתבצע ישירות מול הבוחן (פרטי הקשר מופיעים מטה) וילווה בהודעה כתובה של יוזם הראיון שתפרט את הנושאים לדיון ואת הטיעונים העיקריים לגביהם. לתשומת לבכם, בקשה לקיום ראיון אינה מהווה תשובה להודעת הליקויים כמשמעה בתקנה 42.

השגה בפני הרשם

על פי סעיף 161 לחוק, הנכם רשאים להשיג על החלטתי בפני רשם הפטנטים תוך ארבעה חודשים ממועד משלוח ההודעה.

בתקווה לימים שקטים ובטוחים יותר.

בכבוד רב

אלברט אקרמן
בוחן פטנטים בכיר
טלפון : 073-3927233
דואר אלקטרוני : albertak@justice.gov.il
ראש צוות : מוריה שלמה לוי



Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)

Approved for use through 05/31/2024. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		18494622
	Filing Date		2023-10-25
	First Named Inventor	Bobby ROGERS	
	Art Unit	3791	
	Examiner Name	DOCKET CENTRAL	
	Attorney Docket Number	069366-0577657_KUR2C05US	

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	3	5147329		1992-09-15	BRANNON JAMES K	
	4	5518005		1996-05-21	BRANNON JAMES K	
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	1	20150314105		2015-11-05	GASPARYAN LEVON	

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	Filing Date	2023-10-25
	First Named Inventor	Bobby ROGERS
	Art Unit	3791
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0577657_KUR2C05US

	2	20150359473		2015-12-17	GARRETT CHAD	
	3	20160262677		2016-09-15	EBETSBERGER FRANZ	
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	6	20190365303		2019-12-05	BULLINGTON GREGORY J	
	7	20180297303		2018-10-18	SEKIGUCHI TAKUMI	
	8	20190175087		2019-06-13	BULLINGTON GREGORY J	
	9	20210145336		2021-05-20	ROGERS BOBBY E	
	10	20060009713		2006-01-12	FLAHERTY PATRICE	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		18494622	
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	Art Unit	3791		
	Examiner Name	DOCKET CENTRAL		
	Attorney Docket Number	069366-0577657_KUR2C05US		

	1	S5643474	JP		1981-10-12			☐
	2	0448795	EP		1991-02-10			☒
	3	1996005875	WO		1996-02-29	BAXTER INT		☒
	4	104107054	CN		2014-10-22	BECTON DICKINSON CO		☒
	5	104981203	CN		2015-10-14	MAGNOLIA MEDICAL TECHNOLOGIES INC		☒
	6	1717280	CN		2006-01-04	SECR DEFENCE		☒
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	1	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐
	2	Notice of Allowance mailed 01-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐

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	First Named Inventor	Bobby ROGERS
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	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0577657_KUR2C05US

	3	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
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	5	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	6	Office Action (Non-Final Rejection) dated 10/04/2023 for US App. No. 17538990 (pages 1-47)	☐
	7	Notice of Allowance mailed 09-14-2023; Attorney Docket No. 069366-0574152_KUR2D02IL. 90 pages.	☐
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	Filing Date	2023-10-25
	First Named Inventor	Bobby ROGERS
	Art Unit	3791
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	Attorney Docket Number	069366-0577657_KUR2C05US

	14	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	☐
	15	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	☐
	16	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	☐
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	23	Office Action (Non-Final Rejection) dated 04/16/2024 for US App. 16838017 (pages 1-19).	☐
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	Examiner Name	DOCKET CENTRAL
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	25	First Office Action (Non-Final Rejection) dated 01/16/2024 for JP App. 2021-558648 (pages 1-6).	☐
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	Attorney Docket Number	069366-0577657_KUR2C05US

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	44	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
	45	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐
	46	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐

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	First Named Inventor	Bobby ROGERS
	Art Unit	3791
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0577657_KUR2C05US

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	50	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐

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EXAMINER SIGNATURE

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	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0577657_KUR2C05US

CERTIFICATION STATEMENT			
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):			
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).			
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☐ See attached certification statement.			
☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.			
☒ A certification statement is not submitted herewith.			
SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474
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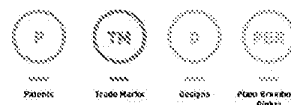
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1 March 2023

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ABN: 38 113 072 755

Griffith Hack

Level 15, 376-390 Collins Street
Melbourne VIC 3000
Australia

Your reference	P108089.AU.1
Application number	2021202622
Applicant name	KURIN, INC.

Dear Griffith Hack,

This patent application was accepted on 21 February 2023. The accepted specification incorporates the following amendments:

S104 amendments up to and including item number: 4

The total number of claims at acceptance has been reported as: 15

Notice of the acceptance will appear in the Australian Official Journal of Patents on 16 March 2023.

Please review the acceptance details attached to this letter to ensure that they are correct. If you wish to amend any details prior to the grant please do so within 3 months of the advertisement of acceptance.

An Invitation to Pay (ITP) the acceptance fee will be issued to you. This fee will include an additional component if the number of claims exceeds 20.

Details of this patent application can be viewed on [AusPat](#), our Australian patent search database.

Yours sincerely,

IP Australia



Acceptance summary

Standard patent details

Patent number: 2021202622

Title: Blood sample optimization system and blood contaminant sequestration device and method

Your reference: P108089.AU.1

Number of claims at acceptance: 15

Applicant and inventor details

Applicant name(s) and address(es) (as it will appear on certificate/s) :

KURIN, INC. of 10755 Scripps Poway Parkway, No. 257 San Diego CA 92131 United States of America

Inventor name(s): ROGERS, Bobby
KANG, Gino
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Address for correspondence: Level 15, 376-390 Collins Street
Melbourne VIC 3000
Australia

Address for legal service: Level 15, 376-390 Collins Street
Melbourne VIC 3000
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Prior art details

Prior art documents:

WO 2011/162772 A1
WO 96/05875 A1
US 2013/0317391 A1
US 4207870 A
US 4416291 A
US 2008/0145933 A1
JP 2001000424 A

Priority details

Divisional of: 2016297849

Your reference P108089.AU.1
Application number 2021202622

International classification

A61B 5/15 (2006.01)
A61B 5/153 (2006.01)
A61B 5/154 (2006.01)

Relevant dates

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Date of patent: 22 July 2016
Expiry date: 22 July 2036
National phase entry date: Not Applicable

⑬ 日本国特許庁 (JP)

⑪ 特許出願公開

⑫ 公開特許公報 (A)

昭56—43474

⑤ Int. Cl.³
D 06 M 5/02

識別記号

庁内整理番号
7199—4L

④ 公開 昭和56年(1981)4月22日

発明の数 1
審査請求 未請求

(全 4 頁)

⑭ ポリエステル系繊維構造物の処理方法

大津市園山一丁目1番1号東レ
株式会社滋賀事業場内

⑮ 特 願 昭54—116657

⑯ 発 明 者 中村暉夫

⑰ 出 願 昭54(1979)9月13日

大津市園山一丁目1番1号東レ
株式会社滋賀事業場内

⑱ 発 明 者 林和也

⑲ 出 願 人 東レ株式会社

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東京都中央区日本橋室町2丁目
2番地

⑳ 発 明 者 小坂義一

明 細 書

1. 発明の名称

ポリエステル系繊維構造物の処理方法

2. 特許請求の範囲

(1) 芯成分がポリエステルから成り、鞘成分がアルカリに侵され難い成分から成る、一芯又は多芯の芯鞘型繊維と、アルカリ処理による見掛けの減量速度が、鞘成分除去後の該芯成分繊維より小さいポリエステル系繊維とを用いて繊維構造物と成し、該芯鞘型繊維の鞘成分を除去する前にアルカリ処理を施すに際し、あらかじめ、該鞘成分の軟化点以上、該芯成分ポリエステルの融点以下の温度で熱処理することを特徴とする、ポリエステル系繊維構造物の処理方法。

(2) 芯成分の単糸繊度が1.0デニール以下であることを特徴とする特許請求の範囲第1項記載のポリエステル系繊維構造物の処理方法。

3. 発明の詳細な説明

本発明は、アルカリ処理による見掛けの減量速度に差のある2種以上のポリエステル系繊維を

含む繊維構造物の製造方法に関するものである。

ポリエステル系繊維構造物を、アルカリ処理することによつて、繊維間空隙を増大させ、シヤリ感のある柔軟で良好な風合を発現させることは、すでに知られている。

しかし、アルカリ処理による見掛けの減量速度に差のある2種以上のポリエステル系繊維を含む繊維構造物においては、一方の繊維の強力低下が過大となり、満足すべき製品は得られなかつた。特に見掛けの減量速度の大きい繊維が0.3デニール以下の場合には該極細糸がアルカリ処理によつて完全に溶解されることさえある。

これに対して見掛けの減量速度の大きい繊維をアルカリに侵され難い成分で保護したまま処理することが検討されたが、期待に反して十分な効果は得られなかつた。たとえば、極細ポリエステを芯とし、ポリスチレンを鞘とする一芯又は多芯の芯鞘繊維と普通繊度のポリエステルからなる布帛の鞘成分を溶出する前にアルカリで減量処理することも試みられたが、極細繊維の強度は極端に低

下するのである。本発明者はかかる問題について鋭意検討した結果、強度低下の原因が、該芯鞘繊維の製糸、製布工程で生じた鞘成分の欠陥によるものであることをつきとめ次の発明に到達したのである。つまり本発明は「芯成分がポリエステルから成り、鞘成分がアルカリに侵され難い成分から成る、一芯又は多芯の芯鞘型繊維とアルカリ処理による見掛けの減量速度が、鞘成分除去後の該芯成分繊維より小さいポリエステル系繊維とを用いて繊維構造物と成し、該芯鞘型繊維の鞘成分を除去する前にアルカリ処理を施すに際し、あらかじめ、該鞘成分の軟化点以上、該芯成分ポリエステルの融点以下の温度で熱処理することを特徴とするポリエステル系繊維構造物の処理方法」である。

以下、本発明をさらに詳細に説明する。

本発明における芯成分ポリエステル及びポリエステル系繊維とは、ポリエチレンテレフタレート、ポリブチレンテレフタレート等のポリエステル及び、それらを易染化、カチオン可染化、酸性可染

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示されるアルカリ溶解速度恒数で示されるが、本発明で使用する見掛けの減量速度とは異なるものである。すなわち、繊維を構成するポリマー、製糸方法及びアルカリ処理条件が同じであれば、アルカリ溶解速度恒数は一定であるが、それらが同じであつても、見掛けの減量速度は、繊維が異なれば変化する。例えば、繊維度が4倍になれば、繊維表面積が1/2になるため、見掛けの減量速度は1/2になる。

つまり一般的な減量速度は次式による。

$$\sqrt{R} = - \frac{2.07 \times 10^4 k}{\sqrt{D}} t + 10 \quad \text{.....式 II}$$

R : t 秒後の不溶解重量分率 (%)

D : デニール

t : 処理時間 (sec)

k : アルカリ溶解速度恒数 (cm/sec)

また、繊維を構成するポリマー、単糸繊維度が同じであつても、製糸方法が異なれば、見掛けの減量速度は変化する。すなわち、芯鞘型の複合繊維の鞘を除去して得られた繊維は構成ポリマー、単

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化、制電化、吸水吸湿化等をした改質ポリエステルをいう。

鞘成分として用いるアルカリに侵され難い成分とは、それ自身がアルカリによつて分解または溶解されないと同時に、アルカリを通しにくいものを指し、ポリスチレン、ポリオレフィン、及びそれらの共重合体などが挙げられる。

見掛けの減量速度とは、苛性ソーダ3%沸騰水溶液中で所定時間処理した時の減量率を測定し、時間を横軸、減量率を縦軸としてグラフを作成し、減量率20%までを最小二乗法で直線近似した場合の直線の傾きで表わされる。一般的には、減量率20%までは直線となるため、見掛けの減量速度は式Iで表わされる。

$$V = \frac{\Delta W}{t} \quad \text{..... 式 I}$$

V : 見掛けの減量速度 (sec⁻¹)

ΔW : 繊維の減量率 (%)

t : 処理時間 (sec)

アルカリ減量速度の遅速は、一般的には式IIで

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糸繊維度が同じであつても、通常の製糸で得た繊維より見掛けの減量速度は大きくなる。

繊維構造物とは、織物、編物、不織布等の形態をいい、その構成繊維としては、芯成分がポリエステルから成り、鞘成分がアルカリに侵され難い成分から成る一芯又は多芯^{のい}芯鞘型繊維と、アルカリ処理による見掛けの減量速度が、鞘成分除去後の該芯繊維より小さいポリエステル系繊維とが、それぞれ10%以上含まれていればよく、それら2種の繊維の他に、見掛けの減量速度の異なるポリエステル系繊維、ポリアミド系繊維、ポリオレフィン系繊維等の合成繊維、綿、絹、羊毛等の天然繊維、アセテート等の半合成繊維、レーヨン等の再成繊維等が含まれていてもよい。またこれらの繊維以外に樹脂、接着剤、割剤などが含浸、コーティング、スプレーなどの手段で付与されたものも含まれるものとする。

鞘成分除去の方法としては、例えば、ポリスチレン系ポリマーを用いた時は、各種の芳香族炭化水素や塩素化炭化水素、その他ポリエステルを溶

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解しないような各種の有機溶剤を用いることができる。

アルカリ処理とは、苛性ソーダ、苛性カリ等の所謂アルカリ化合物及び炭酸ソーダ、炭酸カリ等のアルカリ性化合物を用いて、ポリエステルを加水分解させる処理であり、ポリエステルを加水分解できればどのような方法をとつてもよい。

本発明の一つのポイントは、前述したような芯鞘型繊維を用い、該鞘成分を除去する前にアルカリ処理を施すということである。すなわち、芯繊維を鞘成分によつてアルカリから保護し、他方のポリエステル系繊維のアルカリ減量処理を行なうわけである。しかし、芯繊維が鞘成分によつて完全に保護されていれば問題はないが、實際上、製糸やそれに続く工程、例えば製編織等、繊維構造物と成す工程において、鞘成分に多数の亀裂が生じているため、アルカリがその亀裂から侵入し、また、芯繊維の見掛けの減量速度が大きいかもであり、繊維は部分的にアルカリ加水分解を受け局部的脆化を起こす。

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トで芯成分は融点255℃のポリエチレンテレフタレート、鞘成分は軟化点120℃のポリスチレン、鞘成分の比率は20%。鞘成分除去後の芯繊維の見掛けの減量速度は経糸の1.4倍である。

この織物に通常のリラックス精練処理(95℃)を施し、1疋はそのまま、他の1疋は150℃で乾熱処理し、アルカリ処理によつて、対織物重量比10%の減量を実現させた。鞘成分をトリクレンで除去後、以後常法によつて染色仕上を行なつた。

150℃の乾熱処理を施した製品の緯糸強力は810g/マルチフィラメント(強度4.1g/d強)であるのに対し、乾熱処理を施さなかつた製品の緯糸強力は半分以下の390g/マルチフィラメント(強度2.0g/d弱)しかなく、毛羽立ちも見られた。

実施例2

下記の糸を使用し、ツイル織物を作つた。

- (1) 経糸：150デニール、727フィラメントのポリエチレンテレフタレート糸。

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そこで、本発明の重要なポイントは、アルカリ処理前に、該鞘成分の軟化点以上、該芯成分ポリエステル融点以下の温度で熱処理することである。すなわち、そのような熱処理によつて、鞘成分を流動させ、前述の亀裂を消滅させる効果を持つものである。従つて、該鞘成分の軟化点以下では亀裂をふさぐ効果は望めず、また、該芯成分の融点以上の温度では、該芯鞘型繊維が繊維としての形態をとどめないため、上述の範囲の熱処理が必須となる。なお、本発明でいう軟化点とは、ポリマーが流動を開始する温度で、明瞭な融点を持つ場合には、融点と一致する。

次に、本発明を実施例で詳しく説明するが、本発明はこれらに限定されるものではない。

実施例1

下記の糸を使用し、5枚朱子織物を2疋作つた。

- (1) 経糸：150デニール、48フィラメントのポリエチレンテレフタレート加工糸。
(2) 緯糸：245デニール、40フィラメントの多芯芯鞘型繊維。芯数は36芯/1フィラメン

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(2) 緯糸：200デニール、24フィラメントの多芯芯鞘型繊維。芯数は3芯/1フィラメントで、芯成分は融点230℃の5-ナトリウムスルホインフタル酸を3.8重量%共重合したポリエチレンテレフタレート、鞘成分は軟化点105℃のポリスチレン、鞘成分の比率は25%。鞘成分除去後の芯繊維の見掛けの減量速度は、経糸の約1.0倍である。

この織物に通常のリラックス精練処理(95℃)を施し、160℃で乾熱処理し、アルカリ処理で対織物重量比15%減量させた。鞘成分をトリクレンで除去後、以後常法によつて染色仕上を行なつた。

比較として、緯糸に150デニール、727フィラメントの5-ナトリウムスルホインフタル酸を3.8重量%共重合したポリエチレンテレフタレート糸を使用し、同組織、密度の織物に同様の処理を施し、15%減量させ、以後常法によつて、染色仕上を行なつた。

本発明法による緯糸強度は4.0g/dあるのに

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対し、比較法による線糸強度は 1.5 g/d しか
なかつた。

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特許出願人 東レ株式会社

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 11/28/2022
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER

ABOUELELA, MAY A

ART UNIT PAPER NUMBER

3791

DATE MAILED: 11/28/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	069366-0572168_KUR4002US	6468

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH PASSIVE FLUID CONTROL JUNCTION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	02/28/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 11/28/2022
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

_____ (Typed or printed name)
_____ (Signature)
_____ (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	069366-0572168_KUR4002US	6468

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH PASSIVE FLUID CONTROL JUNCTION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	02/28/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-573000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	069366-0572168_KUR4002US	6468
27500	7590	11/28/2022	EXAMINER	
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)			ABOUELELA, MAY A	
ATTENTION: DOCKETING DEPARTMENT			ART UNIT	
P.O BOX 10500			PAPER NUMBER	
McLean, VA 22102			3791	

DATE MAILED: 11/28/2022

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b) (2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/819,033	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/04/2022.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-23. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892) 2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____. 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material ____. 4. ☒ Interview Summary (PTO-413), Paper No./Mail Date <u>11/16/2022</u> .	5. ☒ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
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/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	
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Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Terminal Disclaimer

2. The terminal disclaimer filed on 11/17/2022 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 17/094692, 17/538990, 11311219, 9820682, 10143412, 11185266 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

3. Authorization for this examiner's amendment was given in an interview with BENJAMIN F. HUDSON on 11/06/2022.

Claim 5 should be amended as follow:

5. (Currently Amended) The device in accordance with claim 1, wherein the junction includes one or more passive structures configured to inhibit a the return to the inlet path of any of the first portion of blood received by the chamber.

Allowable Subject Matter

4. Claims 1-23 are allowed.
5. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Eldridge et al (4,207,870) teaches a device comprising; an inlet path;

an outlet path; a chamber connected to the inlet path; and a sampling channel connected between the inlet path and the outlet path, the sampling channel being configured to convey subsequent amounts of blood between the inlet path and the outlet path after the first amount of blood is received by the sequestration chamber.

The prior art does not teach, disclose and/or fairly suggest a chamber connected with the inlet path by a junction and being configured to receive a first portion of blood through the inlet path, the junction being configured to inhibit a return to the inlet path of any of the first portion of blood received by the chamber.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

<i>Examiner-Initiated Interview Summary</i>	Application No. 16/819,033	Applicant(s) ROGERS et al.		
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (First Inventor to File) Status Yes	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
MAY A ABOUELELA	Primary Examiner	Telephonic
BENJAMIN F. HUDSON	Attorney of Record	

Date of Interview: 16 November 2022

Issues Discussed:

35 U.S.C. 112

Applicant and Examiner discussed the claims set mailed on 11/04/2022. Applicant and Examiner discussed the claim language with respect to the applied prior art and the disclosure. Applicant and Examiner discussed proposed claim amendments represented by the Examiner to overcome 112 rejection for claim 5. The Applicant has authorized the Examiner to amend the claims.

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	
<p>Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04</p> <p>Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing</p>	

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.



רשות המכס



מדינת ישראל
משרד האוצר

פ.ק. 13

תאריך: כ"ג שבט תשפ"ג
14/02/2023
מספרם: 1000-018-01

לכבוד
כץ, פרנטי ושות'
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון: הודעה לפני קיבול בקשת פטנט מספר 267684

סימוכין: מכתבכם מיום 23/10/2022

לתשומת לבכם: מקום בו הנכם מופנים ל"חוק", הכוונה היא לחוק הפטנטים, התשכ"ז – 1967. מקום בו הנכם מופנים ל"תקנות", הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ"ח – 1968. בהתאם לחוזר רשם 035/2017 – פטנטים לא ניתן להשהות פרסום בקשות פטנט לפי סעיף 26 לחוק.

הודעה זו מבוססת על המסמכים הבאים:

שרטוטים מתאריך: 26/06/2019
פרטי הבקשה מתאריך: 26/06/2019
תביעות מתאריך: 23/10/2022

מענה לטיעוני המבקש

מערכת התביעות המוצעת מתקבלת.

הריני להודיעכם כי בחינת הבקשה הנ"ל הושלמה לפי הוראות סעיף 48(ג)1 ו-2 לחוק.

תשלום אגרת קיבול

1. הבקשה תתקבל בהתאם לסעיף 26 לחוק לאחר תשלום אגרת הקיבול.
2. יש לשלם את האגרה תוך 3 חודשים מתאריך הודעה זו.
3. סכום האגרה נכון למועד הודעה זו הינו 764.00 ש"ח. הסכום כפוף לעדכון על פי המדד בהתאם לתקנה 6א.

הפניה בפירוט למסמך הבכורה

לפי הוראות סעיף 20 לחוזר הרשם 034/2017-פטנטים במידה ופירוט הבקשה מכיל הפניה למסמך בכורה באמצעות הביטוי "incorporated by reference" ובמידה וחלפו 14 חודשים ממועד דין הקדימה (אם נדרש) לא ניתן עוד להוסיף דבר מתוך מסמך הבכורה והמבקש לא יכול להסתמך על האמור במסמך הבכורה, לצורך סעיפים 12 ו-13 לחוק.





רשות הפטנטים



מדינת ישראל
משרד המשפטים

עדכון רשימות האסמכתאות והפרסומים לפי סעיף 18 לחוק

לתשומת לבכם, בהתאם להוראות פרק ג' בחוזר רשם 035/2017-פטנטים חובת המבקש לעדכן את הרשות בכל שינוי שחל ברשימת הפרסומים בהתאם לסעיף 18 לחוק נמשכת עד קיבול הבקשה.

באם ברצונכם להחזיר את הבקשה לבחינה בעקבות שינוי ברשימת הפרסומים שהתרחש לאחר תשובתכם להודעת הליקויים האחרונה, עליכם להגיש בקשה לבחינה חוזרת בה עליכם לציין מהו השינוי ברשימת הפרסומים ומתי נודע על שינוי זה.

בקשה לבחינה חוזרת יש להגיש באמצעות פניה ל-"בקשה לתיקונים לאחר פ.ק. 13".

הגשת בקשות חלוקה

בהתאם להוראות סעיף 24(א) לחוק זכאי המבקש כל עוד לא קובלה הבקשה לדרוש את חלוקת הבקשה לבקשות אחדות. לפיכך, באם ברצונכם להגיש בקשות חלוקה מבקשה זו עליכם לעשות זאת בטרם מועד הקיבול. לא נוכל להכיר בבקשות שיוגשו לאחר מועד הקיבול של הבקשה הנוכחית כבקשות חלוקה לעניין סעיף 24(ג) לחוק.

בדיקה פורמלית

להודעה הנוכחית מצורף העתק פירוט הבקשה המעודכן - אם נפלו טעויות נא להודיע עליהן לרשות לפני מועד תשלום אגרת הקיבול.

לצורך אימות פרטי הפרסום בהתאם לסעיף 26 לחוק ניתן לעיין בנסח הבקשה באתר הרשות בקישור הבא :
<https://israelpatents.justice.gov.il/#/en/patent-extract/267684>

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור :

<https://israelpatents.justice.gov.il/#/en/patent-file/details/267684>

בכבוד רב

אלברט אקרמן
 בוחן פטנטים בכיר
 טלפון : 073-3927233
 דואר אלקטרוני : albertak@justice.gov.il
 ראש צוות : מוריה שלמה לוי



Attached for your kind attention are:

- The allowed Description
- The allowed Claims
- The allowed Drawings

Please review the attached documents, namely the allowed description, claims and drawings before authorizing us to pay the allowance fee. Of course, we will review the documents as well.

We additionally remind you of the continuing responsibility of the Applicant to update the ILPO with information of cited art and/or opposition procedure and/or cancellation procedures in corresponding Applications under Section 18 of the Israel Patent Law - until the payment of the allowance fee. When the Applicant becomes aware of publications or other citations that may be relevant information/material to the examination of this application, such information/material must be forwarded to us for reporting to the ILPO. Failure to disclose such information to the ILPO may result in cancellation of an issued IL patent.

Publications filed after this notice will not be reviewed but will be on record. Should the applicant wish to receive continued examination based on new publications, a request to file for re-examination must be filed along with an update of the list of publications.

Divisional Applications

Please be advised that pursuant to Art. 24(a) of the Act, divisional applications may be filed after the payment of the Allowance fee but before the publication. We highly recommend filing divisional applications before the payment of the allowance fee.

We look forward to receiving your instructions in due course.

Yours sincerely,



Ronen Presenti



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www.patents-il.com

- > The original notice in Hebrew.
- > The publication documents, namely, Description, Claims, Drawings.
- > Our invoice number 3083.

3



5250607 | רמת גן, קומה 11, בית 14, חלל הילד אבנא |  info@patents-il.com | 03-9093614 | 03-9326393 | 
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BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

ABSTRACT

Blood sample optimization systems and methods are described that reduce or eliminate contaminants in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

BACKGROUND

[0001] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0002] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0003] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of

rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0004] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0005] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0006] Blood culture collection kits generally consist of a “butterfly” set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a “Vacutainer,” which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0007] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0008] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic

needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0009] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0010] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0011] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

[0012] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0013] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate

short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0014] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0015] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0016] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0017] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0018] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

[0019] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0020] The blood sequestration device, in one aspect can include an inlet port, an outlet port, a sequestration chamber connected with the inlet port via a junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further includes a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber, and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In certain related aspects, the sequestration chamber, the sampling channel and the junction are sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0021] In another aspect, the sampling channel and the junction is sized and configured such that a first portion of blood flows into and fills the sequestration chamber to displace air therein through the vent, and such that a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0022] The blood sequestration and sampling system sequestration device, in certain aspects can include a blood sampling pathway having a patient needle on a proximal end and a sample collection device on a distal end; and a blood sequestration device attached on the blood sampling pathway between the proximal end and distal end of the blood sampling pathway. The blood sequestration device in one aspect can include an inlet port coupled with the blood sampling pathway toward the patient needle, an outlet port coupled with the blood sampling pathway toward the sample collection device, a sequestration chamber connected with the inlet port via a junction, which chamber has a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In a certain related aspect, the sequestration chamber, the sampling channel and the junction can be sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0023] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the

sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0024] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] These and other aspects will now be described in detail with reference to the following drawings.

[0026] FIG. 1 illustrates a blood sample optimization system.

[0027] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0028] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0030] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0031] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0032] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0033] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

- [0034]** FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.
- [0035]** FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.
- [0036]** FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.
- [0037]** FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.
- [0038]** FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.
- [0039]** FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminants of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.
- [0040]** FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.
- [0041]** FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.
- [0042]** FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.
- [0043]** FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.
- [0044]** FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.
- [0045]** FIG. 20 shows a blood sample optimization system including a blood sequestration device.
- [0046]** FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0047] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0048] FIGS. 23A – 23E illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0049] FIGS. 24A – 24D illustrate another implementation of a blood optimization system and blood sequestration device.

[0050] FIGS. 25A – 25D illustrate another implementation of a blood optimization system and blood sequestration device.

[0051] FIGS. 26A – 26E illustrate another implementation of a blood optimization system and blood sequestration device.

[0052] FIGS. 27A – 27D illustrate another implementation of a blood optimization system and blood sequestration device.

[0053] FIGS. 28A – 28F illustrate another implementation of a blood optimization system and blood sequestration device.

[0054] FIGS. 29A – 29C illustrate another implementation of a blood optimization system and blood sequestration device.

[0055] FIGS. 30A – 30G illustrate another implementation of a blood optimization system and blood sequestration device.

[0056] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0057] This document describes blood sample optimization systems and methods for reducing or eliminating contaminants in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and

a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0058] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0059] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0060] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable

material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term “air permeable blood barrier” means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0061] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a “duck bill” or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0062] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0063] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0064] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0065] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0066] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a “T” or “Y” connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0067] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient’s own blood pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0068] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0069] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to

obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0070] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A “T” or “Y” connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0071] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0072] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient’s own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0073] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient’s vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out

of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0074] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indicator or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0075] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0076] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be

connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0077] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0078] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0079] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a

patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0080] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0081] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0082] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration

chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0083] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0084] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0085] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0086] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™,

associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0087] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0088] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0089] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0090] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define

housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0091] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0092] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminants of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a

blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0093] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0094] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0095] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air

permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0097] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0098] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0099] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00100] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[00101] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[00102] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[00103] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[00104] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00105] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration

device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[00106] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[00107] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[00108] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00109] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The

protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00110] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00111] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the inlet port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or

partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00112] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00113] In some instances, as shown in FIG. 15H, an inlet port 1532 can include a male luer connector for connecting to a removable patient needle, and an outlet port 11534 can include a female luer connector for connecting with a syringe. This implementation of the inlet port and outlet port can be used with any device described herein, for avoiding a propensity of a Vacutainer-type device collapsing a patient's vein. In this implementation, a clinician can use the syringe in a modulated fashion to obtain a blood sample. In operation, the syringe is attached to the outlet port 1004, and the needle is attached to the inlet port 1002. A venipuncture is performed with the needle, and without the clinician pulling on the syringe. An initial aliquot of blood fills a sequestration chamber, and then the syringe can be used to draw a sample of blood through the collection channel, bypassing the sequestered blood in the sequestration chamber.

[00114] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an inlet port, and outlet port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be

understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00115] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00116] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00117] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00118] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber

1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00119] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00120] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00121] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17E and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17E illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or

other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00122] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00123] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00124] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00125] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member

1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective member 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00126] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 1606 is directed to an outlet port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00127] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00128] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be

provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00129] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00130] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00131] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00132] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00133] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling

device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminant, or other additive.

[00134] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00135] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[00136] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel 2308

before the initial aliquot of blood is sequestered in the sequestration chamber 2306. For instance, valve 2308 can also be formed as a flap, door or closable window or barrier within the sampling channel 2308.

[00137] FIGS. 23C – 23E illustrate an alternative implementation of the blood sequestration device 2300', in which a sequestration chamber 2320 branches off from a main collection channel 2322 between an inlet port 2316 to connect with a patient needle and an outlet port 2318 to connect with a blood sample collection device, such as a Vacutainer, a syringe, or the like. The sequestration chamber 2320 includes an air-permeable, blood impermeable blood barrier 2324, such as a hydrophobic plug of material, or a filter formed of one or more layers, for example. A valve 2324 closes off and opens the collection channel 2322, and the device 2300' can be used similarly as described above.

[00138] FIG. 24A – 24D illustrate a blood sample optimization system 2400 that includes a patient needle 2402 for vascular access to a patient's bloodstream, a blood sample collection device 2404 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2406 providing a fluid connection between the patient needle 2402 and the blood sample collection device 2404. In some implementations, the blood sample collection device 2404 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2406 from the patient needle 2402.

[00139] The blood sample optimization system 2400 further includes a blood sequestration device 2408, located at any point on the conduit 2406 between the patient needle 2402 and the blood sample collection device 2404. The location of the blood sequestration device 2408 can be based on a length of the conduit between the blood sequestration device 2408 and the patient needle 2402, and the associated volume that length provides.

[00140] The blood sequestration device 2408 includes an inlet port 2412 for being connected to the conduit 2406 toward the patient needle 2402, and an outlet port 2414 for being connected to the conduit 2406 toward the blood sample collection device 2404, and a housing 2416. The housing 2416 can be any shape, although it is shown in FIGS. 24A

– D as being substantially cylindrical, and includes the inlet port 2412 and outlet port 2414, which can be located anywhere on the housing although shown as being located on opposite ends of the housing 2416.

[00141] The blood sequestration device 2408 further includes a blood sequestration chamber 2418 connected with the inlet port 2412. The blood sequestration chamber 2418 is defined by an inner chamber housing 2419 that is movable from a first position to receive and sequester a first aliquot of blood, to a second position to expose one or more apertures 2424 at a proximal end of the inner chamber housing 2419 to allow blood to bypass and/or flow around the inner chamber housing 2419 and through a blood sample channel 2422 defined by the outer surface of the inner chamber housing 2419 and the inner surface of the housing 2416. The blood sequestration chamber 2418 includes an air permeable blood barrier 2420 at a distal end of the blood sequestration chamber 2418.

[00142] In operation, the inner chamber housing 2419 is in the first position toward the inlet port 2412, such that the one or more apertures 2424 are closed, and the blood sequestration chamber 2418 is in a direct path from the patient needle. Upon venipuncture of a patient, and drawing of blood by way of a syringe or Vacutainer, or other blood collection device 2404, the initial aliquot of blood flows into the blood sequestration chamber 2418. As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position. The inner chamber housing 2419 and/or housing 2416 can include a locking mechanism of one or more small tabs, grooves, detents, bumps, ridges, or the like, to maintain the inner chamber housing 2419 in the first position until the blood sequestration chamber 2418 is filled, providing force to overcome the locking mechanism to enable movement of the inner chamber housing 2419 to the second position. Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.

[00143] As described above, the housing 2416 and/or inner chamber housing 2419 can be formed as cylindrical and concentric, but can be any shape, such as squared, rectangular, elliptical, oval, or other cross-sectional shape. The outer surface of the distal

end of the inner chamber housing 2419 can have one or more outwardly projecting tangs 2421 with gaps therebetween. The tangs 2421 contact the inner surface of the housing 2416 to help define the blood sampling channel 2422 therebetween, and to help stop the inner chamber housing 2419 in the second position. The gaps between the tangs 2421 enable blood to flow through the blood sampling channel 2422 and to the outlet port 2414. When the inner chamber housing 2419 is in the second position and the blood sequestration chamber 2418 is filled with the first aliquot of blood, further blood samples will automatically flow through the inlet port 2412, through the one or more apertures 2424, through the blood sampling channel 2422, through the gaps between the tangs 2421, and ultimately through the outlet port 2414 to be collected by a blood sampling device 2404.

[00144] FIGS. 25A – D show a blood optimization system 2500 and blood sequestration device 2502, formed substantially as described in FIGS. 15, 16, 17, 18 and 19, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2520. Air initially in the blood sequestration chamber 2520 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2520. The air venting mechanism includes an air permeable blood barrier 2506, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2520.

[00145] The air venting mechanism includes an inner wall 2516 that at least partially circumscribes or surrounds the air permeable blood barrier 2506, and an outer wall 2504 spaced apart from the inner wall 2516. The outer wall 2504 can have one or more air vents 2514 formed therein. The outer wall 2504 extends higher upward than the inner wall 2516, such that a lid 2510, such as a cap, plug, cover, etc., can be attached to the outer wall 2504 and be displaced by a small distance from the top of the inner wall 2516. A seal 2508 in the form of a silicone wafer, or other elastomeric material, fits within the outer wall 2504 to cover the air permeable blood barrier 2506 and abut the top of the inner wall 2516. The seal 2508 covers and seals the air permeable blood barrier 2506 and inhibits air from entering the blood sequestration chamber 2520 through the air permeable blood barrier 2506. A fulcrum 2512 on an underside of the lid 2510 allows the seal 2508 to flexibly disconnect from the top of the inner wall 2516 when pushed by air displaced from the blood sequestration chamber 2520, to allow air to vent from the air

permeable blood barrier 2506 and through the one or more air vents 2514 in the outer wall 2504.

[00146] FIG. 26A – E illustrate a blood sample optimization system 2600 that includes a patient needle 2602 for vascular access to a patient's bloodstream, a blood sample collection device 2604 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2606 providing a fluid connection between the patient needle 2602 and the blood sample collection device 2604. The conduit 2606 can include flexible tubing. In preferred implementations, the blood sample collection device 2604 includes a protective shield 2605 that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2606 from the patient needle 2602.

[00147] The blood sample optimization system 2600 further includes a blood sequestration device 2608, located at any point on the conduit 2606 between the patient needle 2602 and the blood sample collection device 2604. The location of the blood sequestration device 2608 can be based on a length of the conduit between the blood sequestration device 2608 and the patient needle 2602, and the associated volume that length provides.

[00148] The blood sequestration device 2608 includes an inlet port 2612 for being connected to the conduit 2606 toward the patient needle 2602, and an outlet port 2614 for being connected to the conduit 2606 toward the blood sample collection device 2604. The blood sequestration device 2608 includes an outer housing 2616 and an inner housing 2617, both having a cylindrical form, and being connected concentrically. The outer housing 2616 includes an outer wall 2618 and an inner conduit 2620 that defines a blood sampling channel 2622 to convey blood through the conduit 2606 to the blood sampling device 2604. The inner housing 2617 fits snugly between the inner conduit 2620 and the outer wall 2618 of the outer housing, and is rotatable in relation to the outer housing 2616. The fit between the outer housing 2616 and the inner housing 2617 can be a friction fit that maintains the housings in a particular position. The inner housing 2617 defines a blood sequestration chamber 2624, preferably a helical or corkscrew channel around the outer surface of inner conduit 2620 of the outer housing 2616, and which

terminates at an air vent 2628 having an air permeable blood barrier, as shown in FIG. 26E.

[00149] The blood sequestration chamber 2624 is connected with the blood sampling channel 2622 via diversion junction 2624 formed in the inner conduit 2620, when the blood sequestration device is in a first state, illustrated in FIG. 26C. The protective shield 2606 on the collection needle 2604 provides a block for air or blood, enabling a diversion of an initial aliquot of blood into the blood sequestration chamber 2624 as the patient's blood pressure overcomes the ambient air pressure in the blood sequestration channel 2624 to displace air therefrom through air vent 2628.

[00150] When the inner housing 2617 is rotated relative to the outer housing 2616, or vice versa, to a second state, as illustrated in FIG. 26D, the blood sequestration chamber 2624 is shut off from diversion junction 2624, enabling a direct path from the patient needle through the conduit 2606 to the collection needle 2604, via blood sampling channel 2622. The outer housing 2616 and/or inner housing 2617 can include ridges or grooves formed within a portion of their surfaces, to facilitate relative rotation from the first state to the second state.

[00151] FIGS. 27A – D illustrate a blood optimization system 2700 and blood sequestration device 2702, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, and 25, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2720. Air initially in the blood sequestration chamber 2720 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2720. The air venting mechanism includes an air permeable blood barrier 2706, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2720.

[00152] The air venting mechanism includes an inner wall 2716 that at least partially circumscribes or surrounds the air permeable blood barrier 2706, and an outer wall 2704 spaced apart from the inner wall 2716. A cap 2722 is positioned on the air venting mechanism, preferably by having a lower cap wall 2728 that fits between the inner wall 2716 and the outer wall 2704 of the air venting mechanism, and frictionally abutting either the inner wall 2716 or the outer wall 2704 or both. The cap 2722

further includes one or more vent holes 2724 or slits, apertures, openings, or the like, which extend through an upper surface of the cap 2722 around a downwardly extending plug 2726. The plug 2726 is sized and adapted to fit snugly within the space defined by inner wall 2716.

[00153] In a first position, as illustrated in FIG. 27C, the cap 2722 is extended from the air venting mechanism to allow air from the blood sequestration chamber 2720 to exit through the air permeable blood barrier 2706 and through the one or more vent holes 2724. Once the air from the blood sequestration chamber 2720 has been displaced, i.e., when the blood sequestration chamber 2720 is filled with the first aliquot of potentially tainted blood from the patient, then the cap 2722 can be pushed down on the air venting mechanism in a second position as shown in FIG. 27D, so that the plug 2726 fits within the inner wall 2716 over the air permeable blood barrier 2706 to seal the air venting mechanism. In either the first position or the second position, the cap 2722 protects the air permeable blood barrier 2706 from outside air or from being touched by a user.

[00154] FIGS. 28A – F illustrate a blood optimization system 2800 and blood sequestration device 2802, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but utilizing a multi-layered filter, and in some implementations, a filter with trapped reactive material, for an air permeable blood barrier. As shown in FIGS. 28C and D, an air permeable blood barrier 2803 includes a first layer 2804 of an air permeable but blood impermeable material, and a second layer 2806 that includes a reactive material, such as a hydrophobic material, for repelling blood while still allowing air to pass through both layers. As shown in FIGS. 28E and F, the air permeable blood barrier 2803 can include any number of layers, such as a third layer 2808 formed of the same air permeable but blood impermeable material as first layer 2804, while a second layer 2806 includes trapped or embedded blood reactive material.

[00155] FIGS. 29A – C illustrate a blood optimization system 2900 and blood sequestration device 2902, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but in which a blood sequestration chamber 2904 is at least partially filled with a blood-absorptive material 2906. The blood-absorptive material 2906 can act as a wicking material to further draw in blood to be sequestered upon venipuncture of the patient, and prior to use of a blood drawing device such as a Vacutainer™ or a syringe, or the like.

[00156] FIGS. 30A – G illustrate a blood optimization system 3000 and blood sequestration device 3002, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26. The blood sequestration device 3000 includes an inlet port 3002 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 3002 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 3002 defines an opening into the blood sequestration device 3000, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00157] The inlet port 3002 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 3002, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 3000 at the time of blood draw or sampling.

[00158] The blood sequestration device 3000 further includes an outlet port 3004, which defines an opening out of the blood sequestration device 3000 and to the blood sample collection device. The outlet port 3004 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 3000 at the time of blood draw or sampling.

[00159] The blood sequestration device 3000 further includes a sampling channel 3006 between the inlet port 3002 and the outlet port 3004, and a sequestration chamber 3008 that is connected to and split off or diverted from the sampling channel 3006 at any

point between the inlet port 3002 and the outlet port 3004. The sampling channel 3006 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 3008. The sampling channel 3006 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 3006 has a substantially similar cross sectional area as the opening of the inlet port 3002. In other implementations, the sampling channel 3006 can gradually widen from the inlet port 3002 to the outlet port 3004. The sequestration chamber 3008 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 3006.

[00160] In some exemplary implementations, the diversion between the sampling channel 3006 and the sequestration chamber 3008 is by diverter junction 3007. Diverter junction 3007 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008. The sequestration chamber 3008 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 3008.

[00161] The sequestration chamber 3008 is preferably maintained at atmospheric pressure, and includes a vent 3010 at or near a distal end of the sequestration chamber 3008. The vent 3010 may include an air permeable blood barrier 3012 as described above.

[00162] The blood sequestration device 3000 can include a housing 3001 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated FIG. 30F, the housing 3001 includes a top member 3020 and a bottom member 3022 that are mated together. The blood sequestration device 3000 can also include a gasket or other sealing member (not shown) so that when the top member 3020 is mechanically attached with the bottom member 3022, the interface between the two is sealed by the gasket or sealing member. The bottom member 3022 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 3006, the sequestration chamber 3008, and diverter junction 3007.

[00163] The sequestration chamber 3008 may have a larger cross section than the sampling channel 3006 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 3006.

[00164] In some implementations, the sampling channel 3006 and the sequestration chamber 3008 are formed by grooves, channels, locks or other pathways formed in housing 3001. The housing 3001 can be made of rubber, plastic, metal or any other suitable material. The housing 3001 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 3001 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 3006 and/or the sequestration chamber 3008 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 3008 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 3006. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 3012 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00165] The air permeable blood barrier 3012 can be covered with, or surrounded by, a cap 3032. The cap 3032 can be sized and configured to inhibit a user from touching the air permeable blood barrier 3012 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 3012 as the air is displaced from the sequestration chamber 3008. The cap 3032 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00166] The air venting mechanism includes a wall 3030 that at least partially circumscribes or surrounds the air permeable blood barrier 3012. The wall 3030 can have one or more air vents formed therein. The cap 3032 covers wall 3030 and can be snapped, glued, or otherwise attached in place. A seal 3017 in the form of a silicone wafer, or other elastomeric material, fits within the wall 3030 to cover the air permeable blood barrier 3012 and abut the top of the wall 3030. The seal 3017 covers and seals the

air permeable blood barrier 3012 and inhibits air from entering the blood sequestration chamber 3008 through the air permeable blood barrier 3012. A fulcrum 3012 on an underside of the cap 3032 allows the seal 3008 to flexibly disconnect from the top of the inner wall 3016 when pushed by air displaced from the blood sequestration chamber 3008, to allow air to vent from the air permeable blood barrier 3012 and through the one or more air vents in the wall 3030 and/or cap 3032.

[00167] In use, the blood sequestration device 3000 includes a sampling channel 3006 and a sequestration chamber 3008. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 3006 is directed to an outlet port 3004 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 3008 terminates at a vent 3010 to atmosphere that includes an air permeable blood barrier 3012.

[00168] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 3002 of blood sequestration device 3000. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 3008 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 3008 to displace air therein through the air permeable blood barrier 3012, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 3006. In various exemplary embodiments, the sequestration chamber 3008 and sampling channel 3006 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00169] Eventually, the sequestration chamber 3008 fills with blood that displaces air through the air permeable blood barrier 3012. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 3012 material to completely or partially seal the vent 3010. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00170] Upon filling the blood sequestration pathway 3008 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 3006, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 3006, queuing up the uncontaminated blood to be drawn through the sampling channel 3006.

[00171] In yet another aspect, the blood sequestration chamber and/or blood sampling channel, or other component, of any of the implementations described herein, can provide a visually discernable warning or result in a component adapted for operative fluid communication with the flash chamber of an introducer for an intravenous catheter into a blood vessel of a patient. The device and method provides a visually discernable alert when blood from the patient communicates with a test component reactive to communicated blood plasma, to visually change. The reaction with the blood or the plasma occurs depending on one or a plurality of reagents positioned therein configured to test for blood contents, substances or threshold high or low levels thereof, to visually change in appearance upon a result.

[00172] In yet other aspects, the blood sequestration chamber and/or blood sampling channel can be sized and adapted to provide a particular volumetric flow of blood, either during the sequestration process and/or the sampling process.

[00173] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

CLAIMS

1. A blood control device comprising; an inlet port; an outlet port;
a chamber connected with the inlet port via a junction, the chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and that includes one or more air vents, the vent further including a cap that at least partially covers the outer wall and including a one-way seal abutting the air permeable blood barrier that inhibits air from entering the chamber; and
a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;
the chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the chamber toward the air permeable blood barrier for being held therein, and a second portion of blood bypasses the chamber and the first portion of blood held therein and is directed into the sampling channel toward the outlet port.
2. The blood control device in accordance with claim 1, further comprising a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.
3. The blood control device in accordance with claim 1, wherein the vent further includes an inner wall within the outer wall and that contains the air permeable blood barrier.
4. The blood control device in accordance with claim 1, wherein the one-way seal is positioned over the inner wall and within the outer wall of the vent.
5. The blood control device in accordance with claim 4, wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the chamber.

6. The blood control device in accordance with claim 1,
wherein the air permeable blood barrier includes a sealing material that seals the vent upon contact with blood.
7. The blood control device in accordance with claim 1,
wherein the air permeable blood barrier includes a filter having a first layer and a second layer, the second layer of the filter having a hydrophobic material to repel blood.
8. A blood control and sampling system comprising:
a blood sampling pathway having a patient needle on a proximal end and a sample collection device on a distal end; and
a blood control device attached on the blood sampling pathway
between the proximal end and distal end of the blood sampling pathway, the blood control device comprising:
an inlet port coupled with the blood sampling pathway toward the patient needle;
an outlet port coupled with the blood sampling pathway toward the sample collection device;
a chamber connected with the inlet port via a junction, the chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and that includes one or more air vents, the vent further including a cap that at least partially covers the outer wall and including a one-way seal abutting the air permeable blood barrier that inhibits air from entering the chamber; and
a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;
the chamber, the sampling channel and the junction
being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for being held therein, and a second portion of blood bypasses the chamber and the first portion of blood held therein and is directed into the sampling channel toward the outlet port.

9. The blood control system in accordance with claim 8,
wherein the blood control device further comprises a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.
10. The blood control system in accordance with claim 8,
wherein the vent of the blood control device further includes an inner wall within the outer wall and that contains the air permeable blood barrier.
11. The blood control system in accordance with claim 8,
wherein the one-way seal of the vent is positioned over an inner wall and within the outer wall of the vent.
12. The blood control system in accordance with claim 11,
wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the chamber.
13. The blood control system in accordance with claim 8,
wherein the air permeable blood barrier of the blood control device includes a sealing material that seals the vent upon contact with blood.
14. The blood control system in accordance with claim 8,
wherein the air permeable blood barrier of the blood control device includes a filter having a first layer and a second layer, the second layer of the filter having a hydrophobic material to repel blood.
15. A blood control device comprising;
an inlet port;
an outlet port;
a chamber connected with the inlet port via a junction, the chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall

that at least partially circumscribes the air permeable blood barrier and that includes one or more air vents, the vent further including a cap that at least partially covers the outer wall and including a one-way seal abutting the air permeable blood barrier that inhibits air from entering the chamber; and

a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;

the chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into and fills the chamber to displace air therein through the vent, and such that a second portion of blood bypasses the chamber and the first portion of blood held therein and is directed into the sampling channel toward the outlet port.

16. The blood control device in accordance with claim 15, further comprising a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.
17. The blood control device in accordance with claim 15, wherein the vent further includes an inner wall within the outer wall and that contains the air permeable blood barrier.
18. The blood control device in accordance with claim 15, wherein the one-way seal is positioned over the inner wall and within the outer wall of the vent.
19. The blood control device in accordance with claim 18, wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the control chamber.
20. The blood control device in accordance with claim 15, wherein the air permeable blood barrier includes a sealing material that seals the vent upon contact with blood.

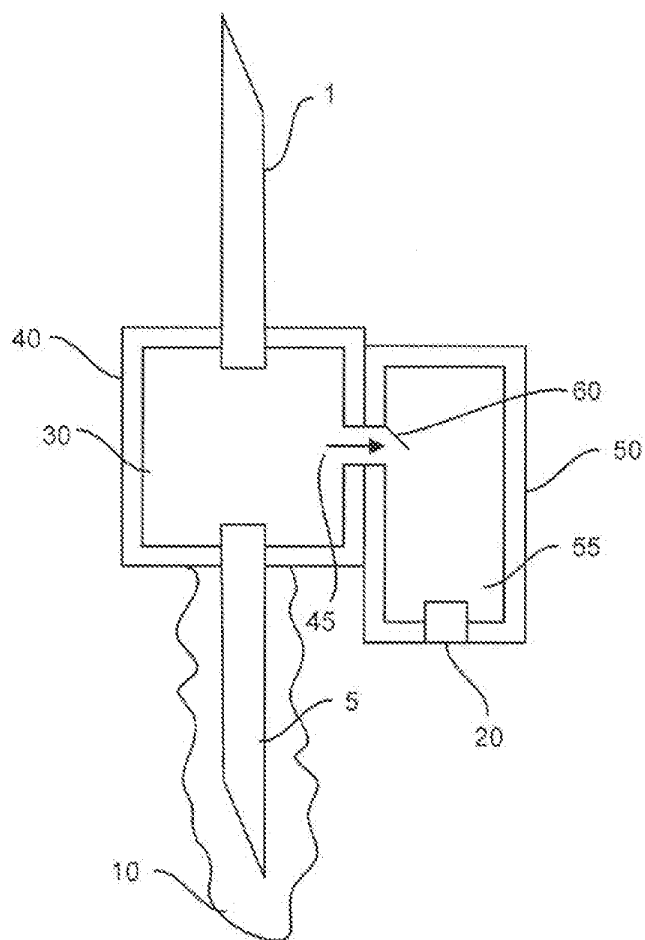


FIG. 1

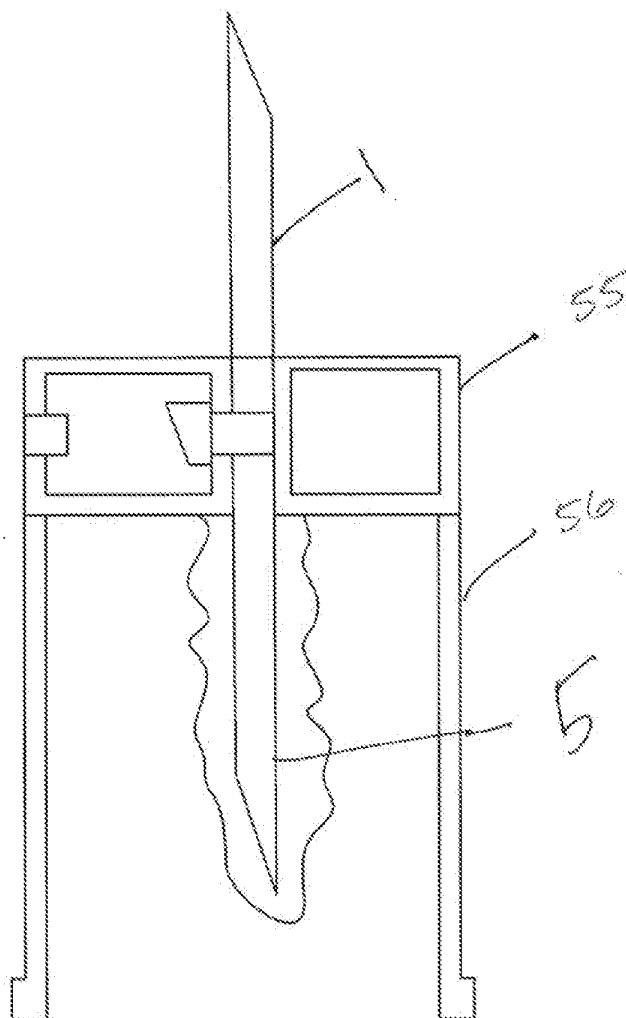


FIG. 2

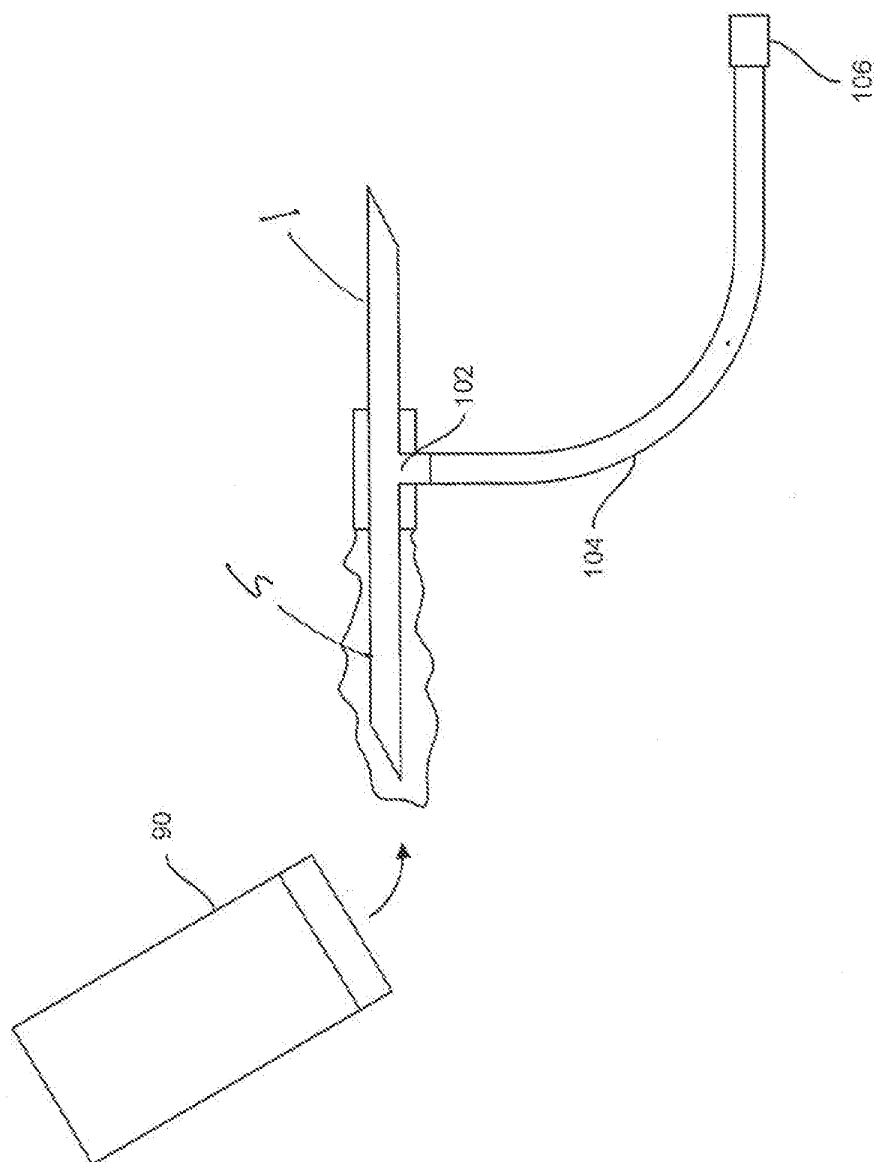


FIG. 3

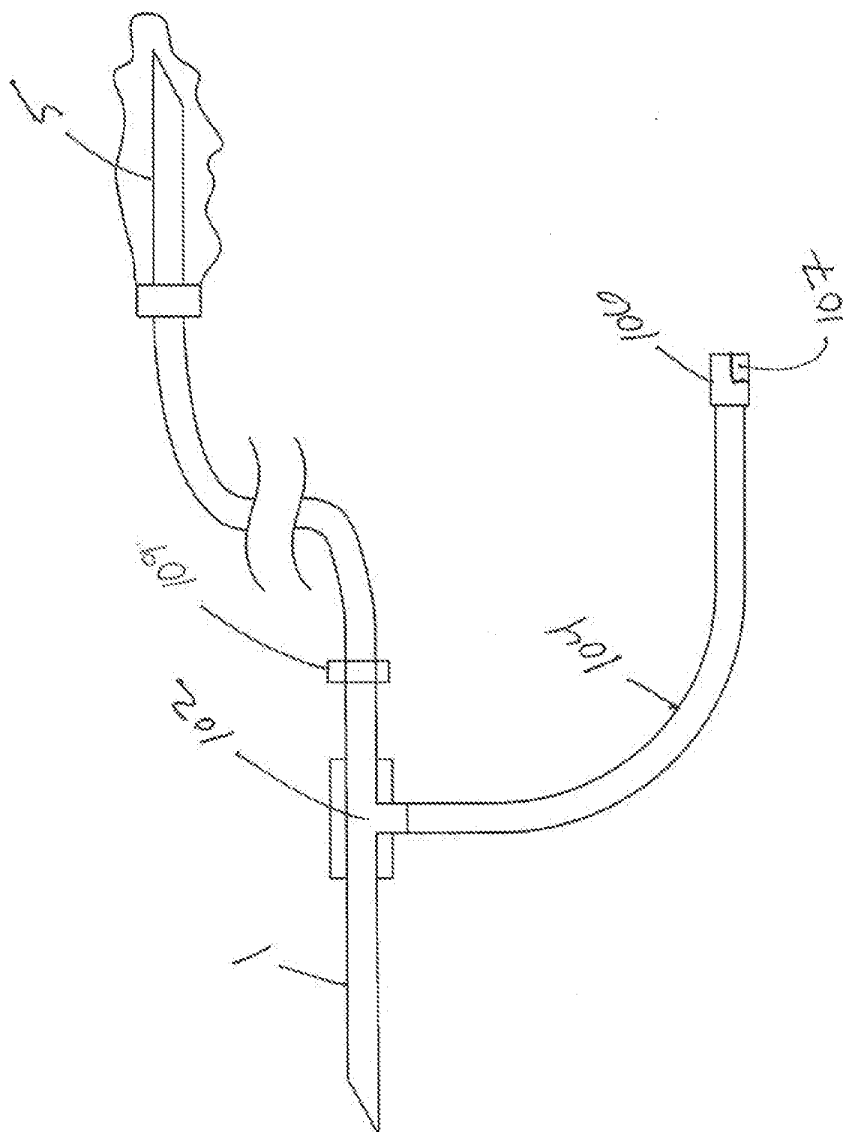


FIG. 4

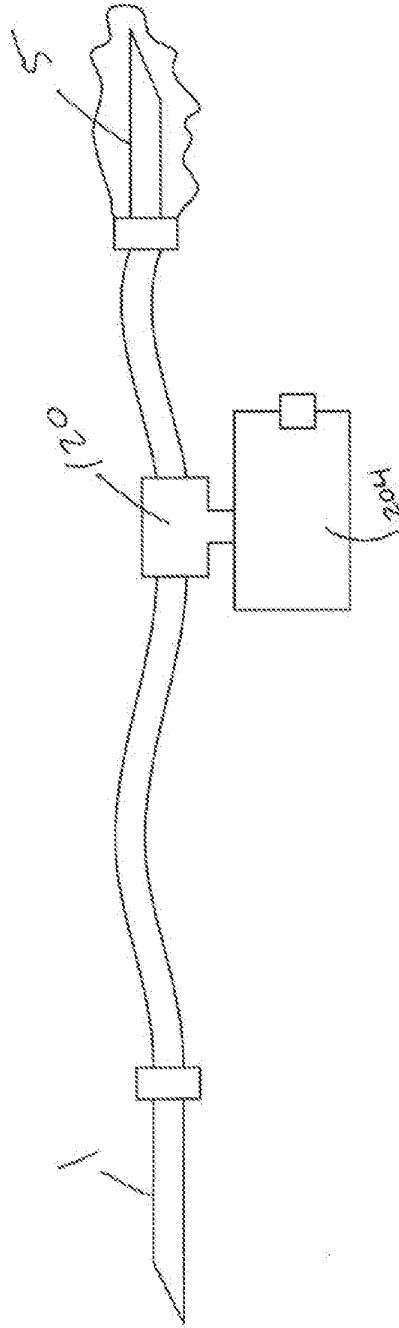


FIG. 5

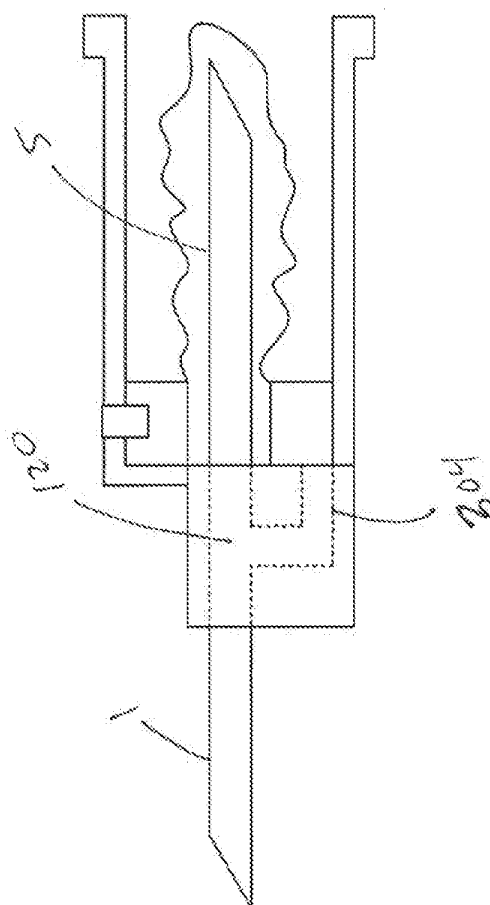
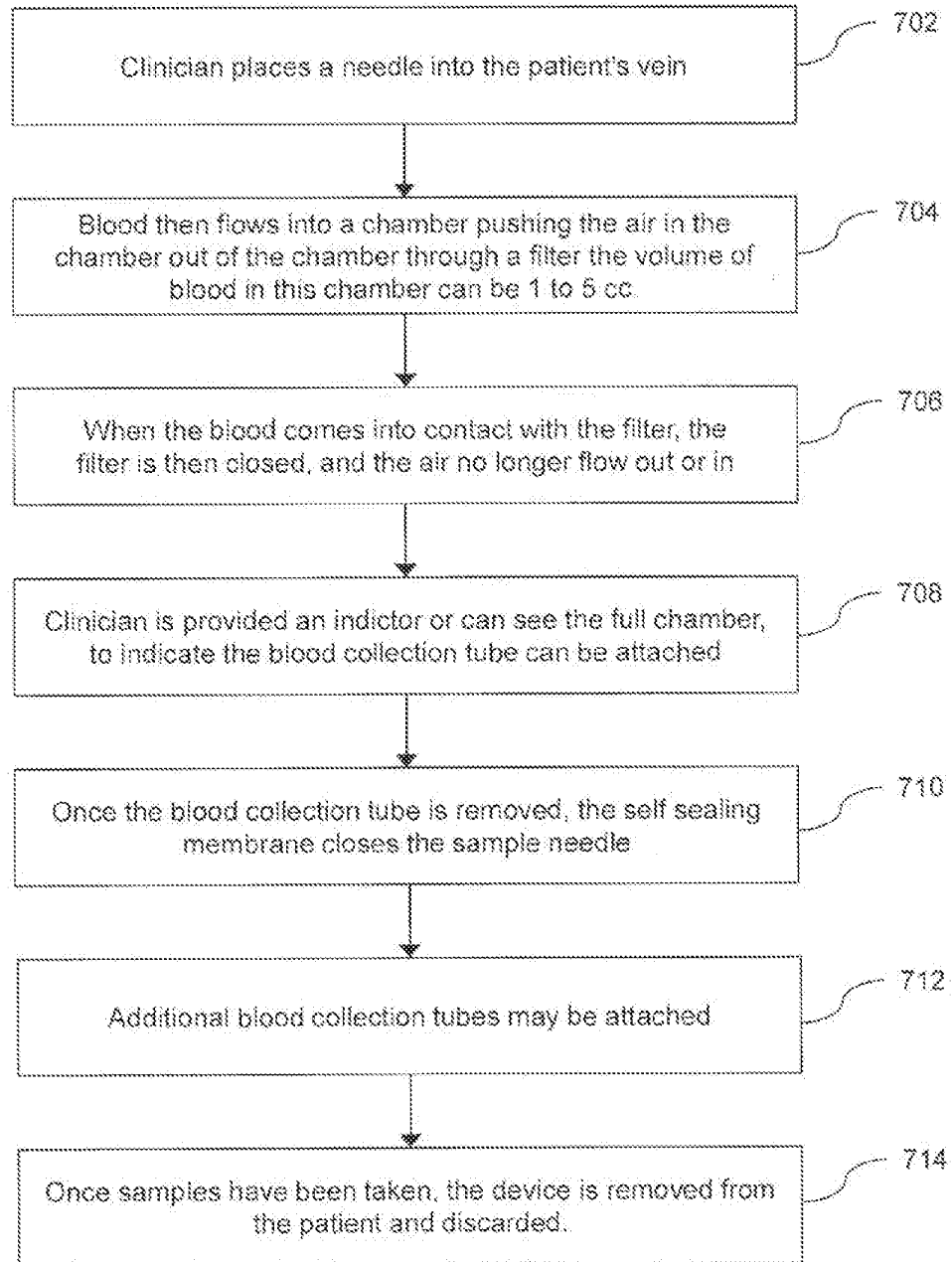


FIG. 6

**FIG. 7**

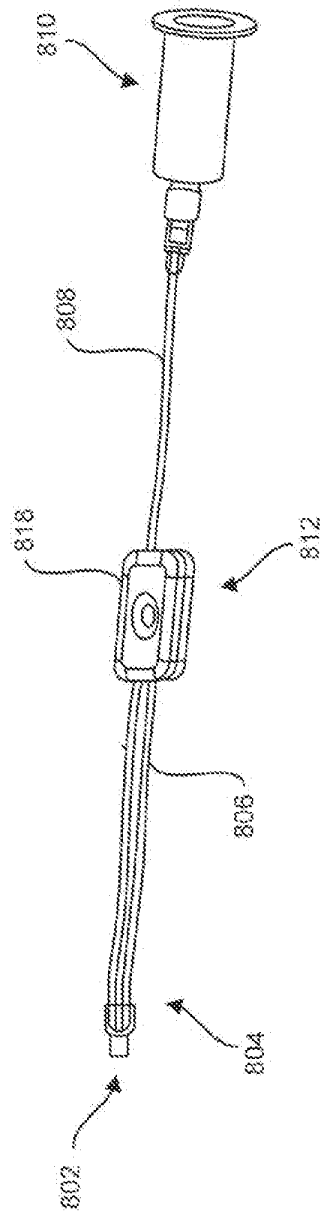
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FIG. 8A

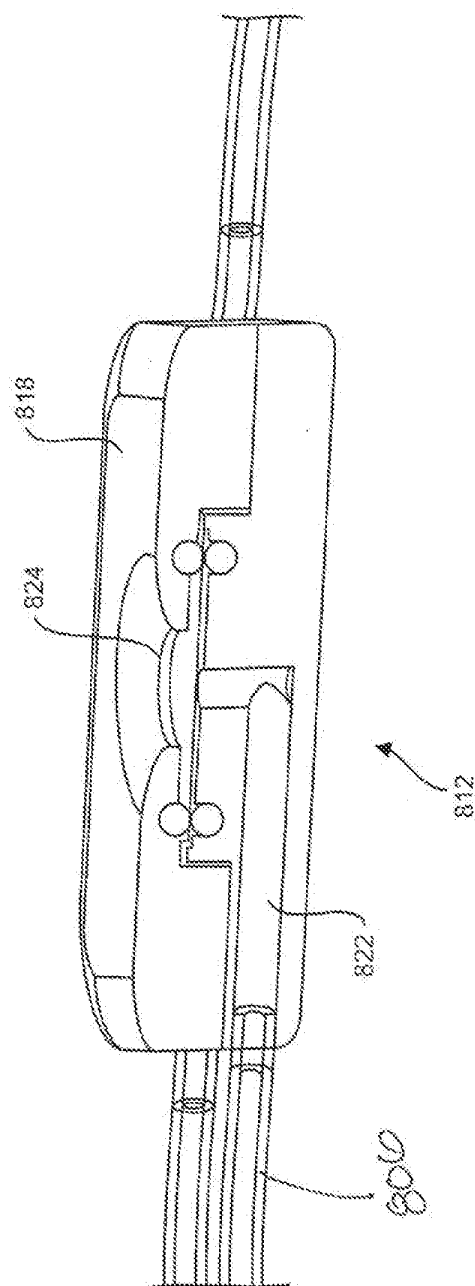


FIG. 8B

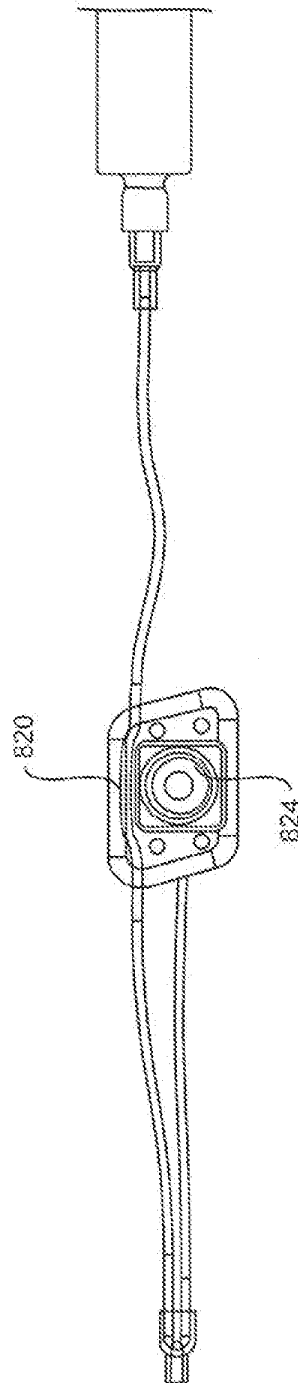


FIG. 8C

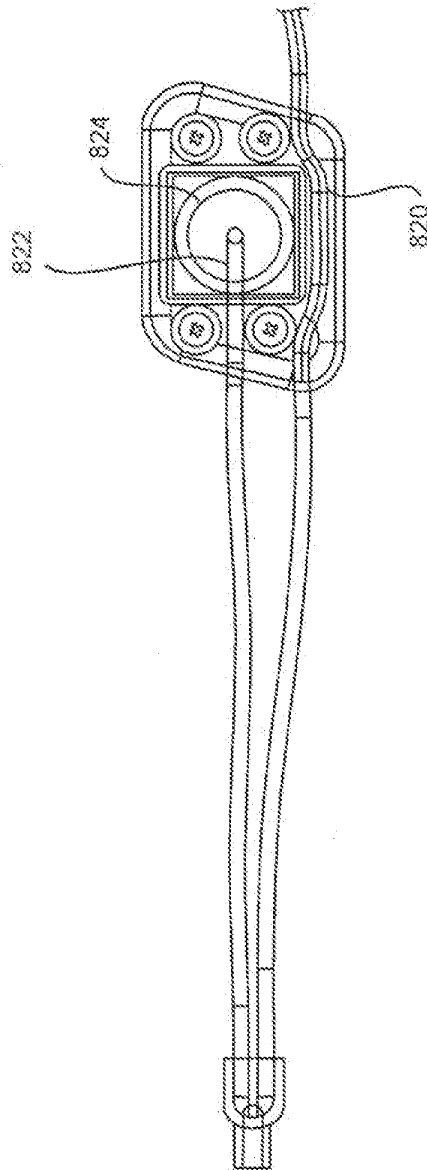


FIG. 8D

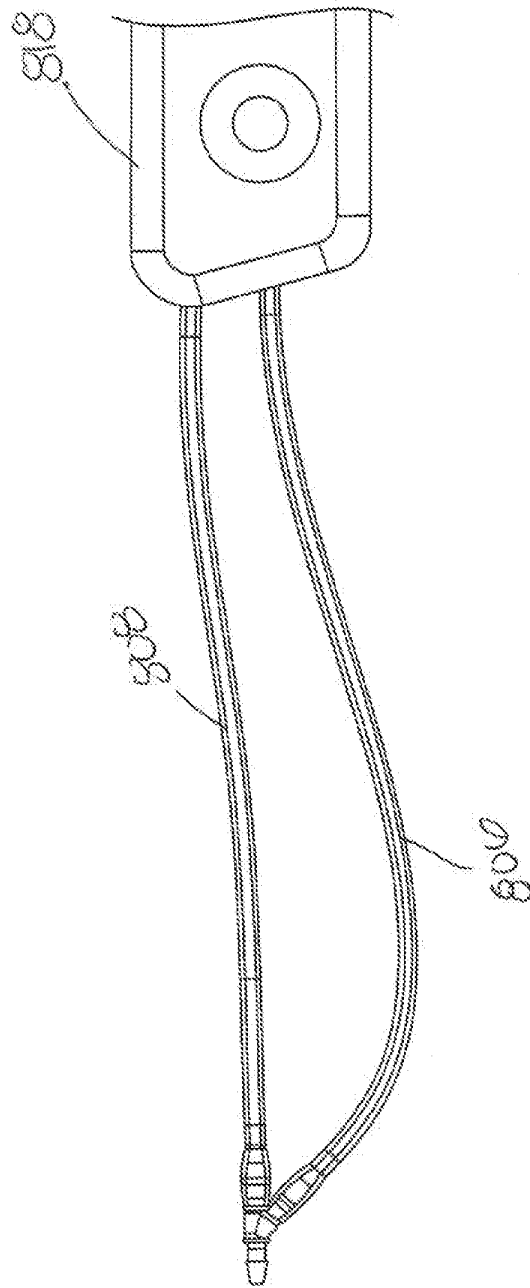


FIG. 8E

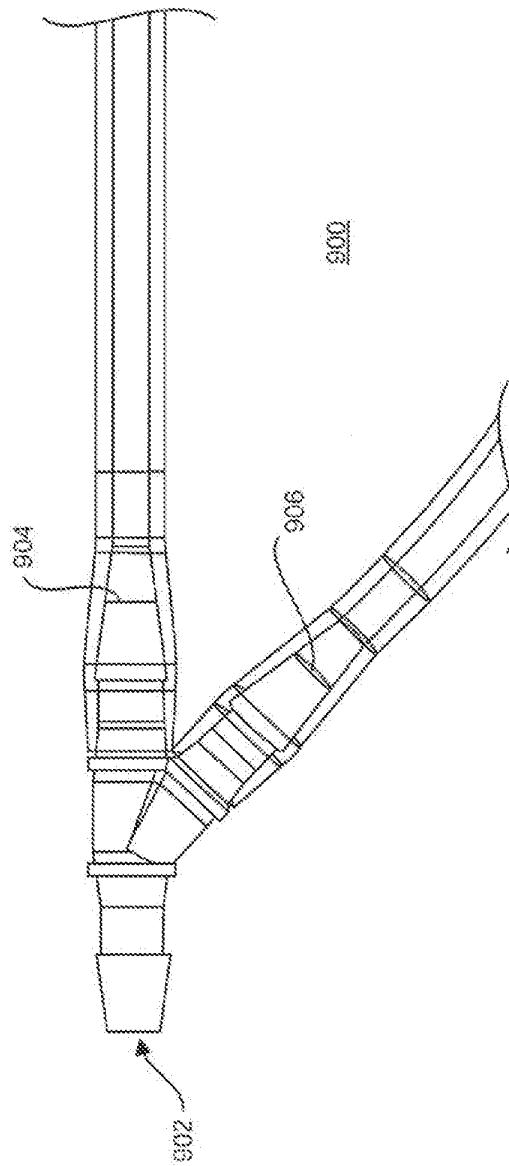


FIG. 9

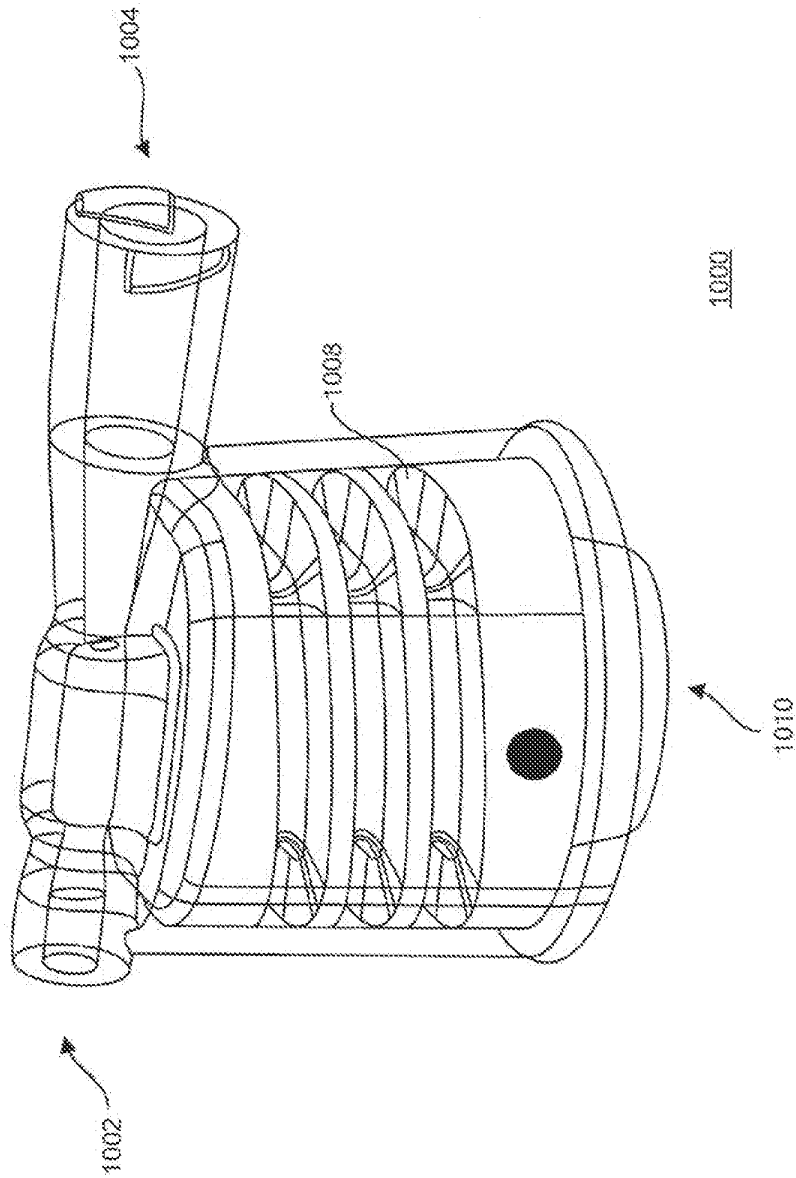


FIG. 10A

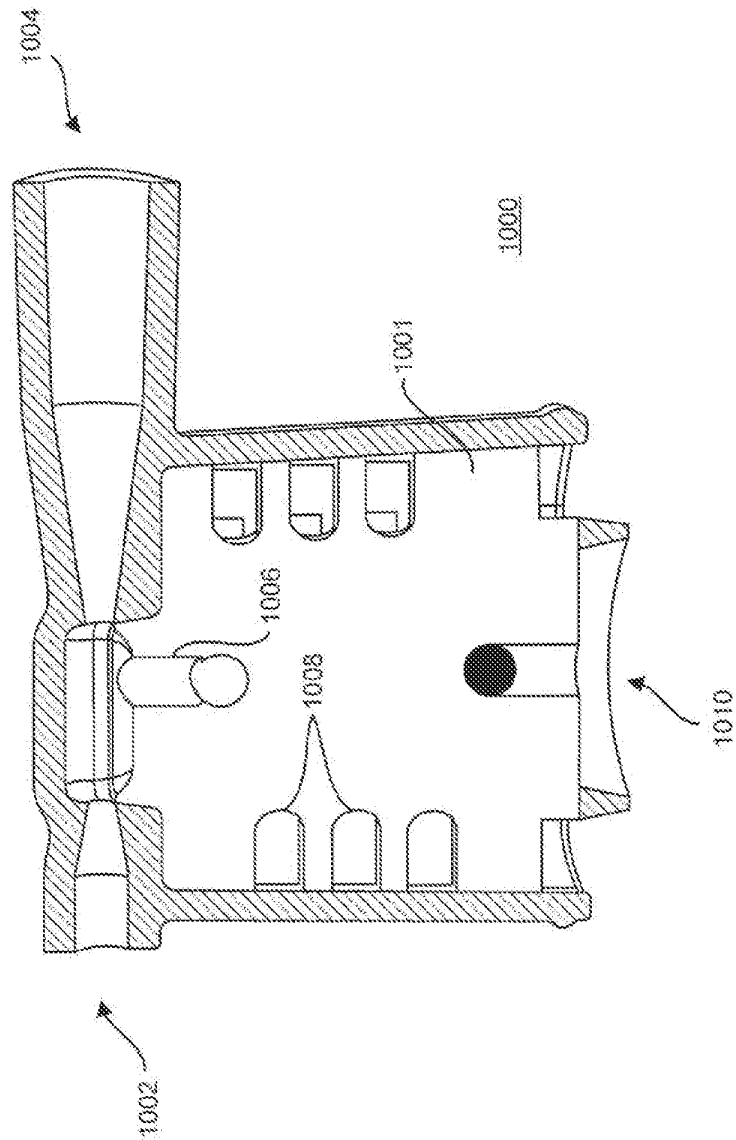


FIG. 10B

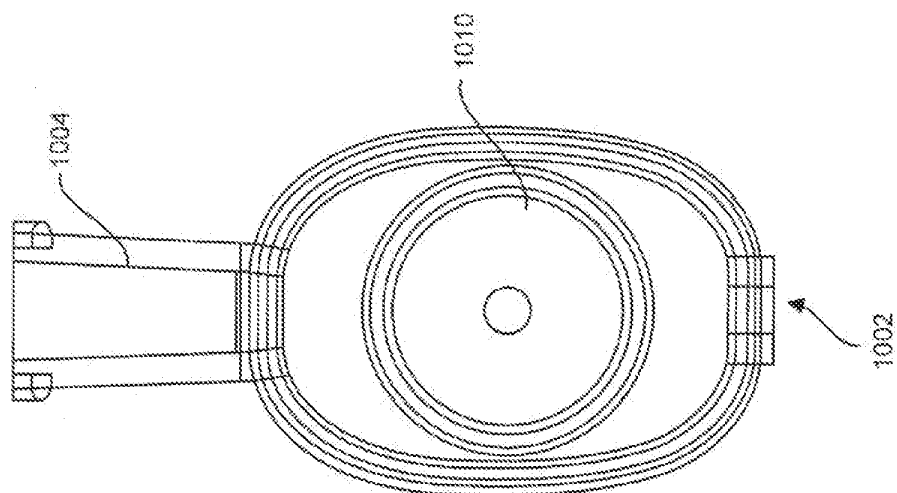


FIG. 10C

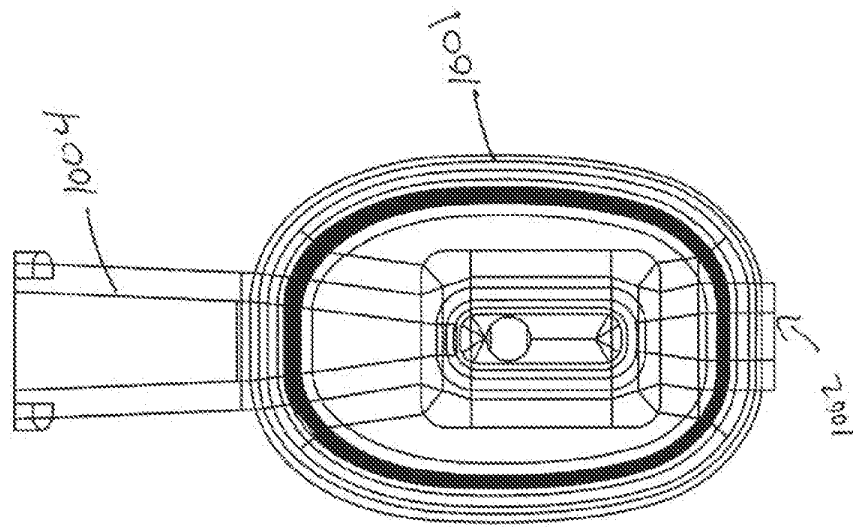


FIG. 10D

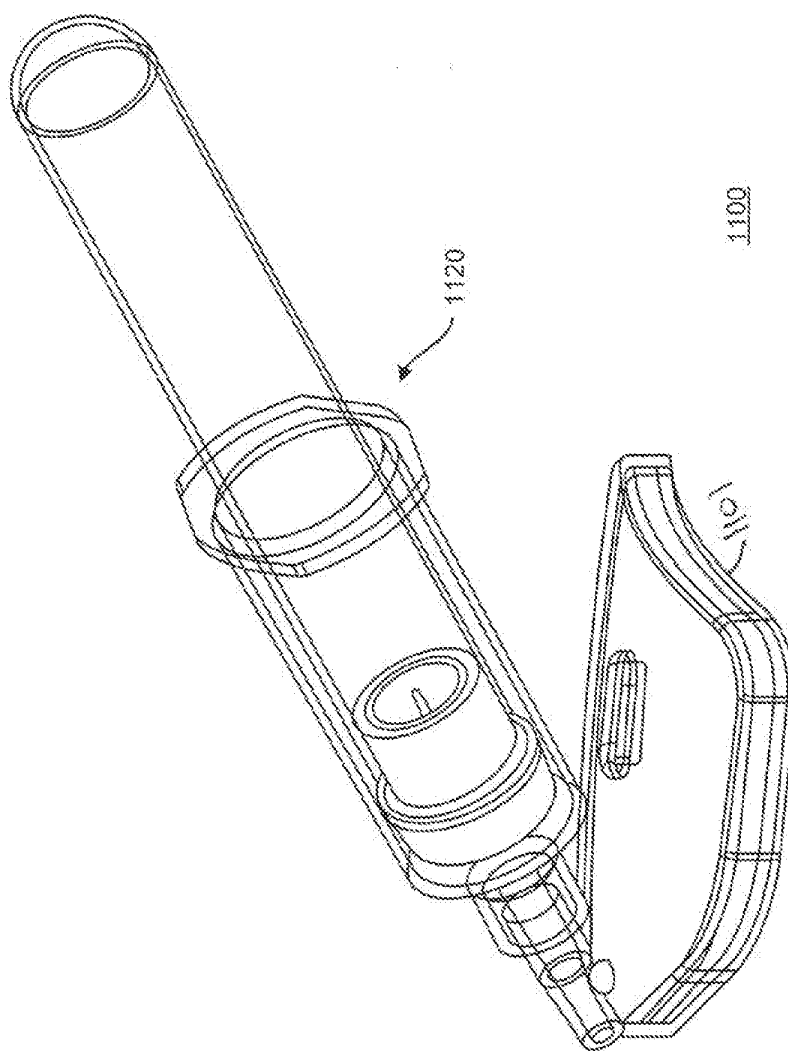


FIG. 11A

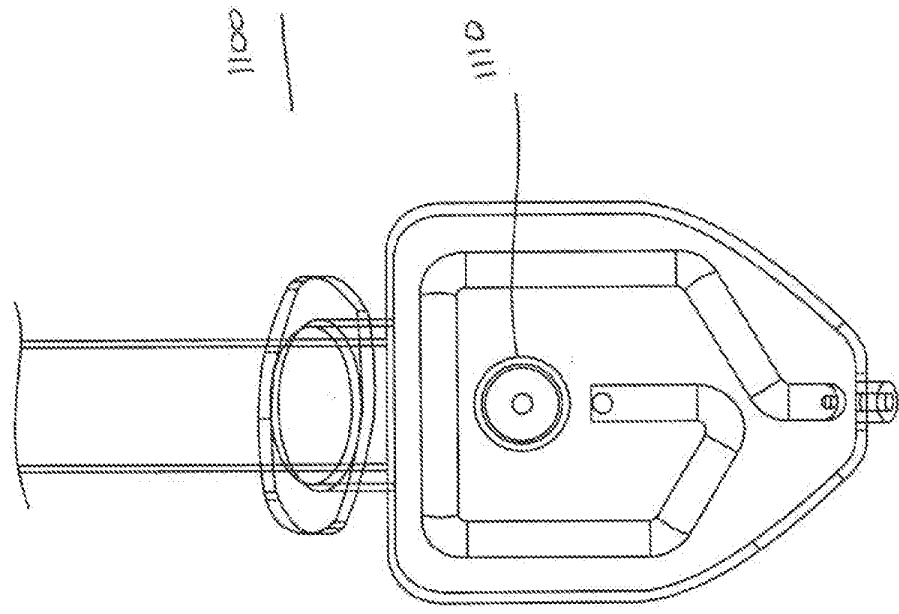


FIG. 11C

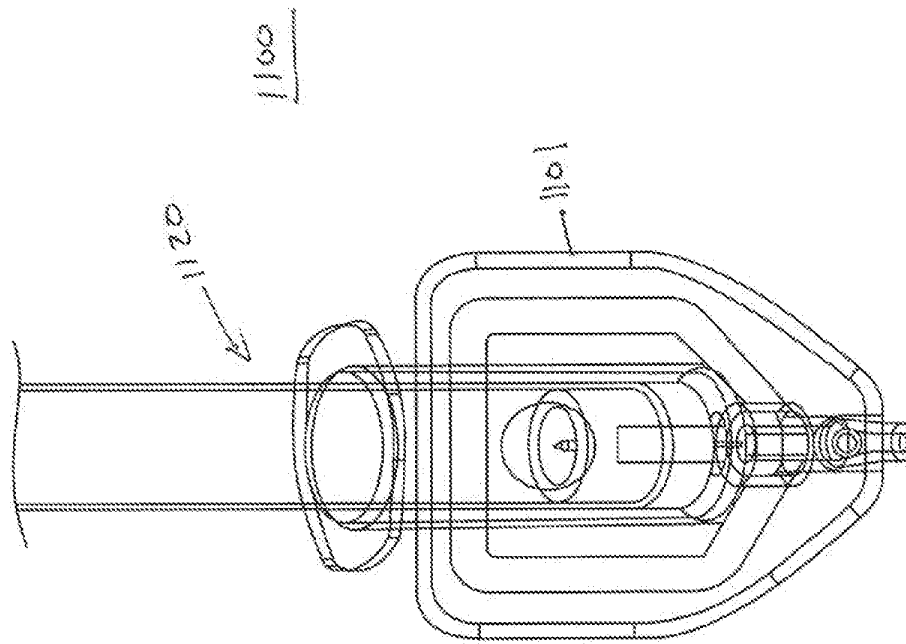


FIG. 11D

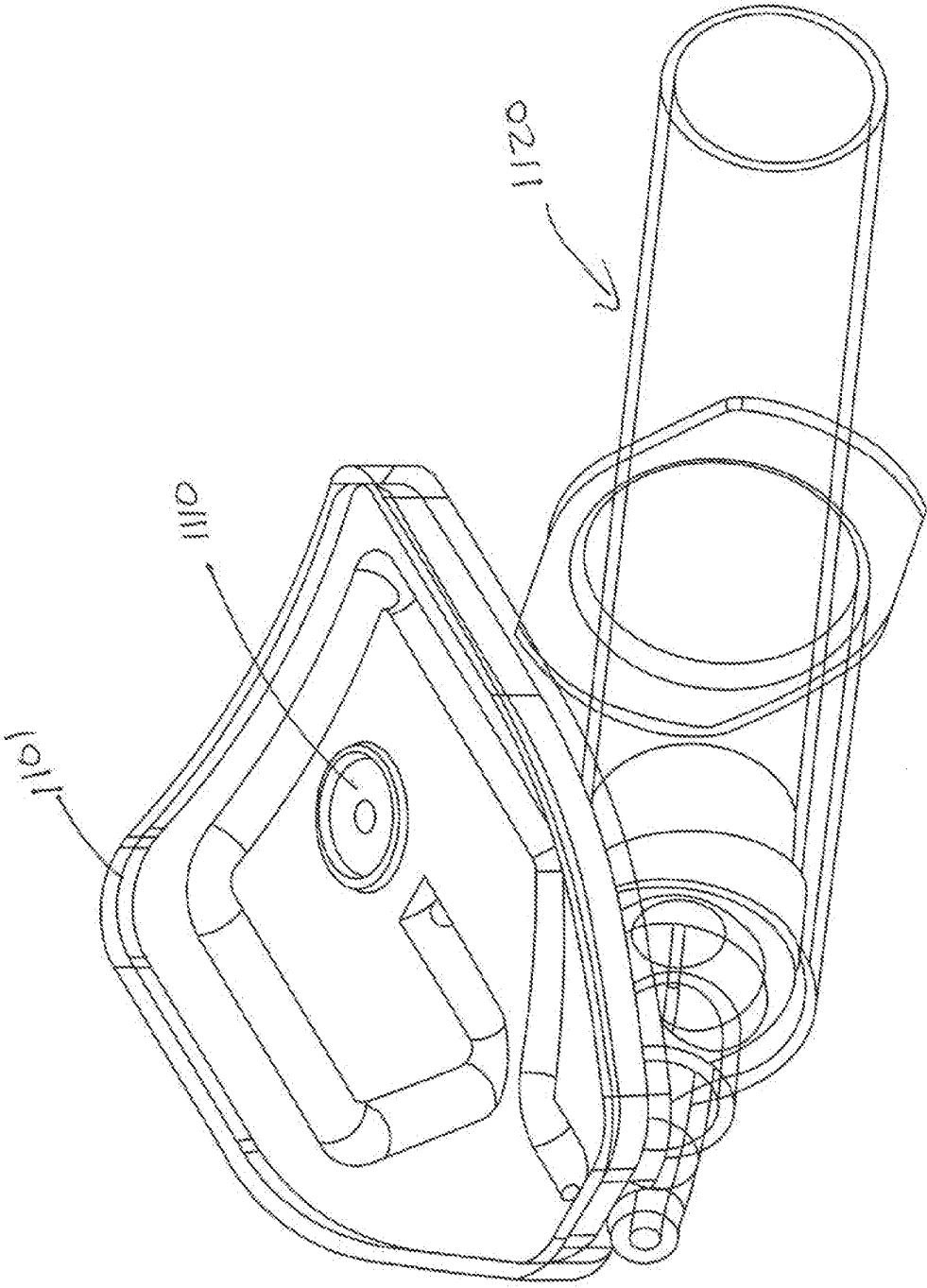
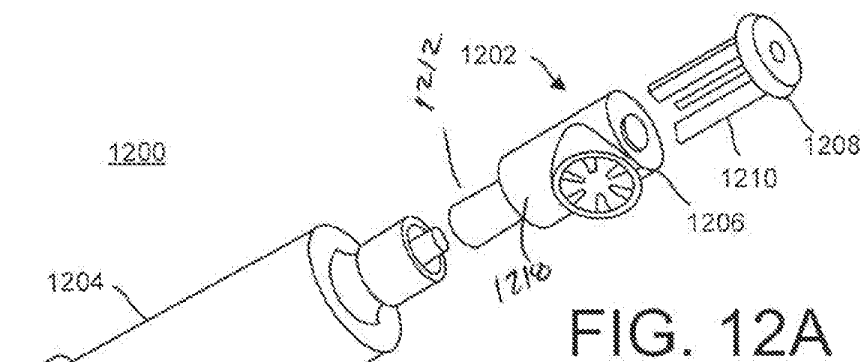
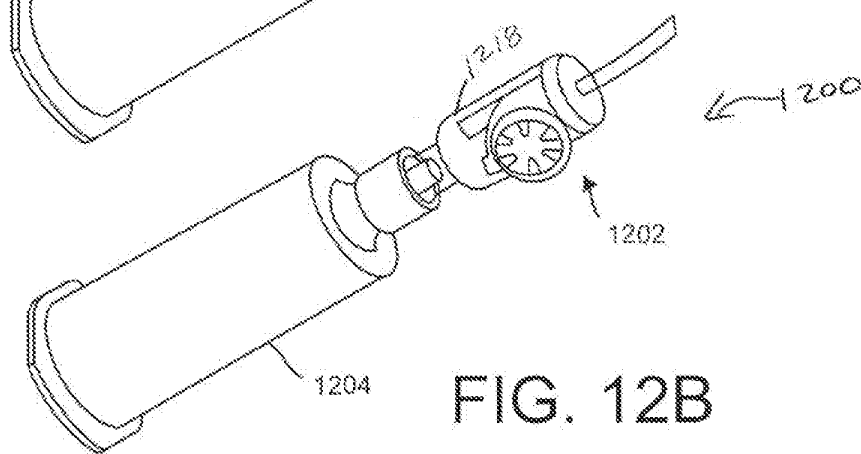
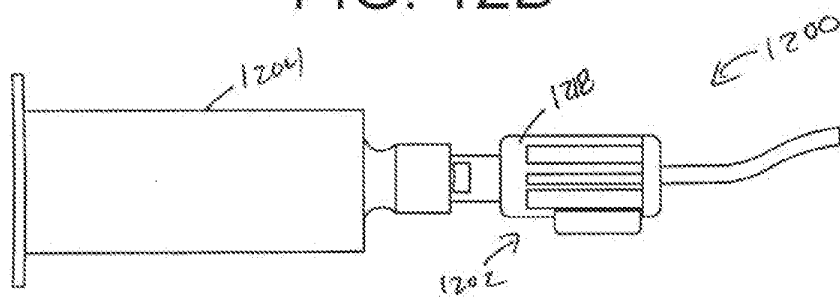
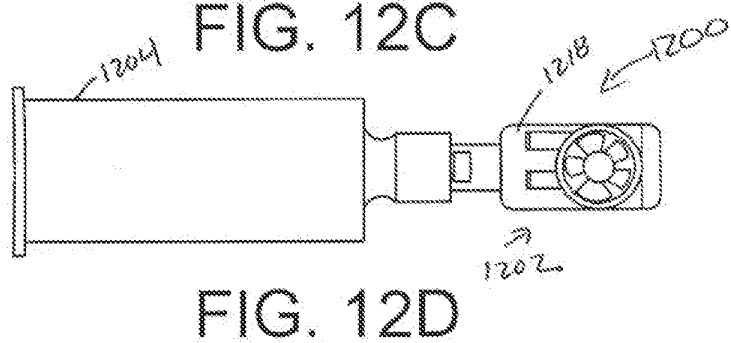


FIG. 11E



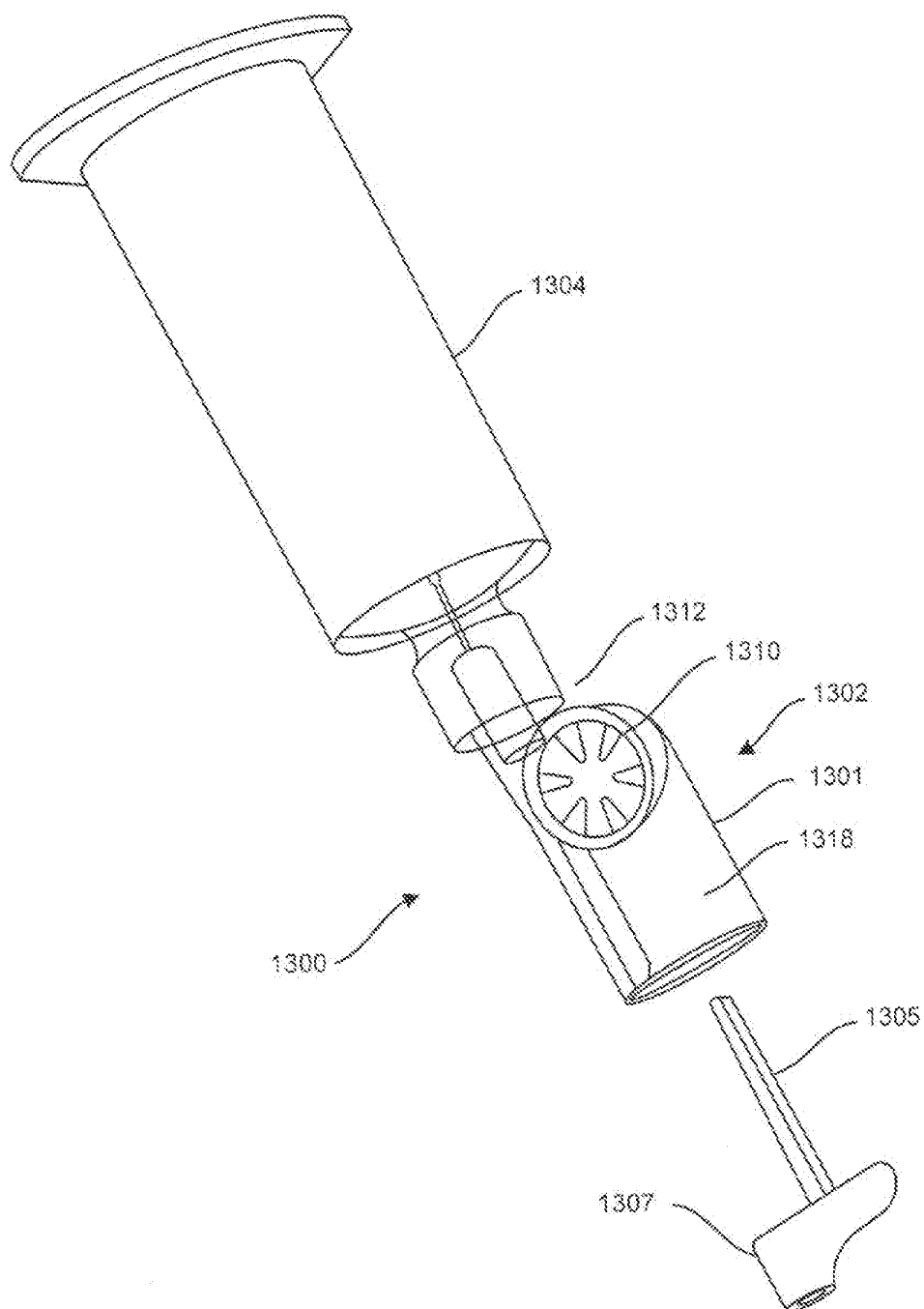
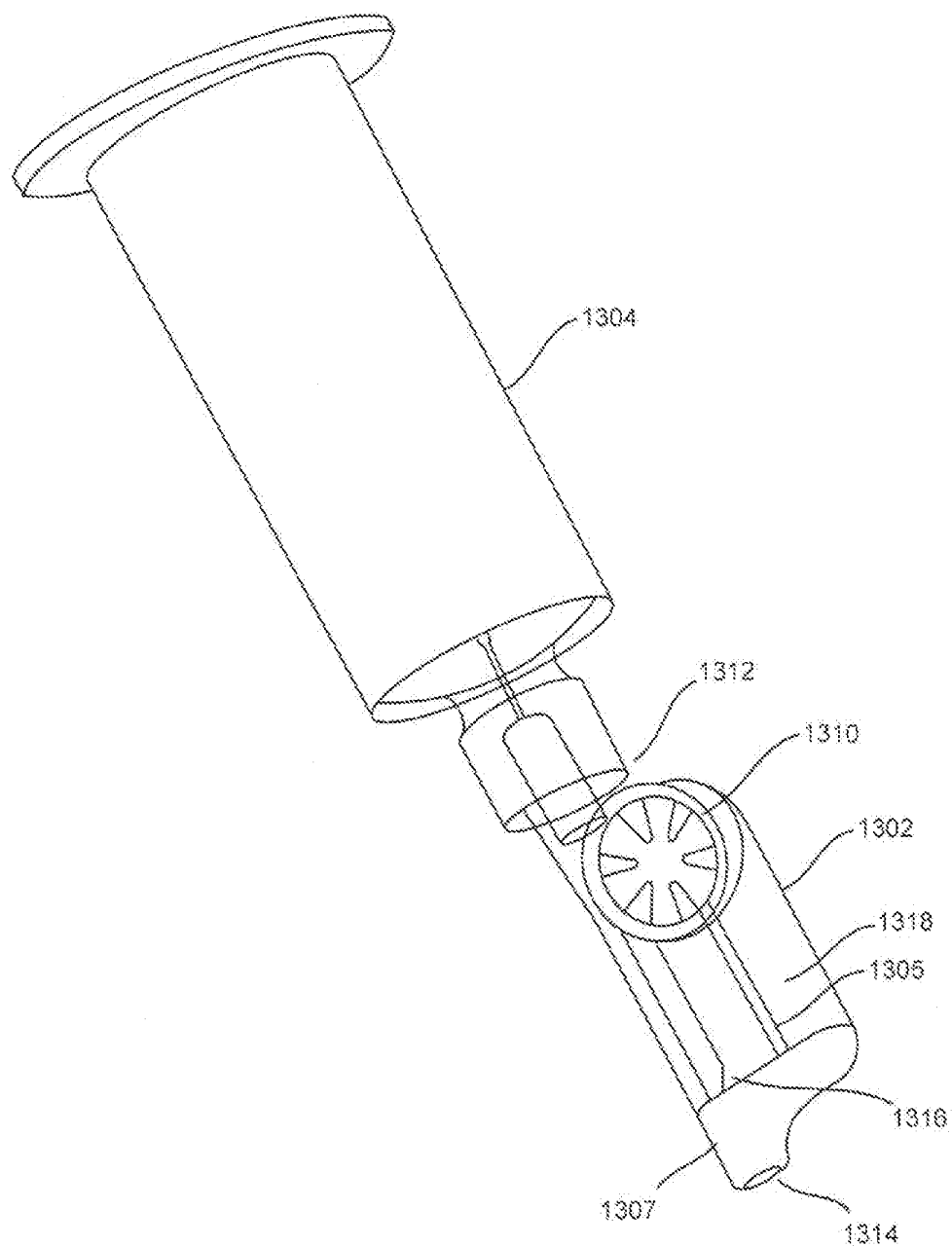


FIG. 13A

**FIG. 13B**

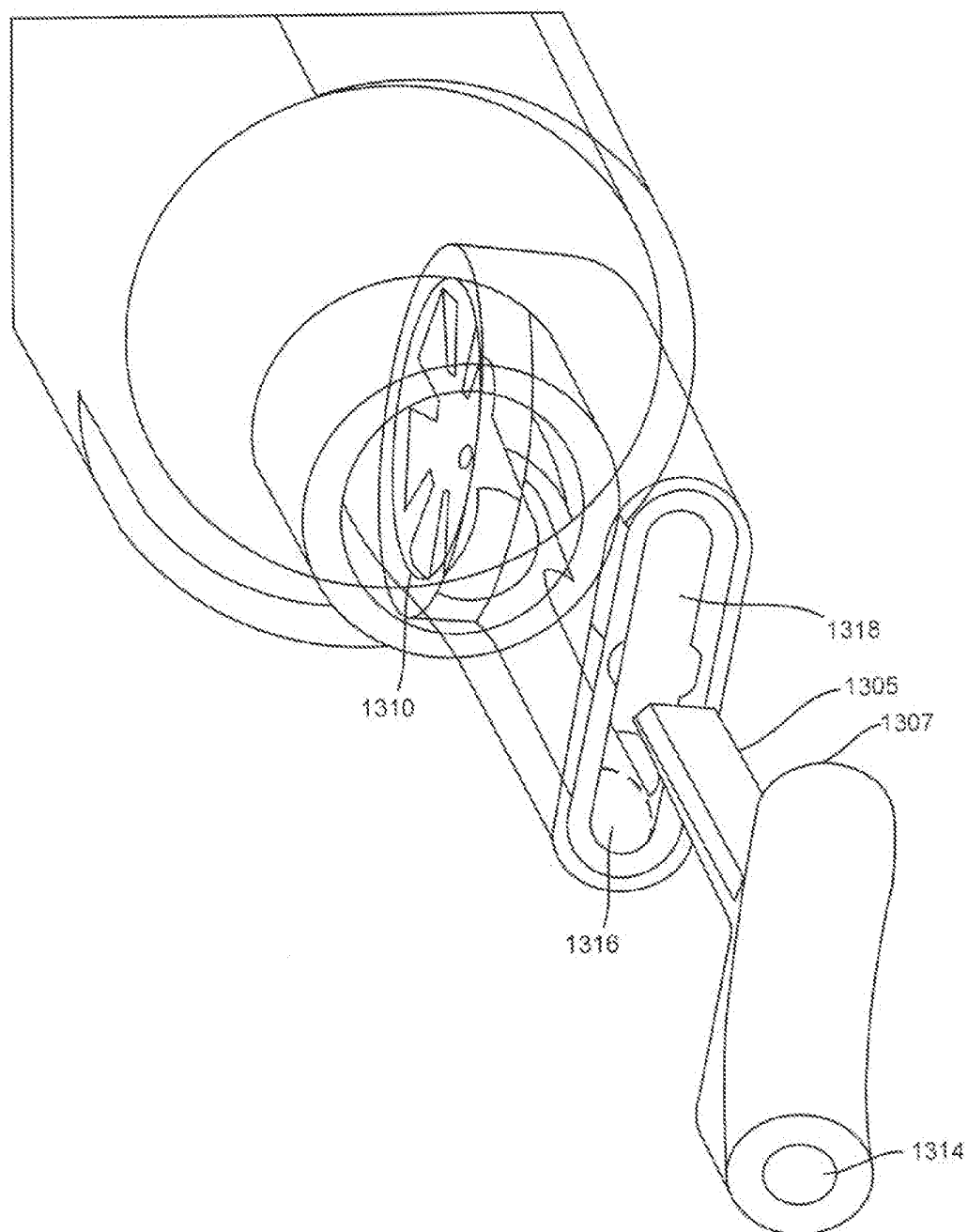


FIG. 13C

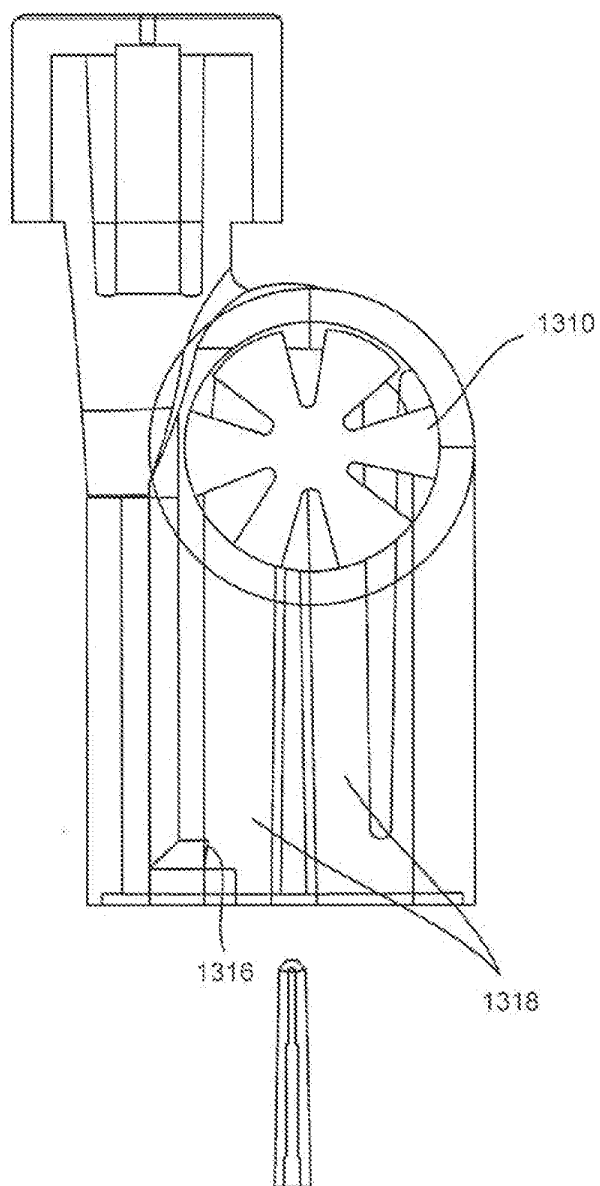


FIG. 13D

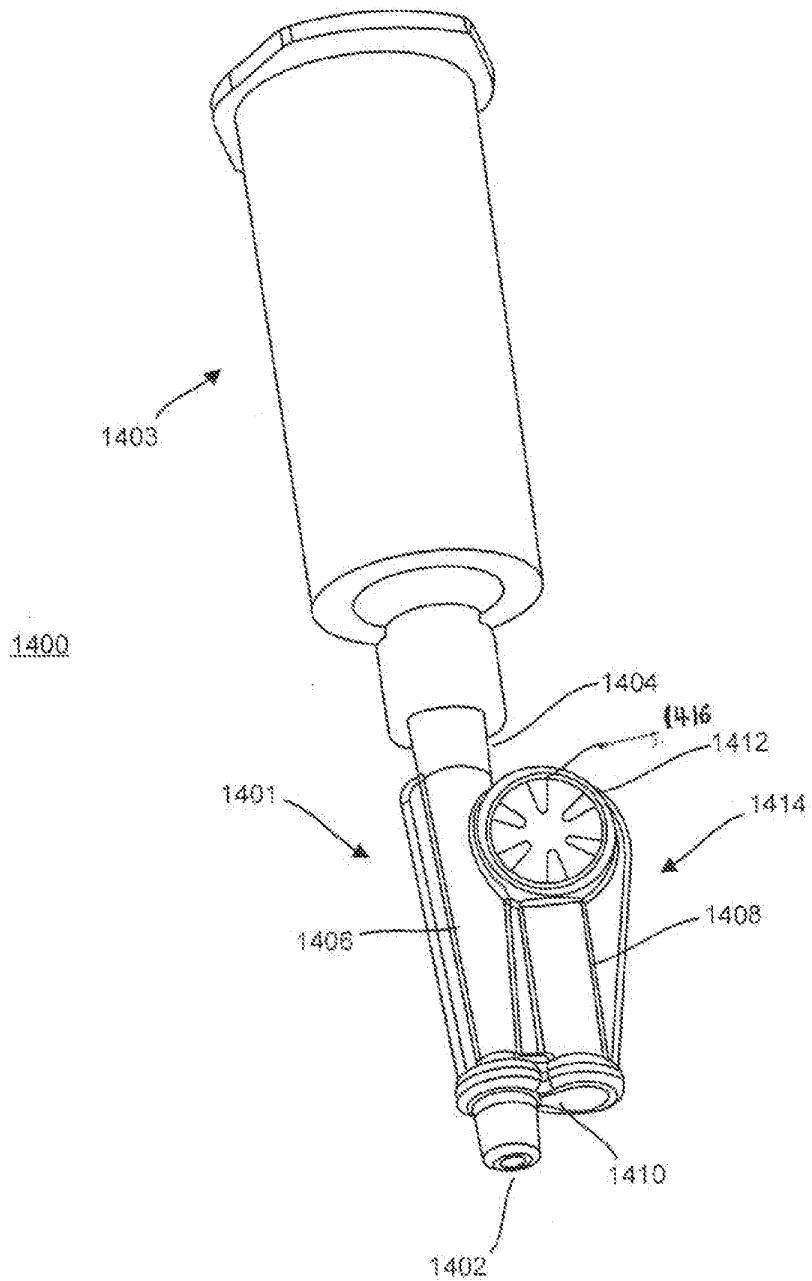


FIG. 14A

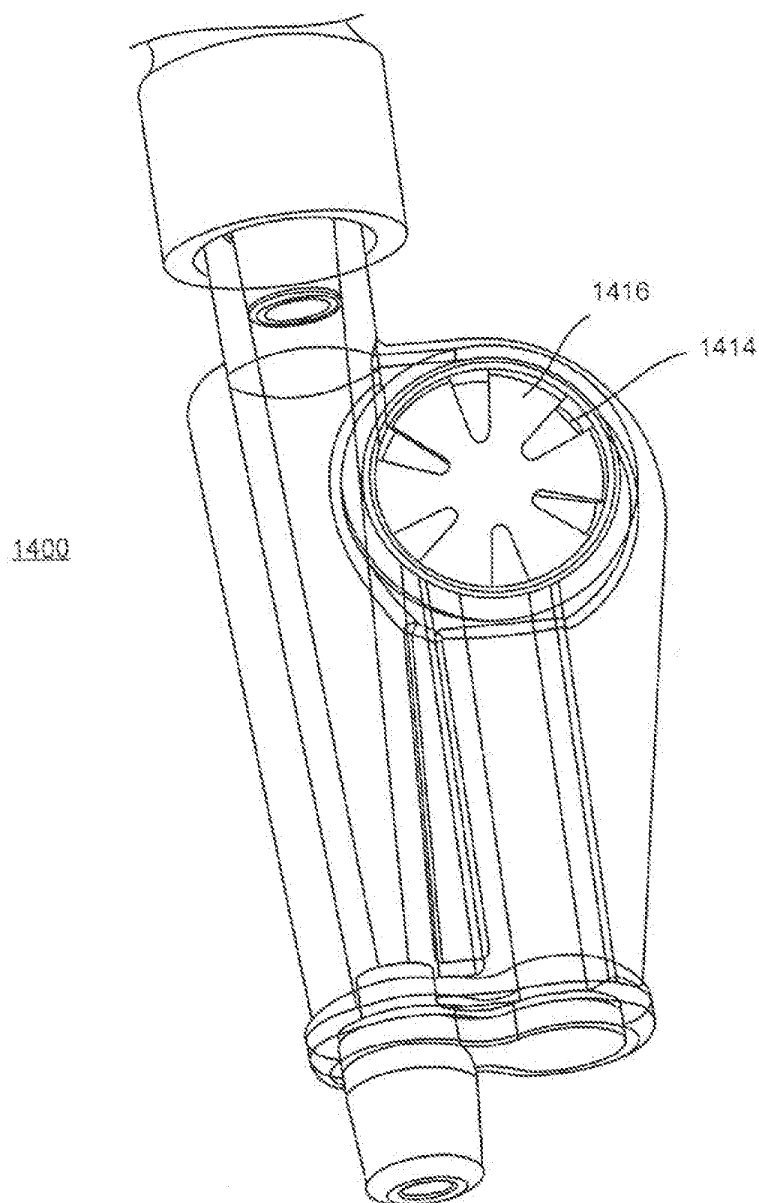


FIG. 14B

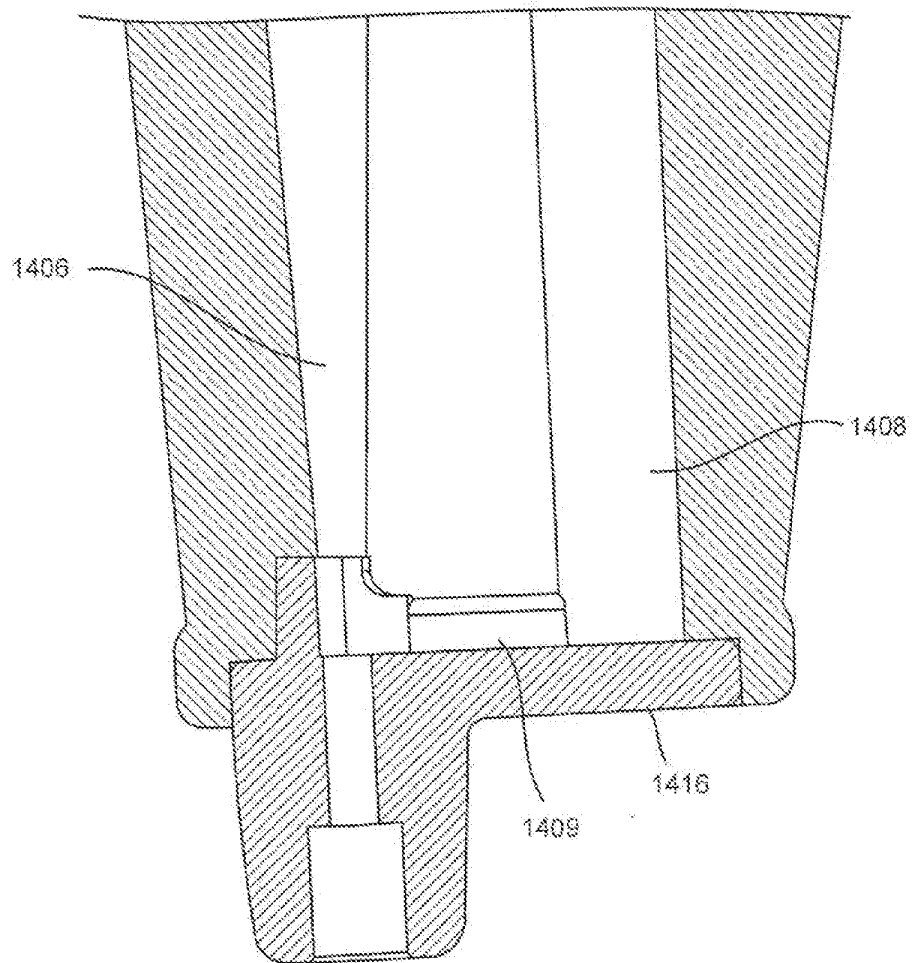
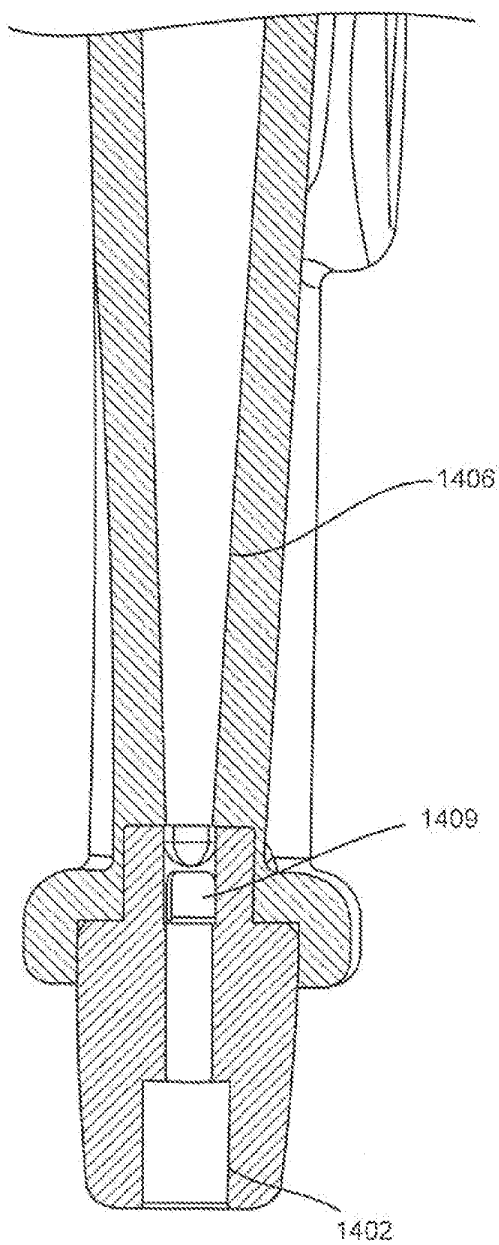


FIG. 14C

**FIG. 14D**

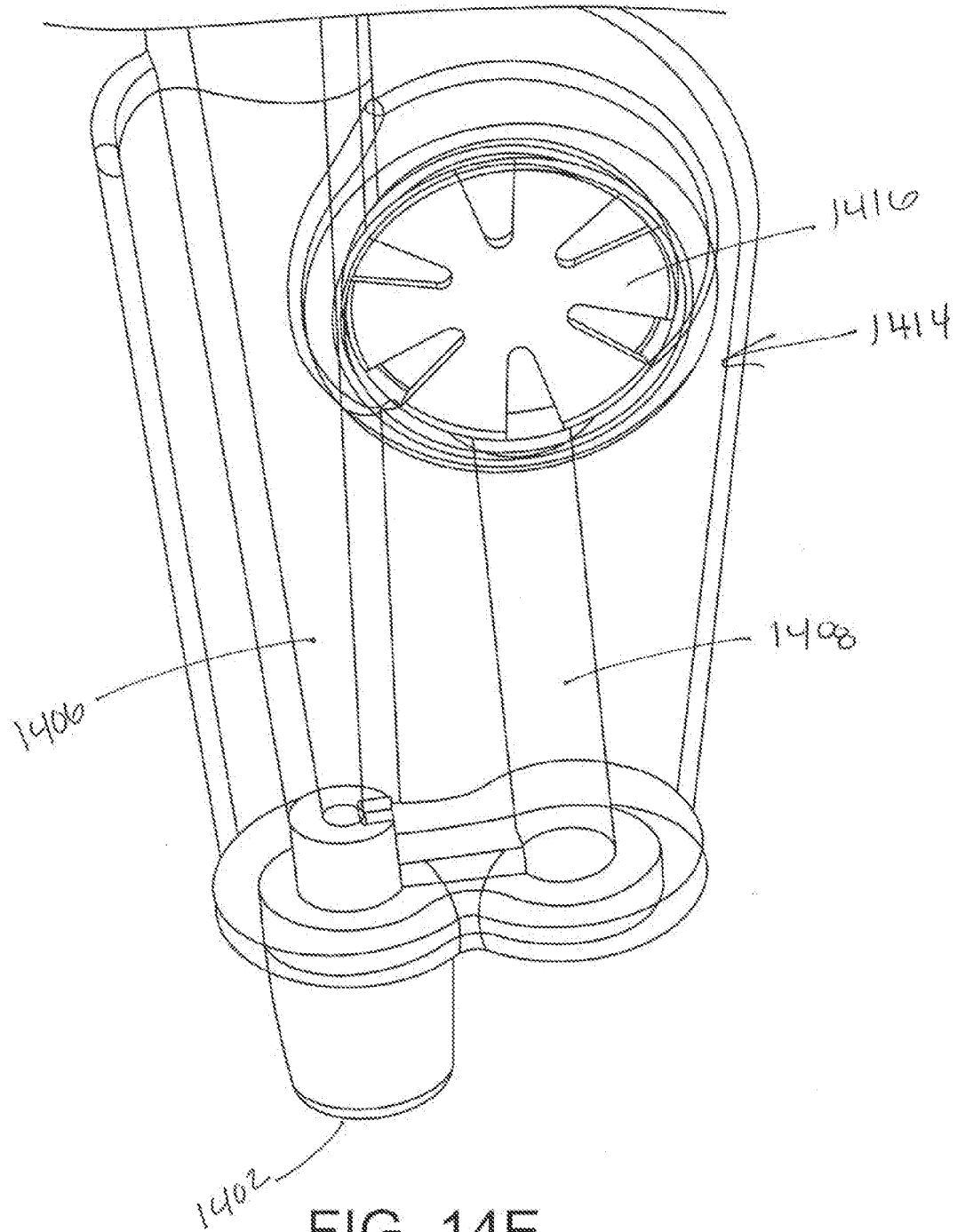


FIG. 14E

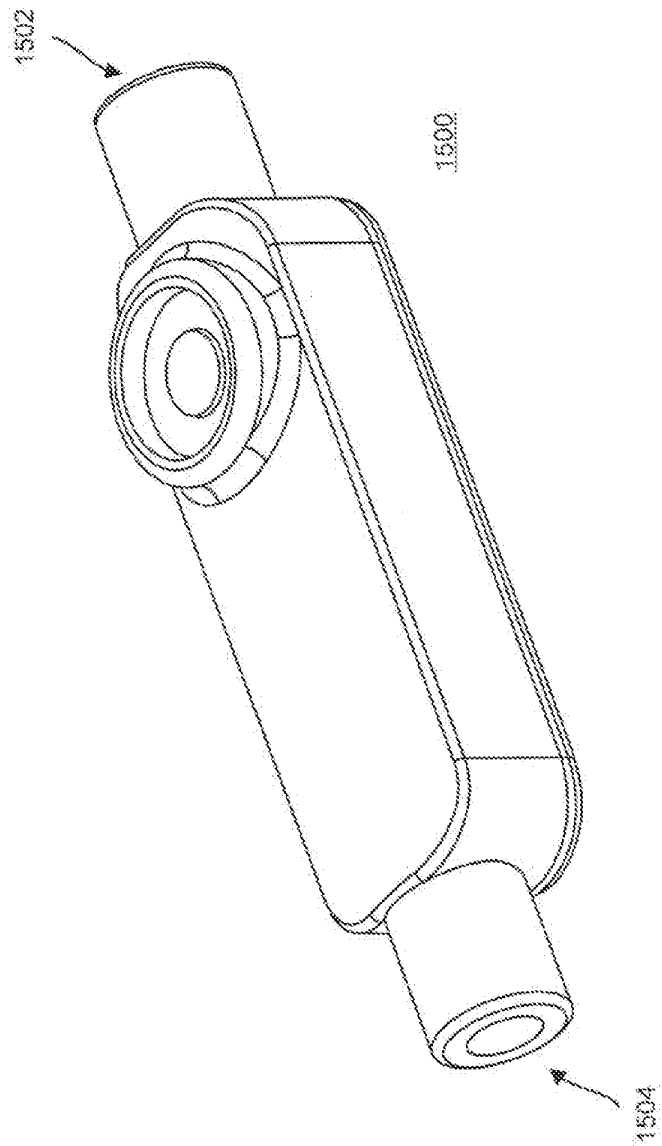


FIG. 15A

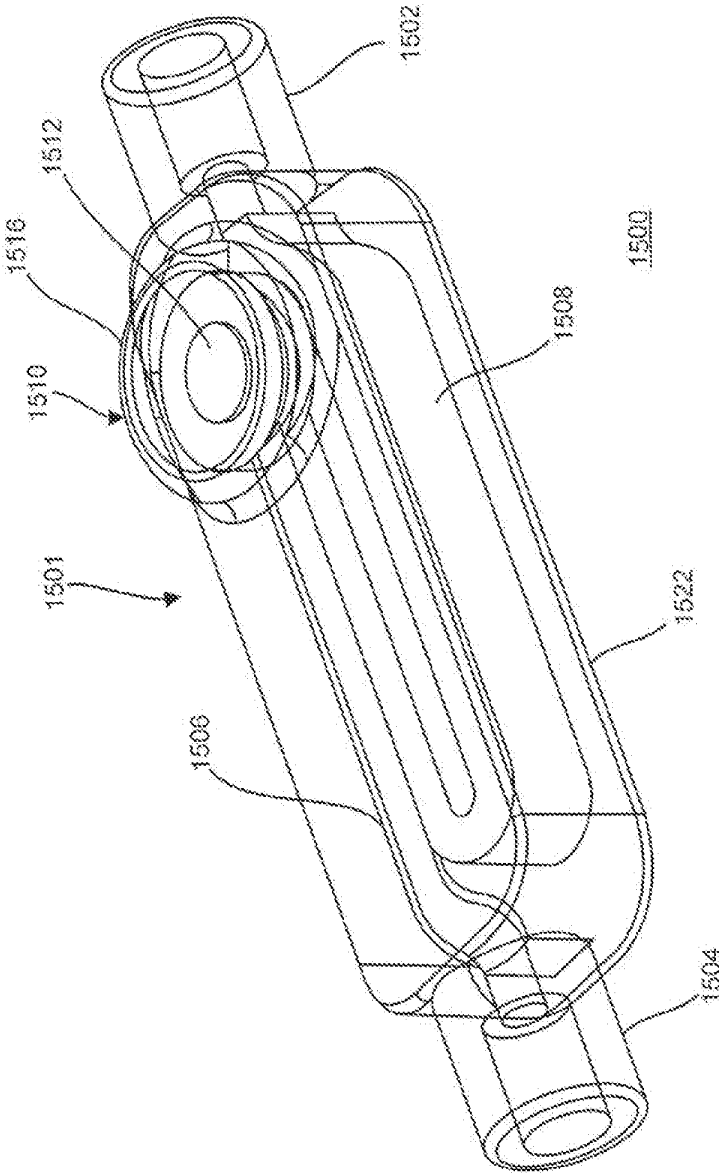


FIG. 15B

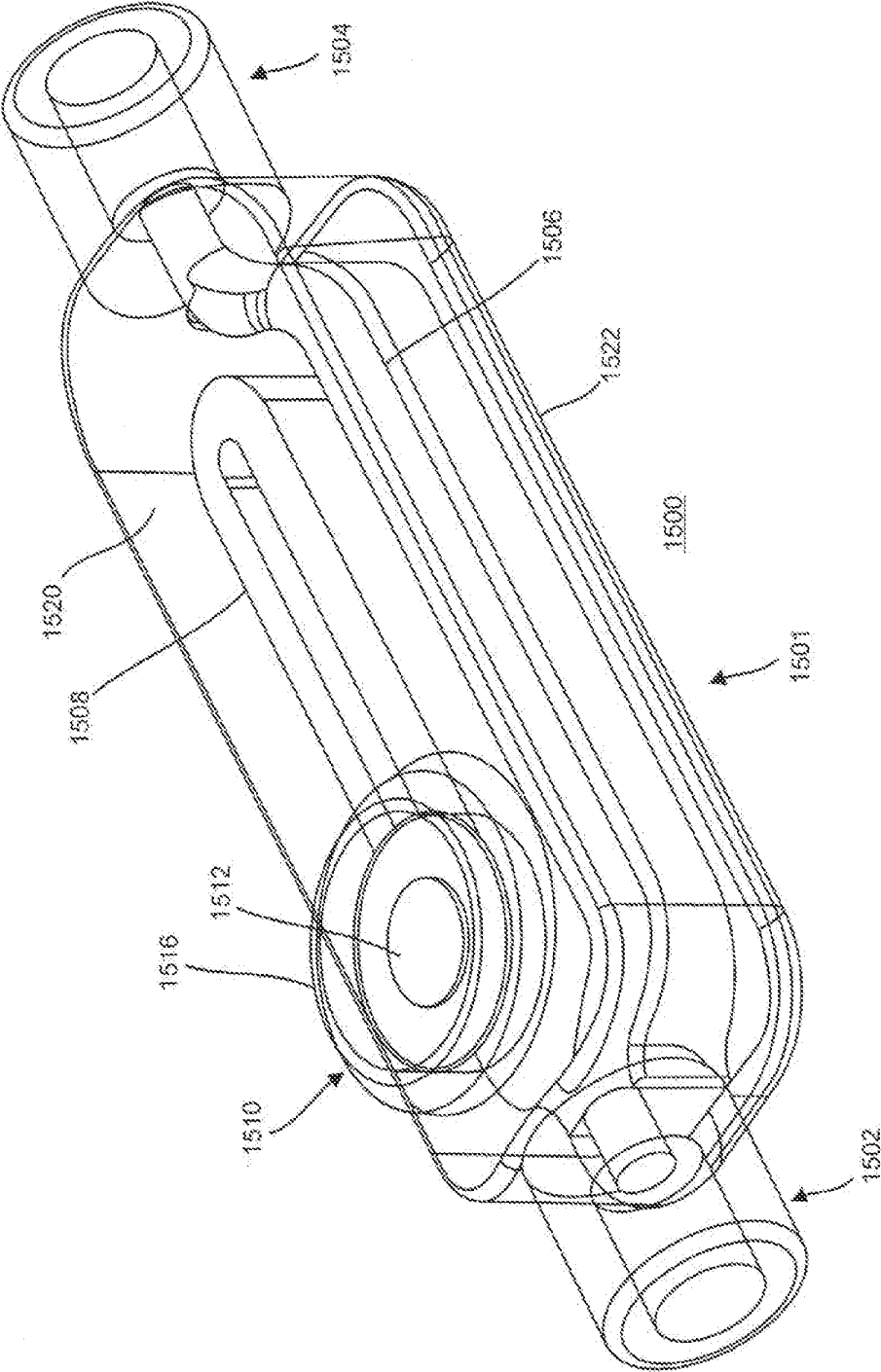


FIG. 15C

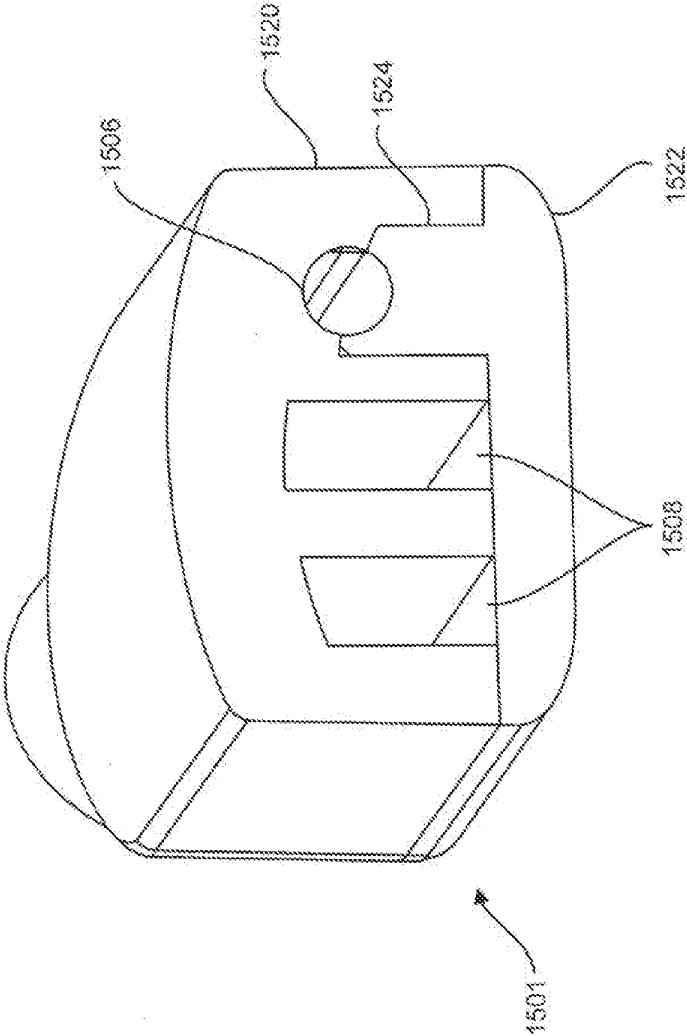


FIG. 15D

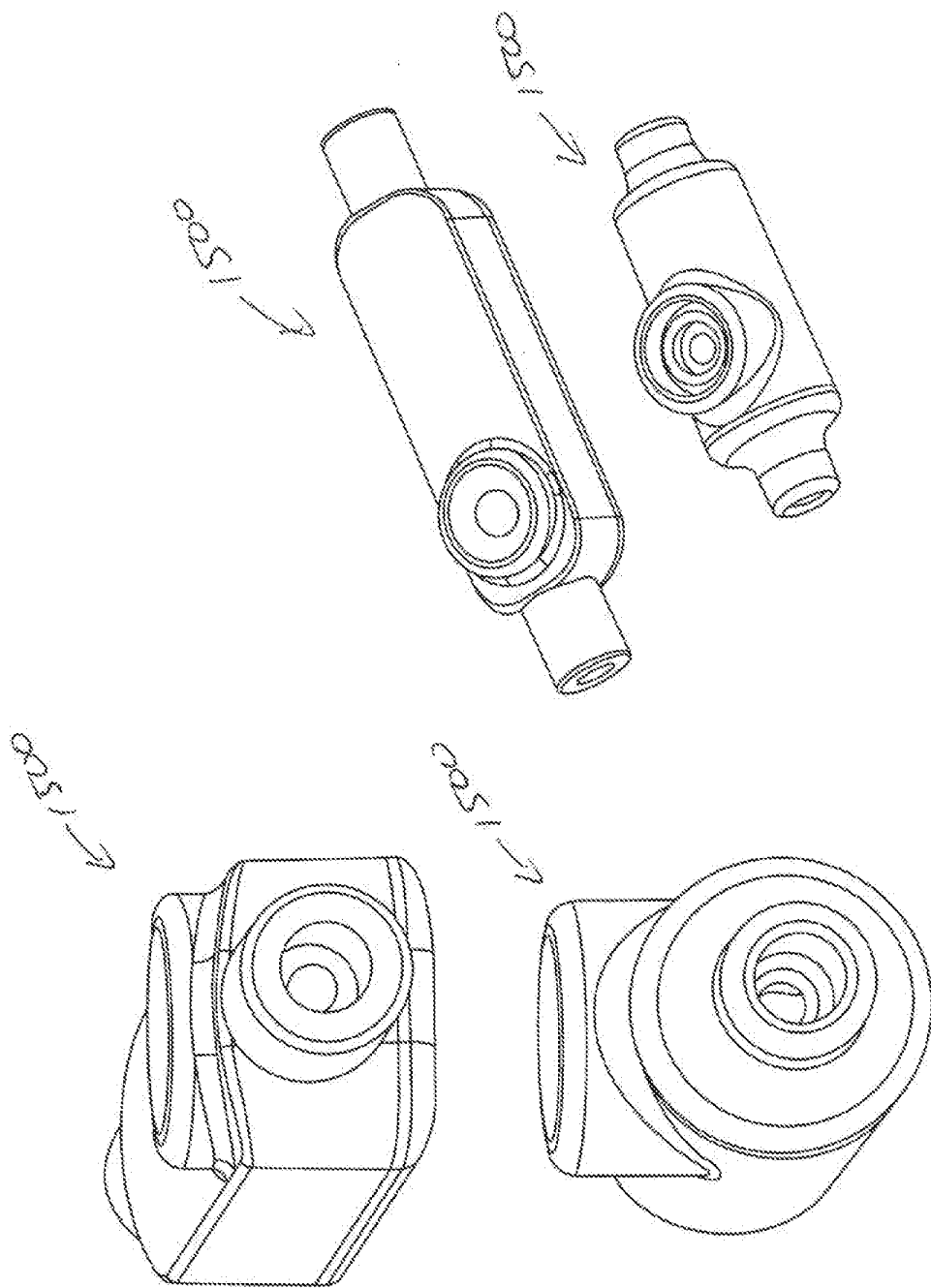


FIG. 15F

FIG. 15E

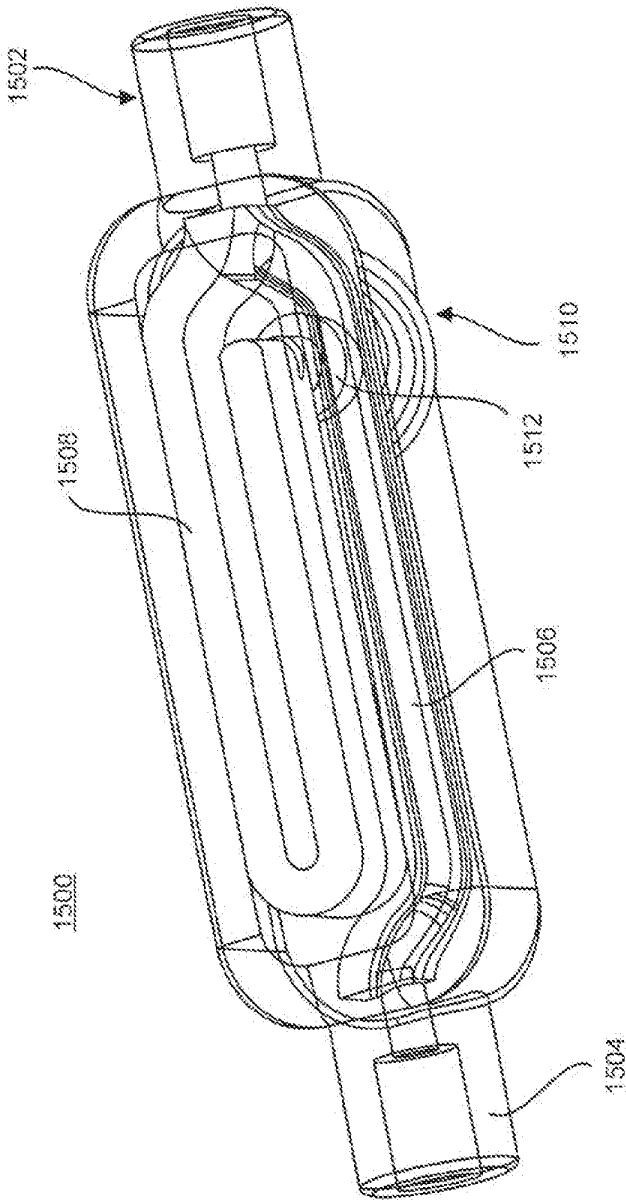


FIG. 15G

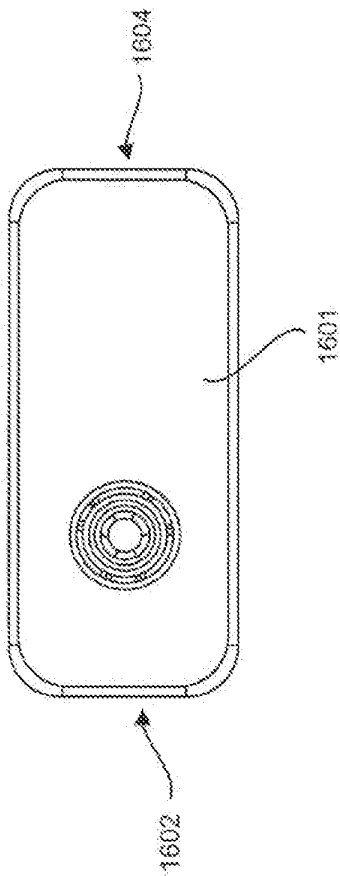


FIG. 16A

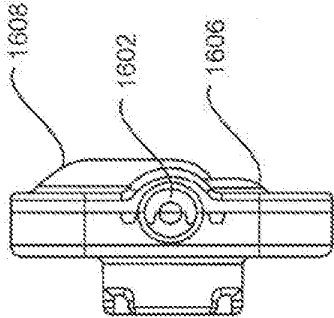


FIG. 16C



FIG. 16B

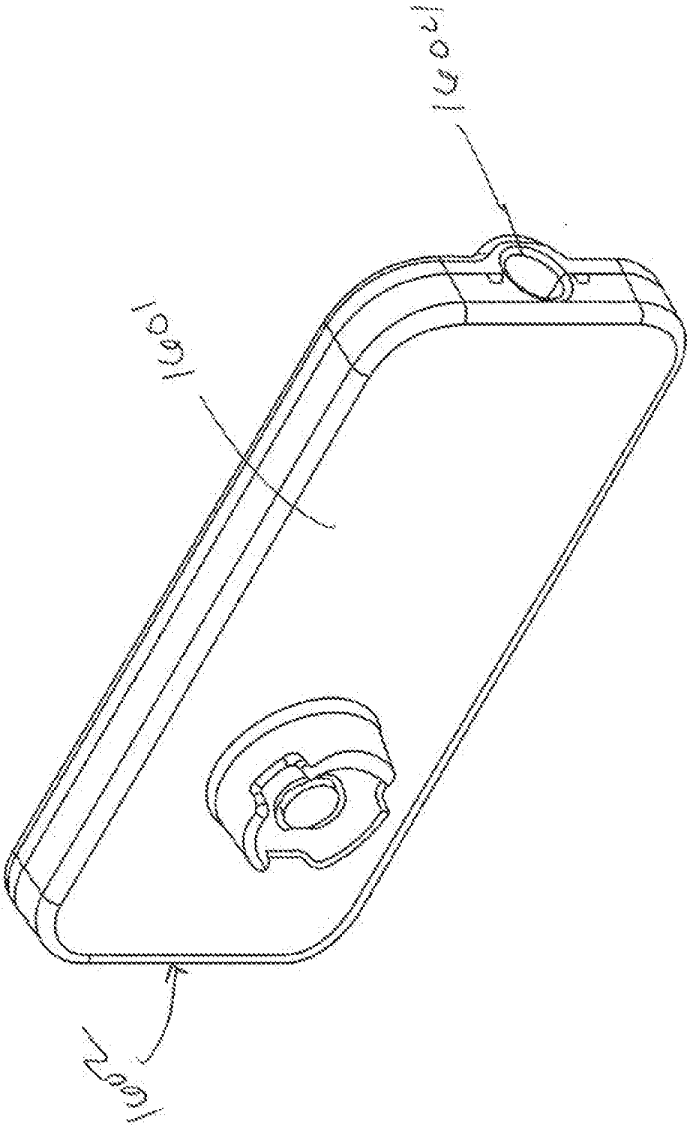


FIG. 16D

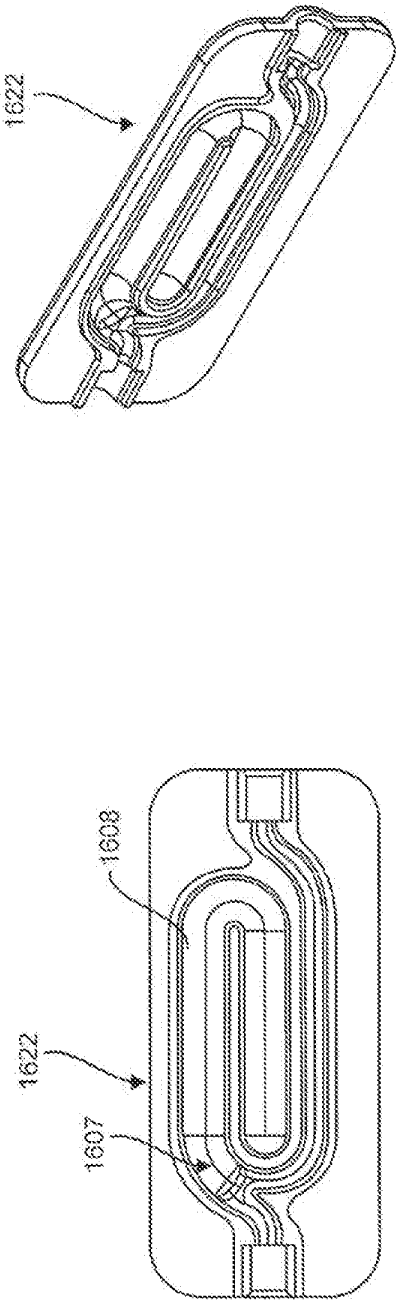


FIG. 17B

FIG. 17A

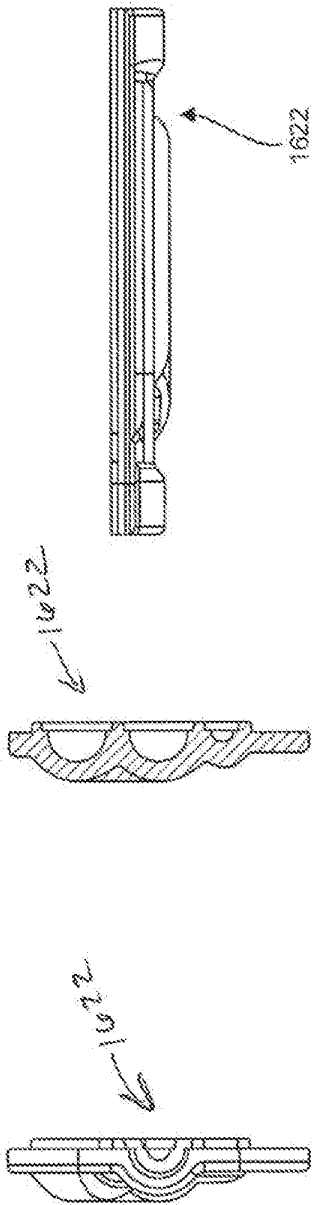


FIG. 17E

FIG. 17D

FIG. 17C

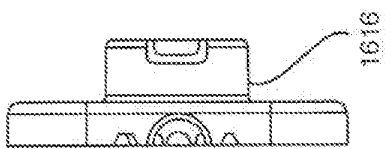


FIG. 18C

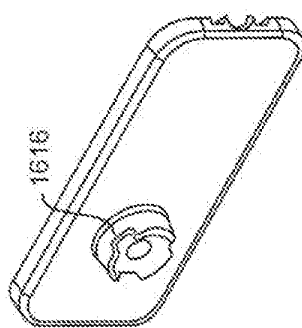


FIG. 18B

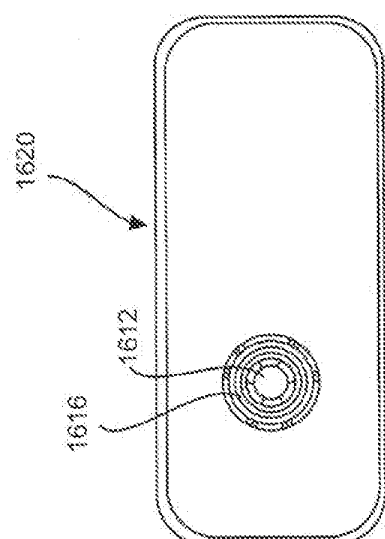
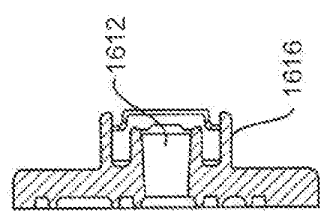


FIG. 18A



SECTION A-A

FIG. 18F

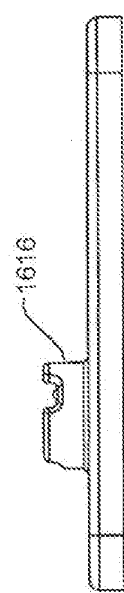
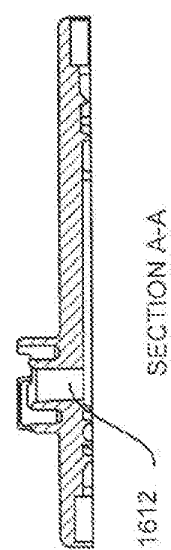


FIG. 18E



SECTION A-A

FIG. 18D

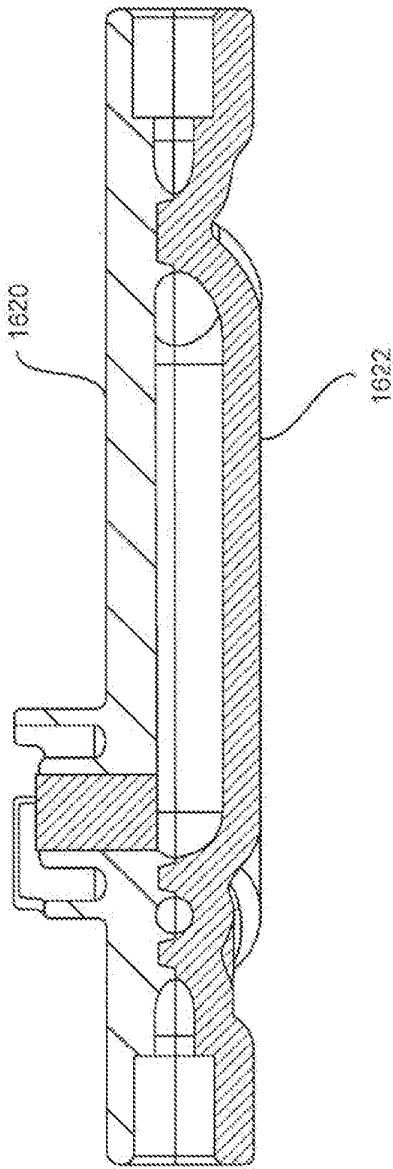


FIG. 19A

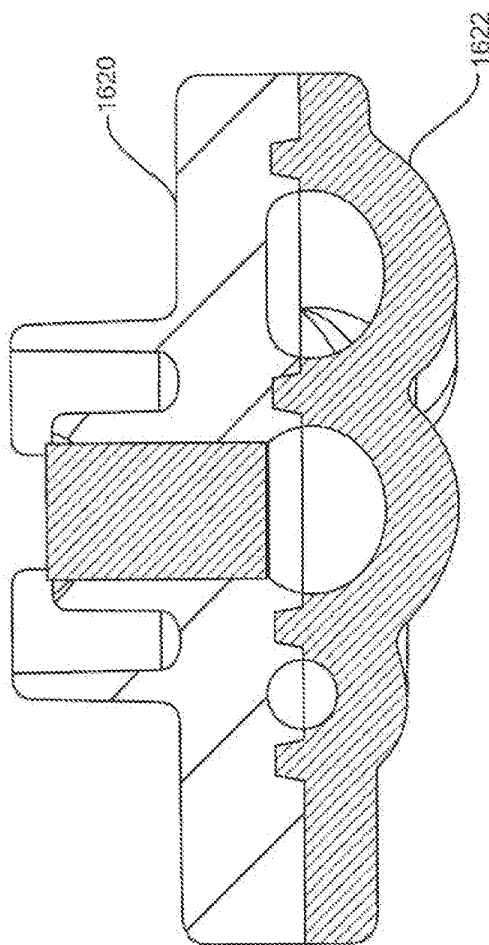


FIG. 19B

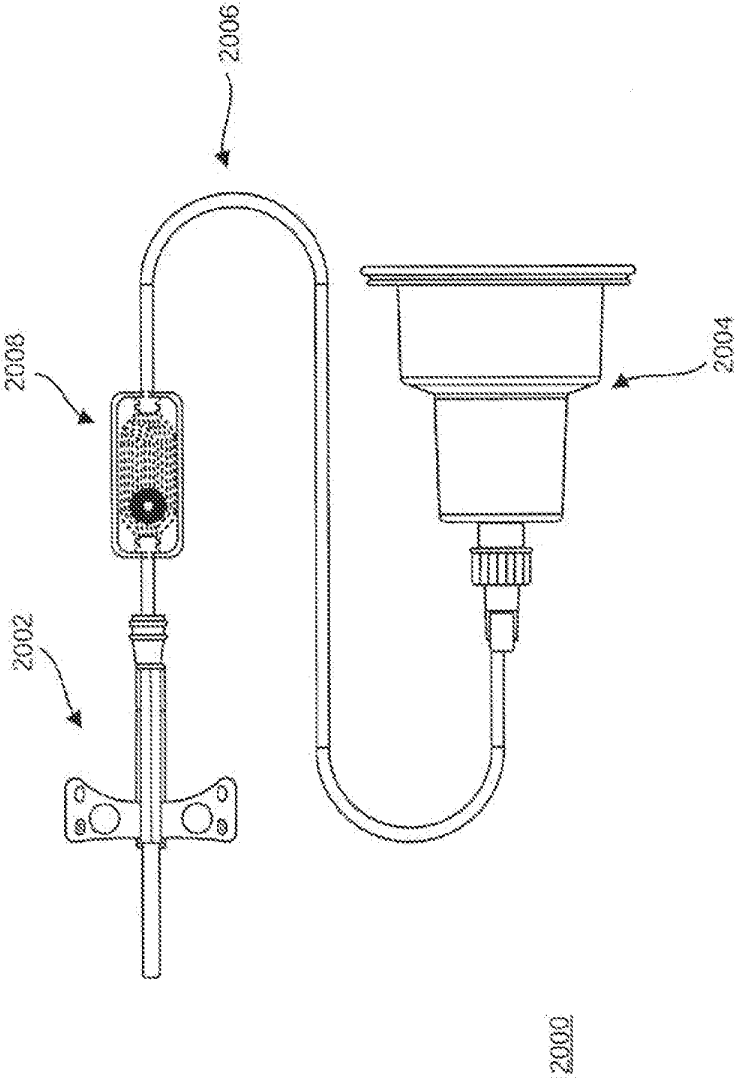


FIG. 20

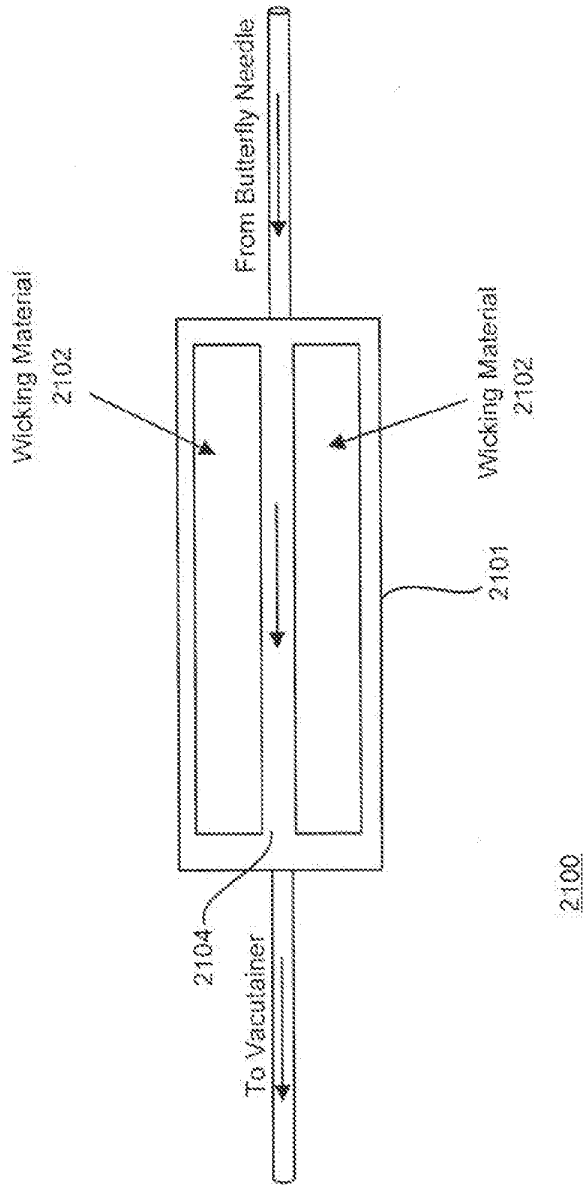


FIG. 21

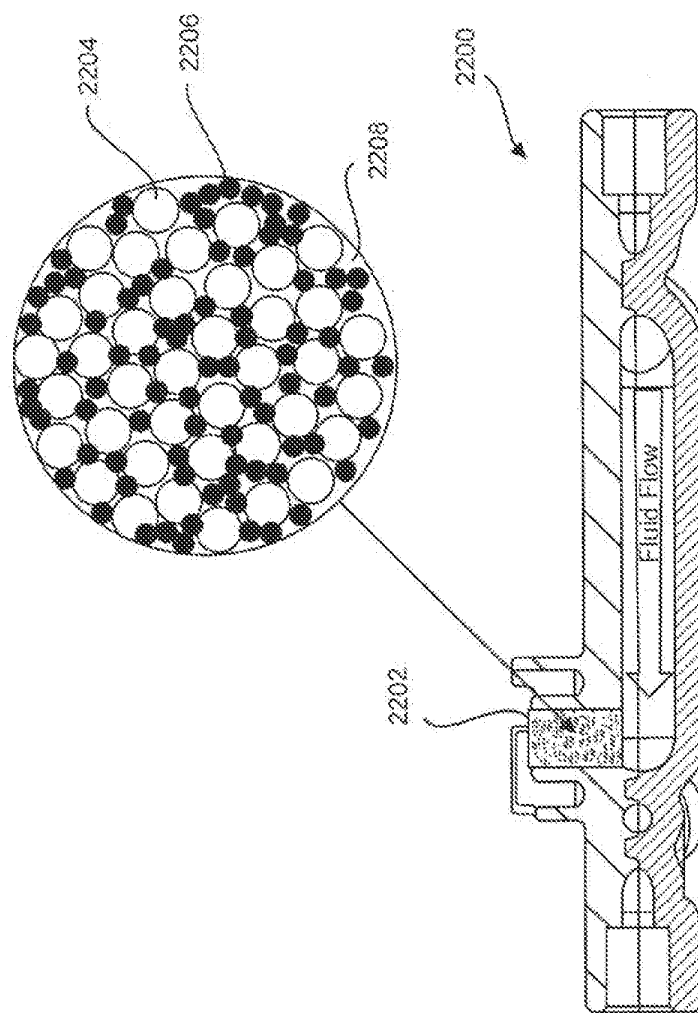


FIG. 22A

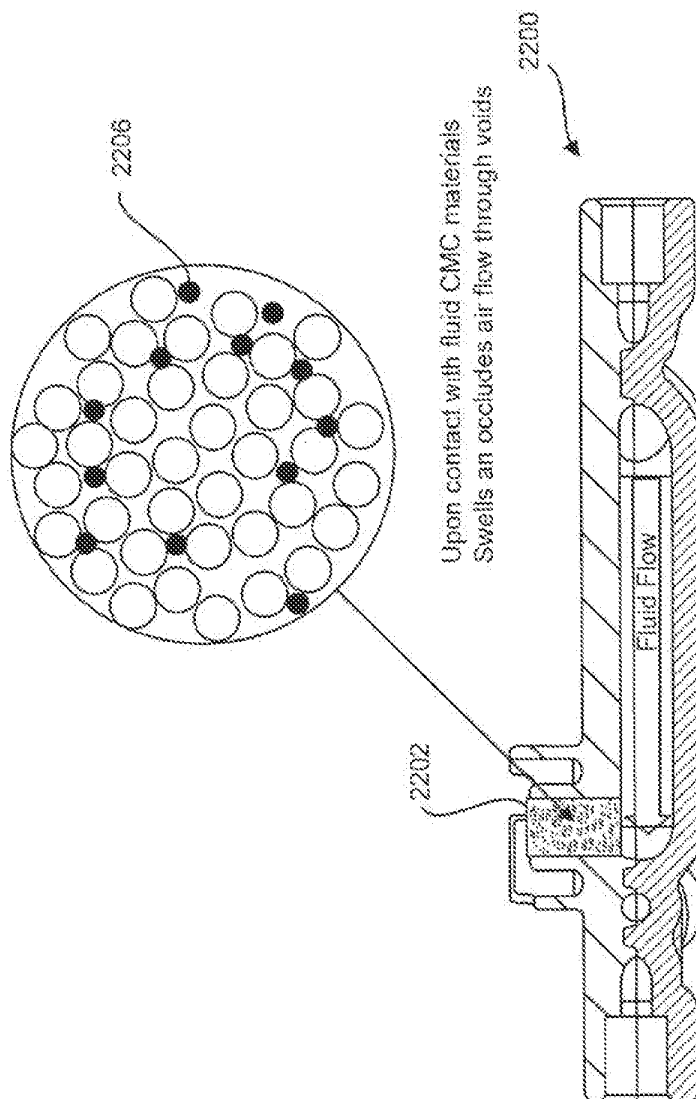


FIG. 22B

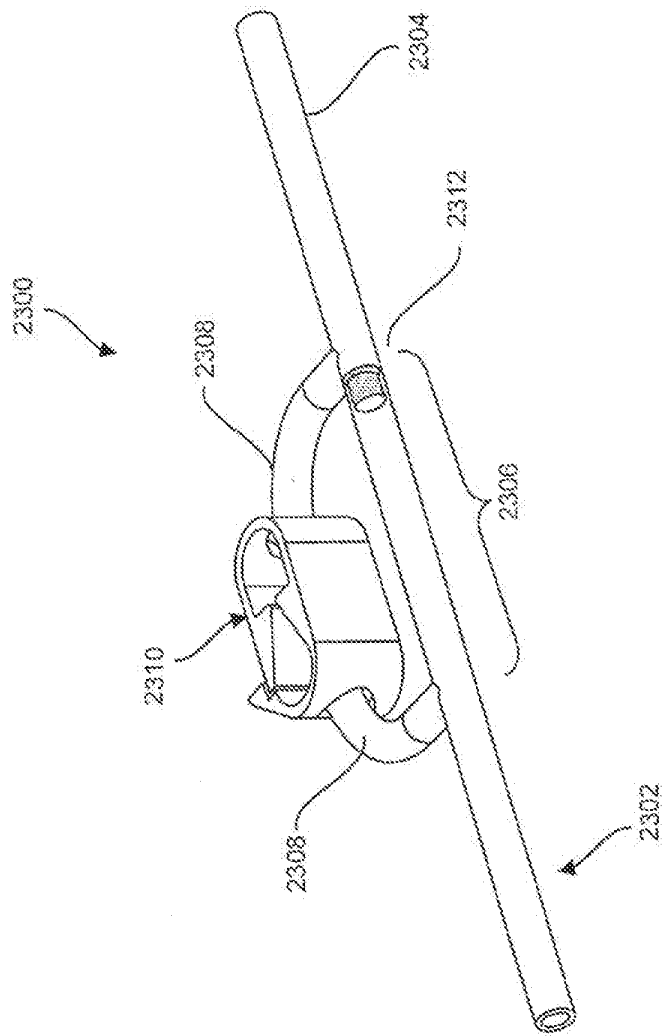


FIG. 23A

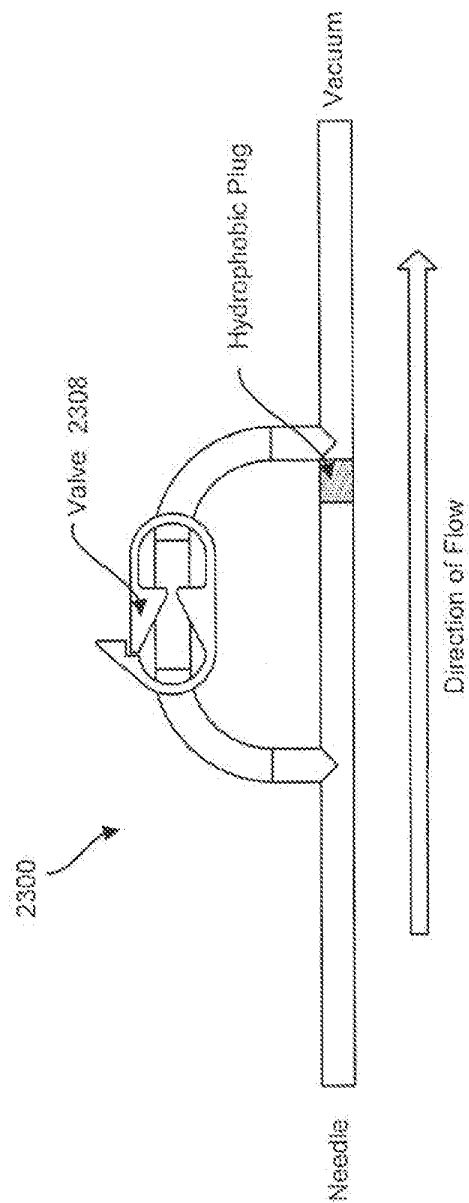


FIG. 23B

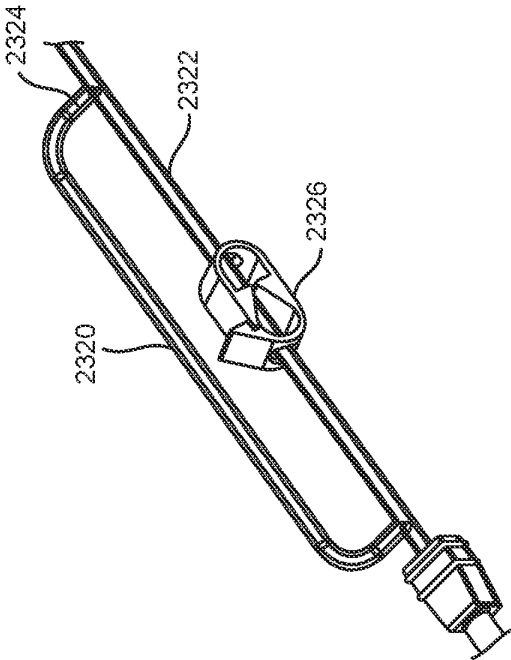


FIG. 23D

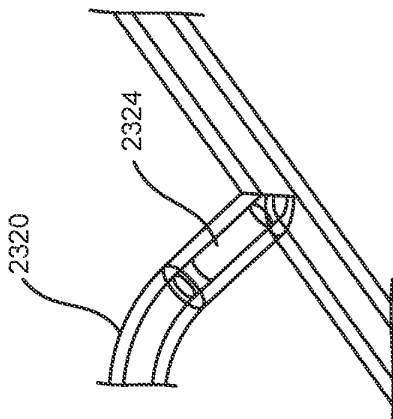


FIG. 23E

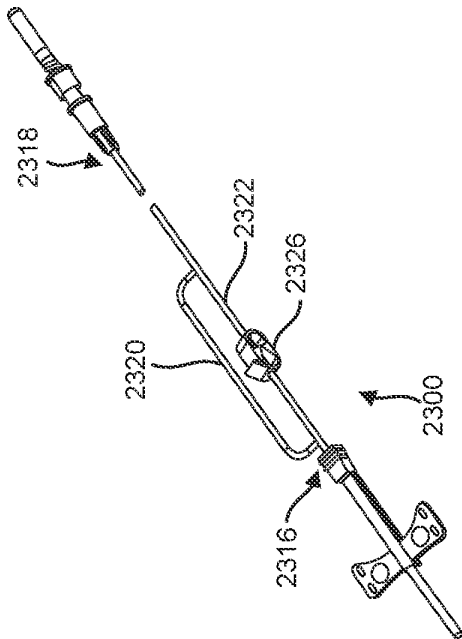


FIG. 23C

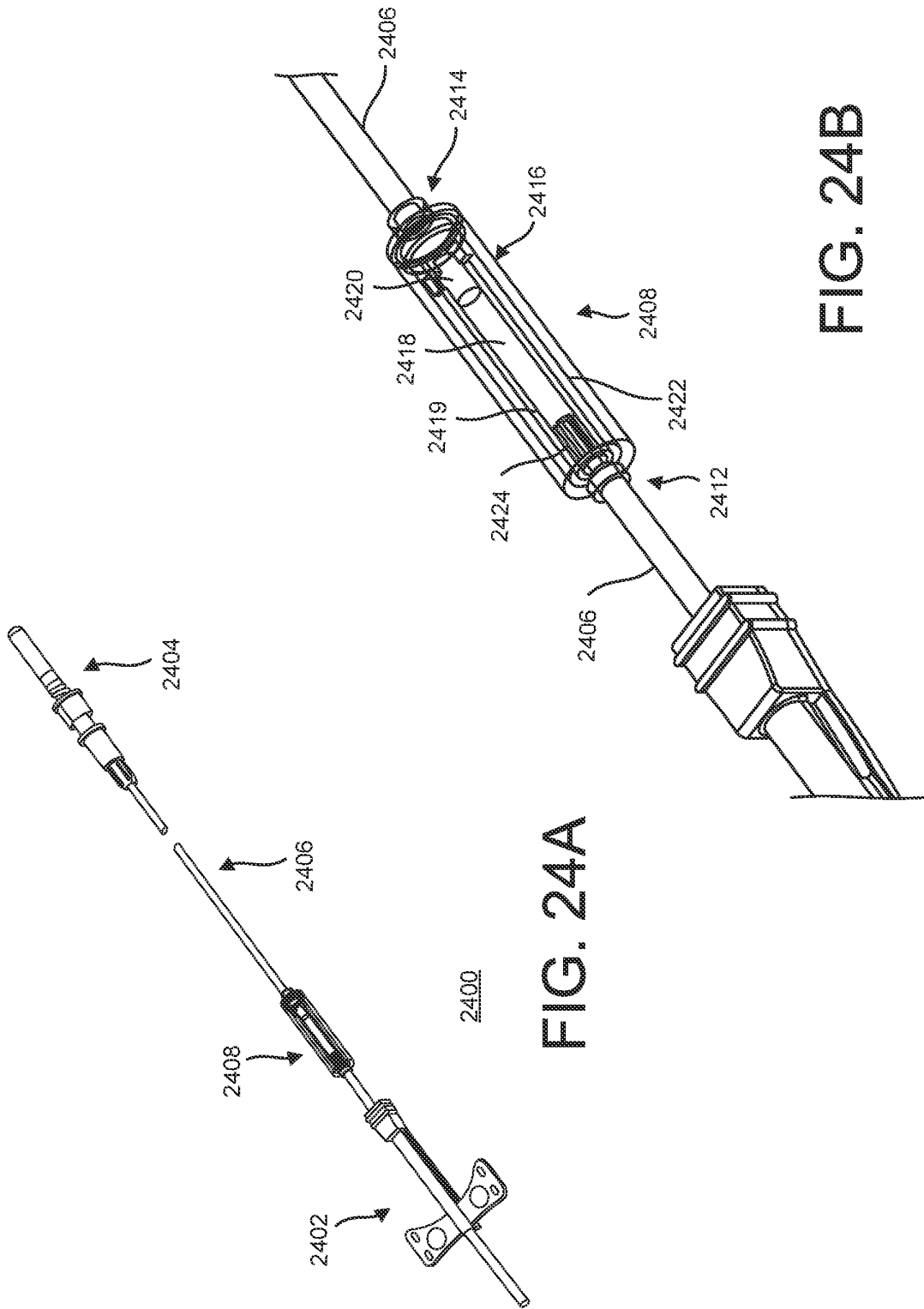


FIG. 24A

FIG. 24B

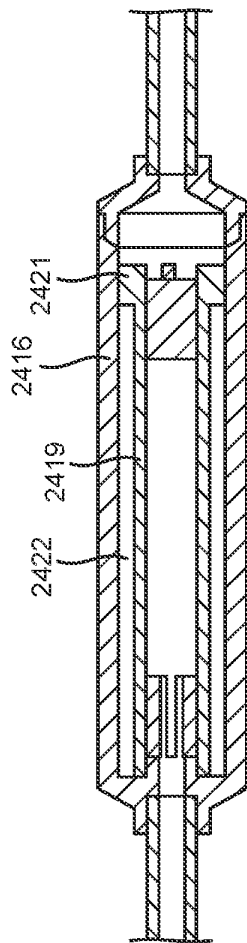


FIG. 24C

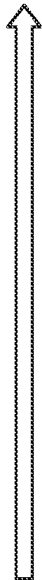
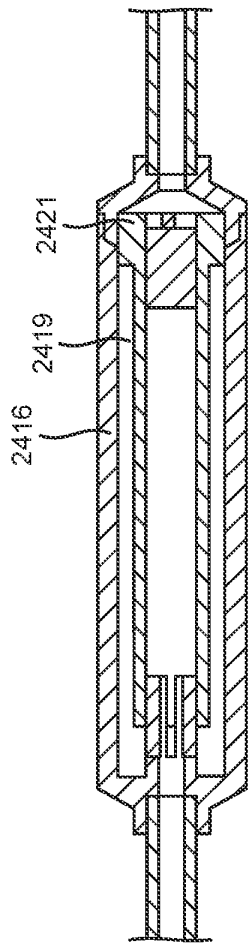
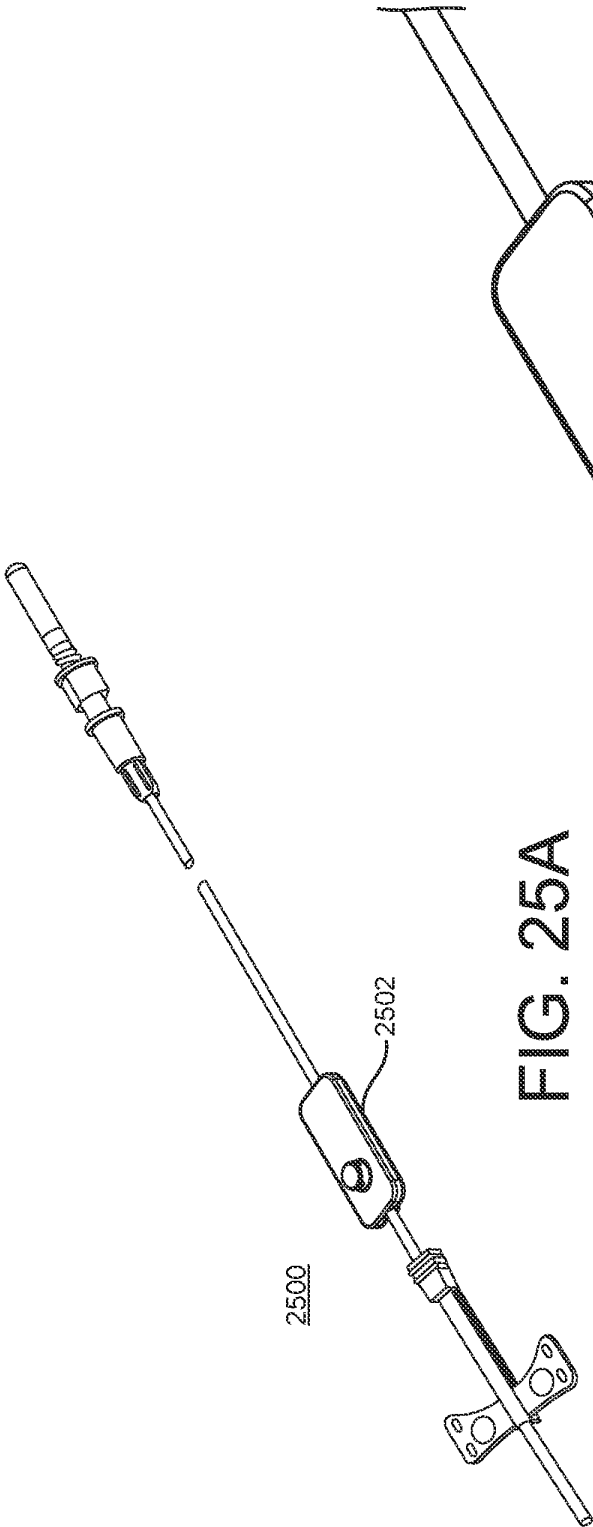
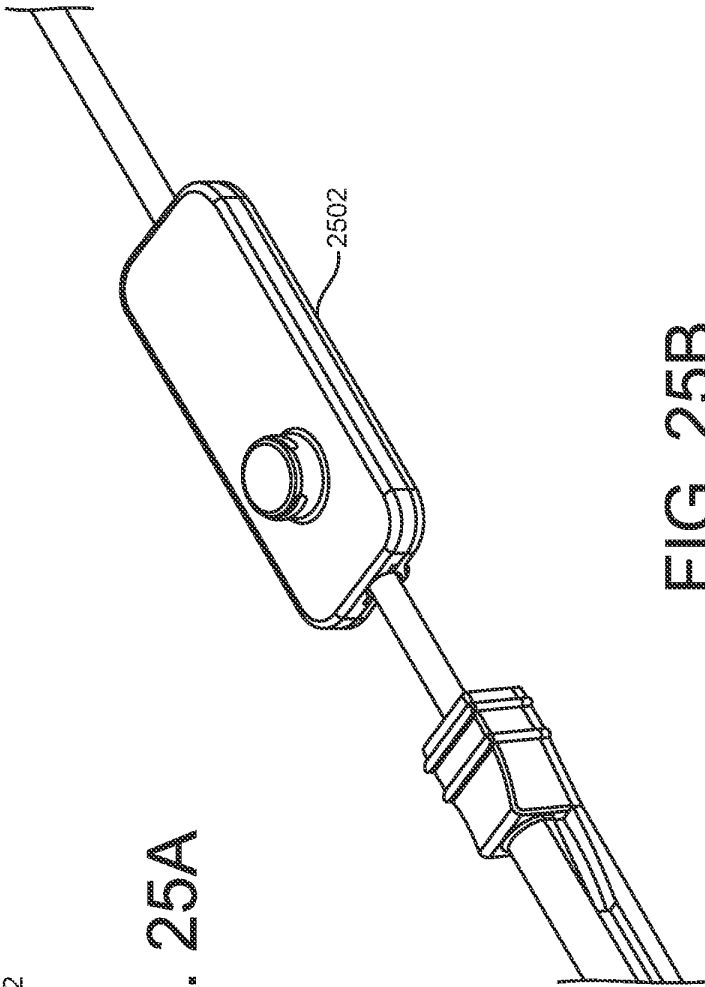


FIG. 24D



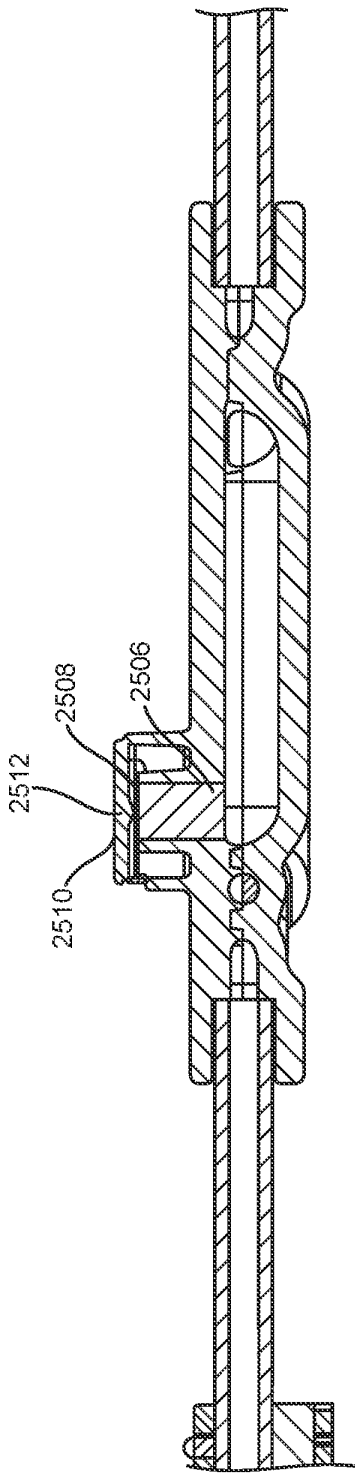


FIG. 25C

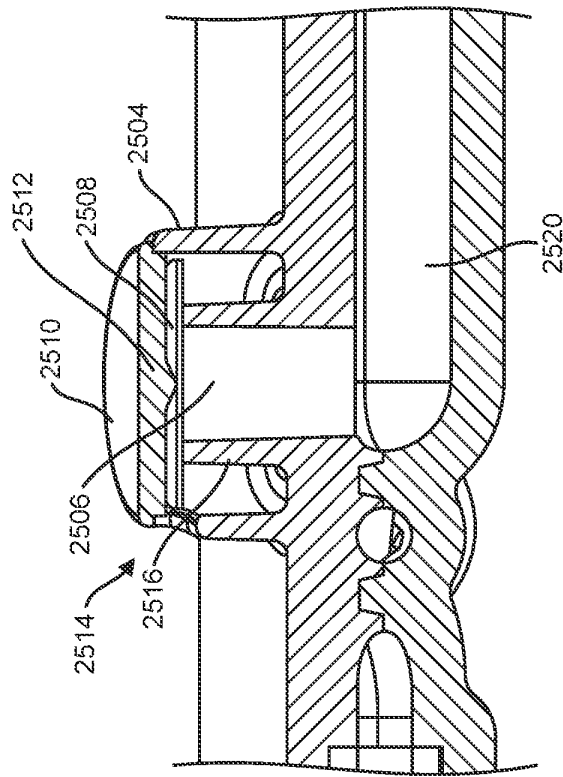
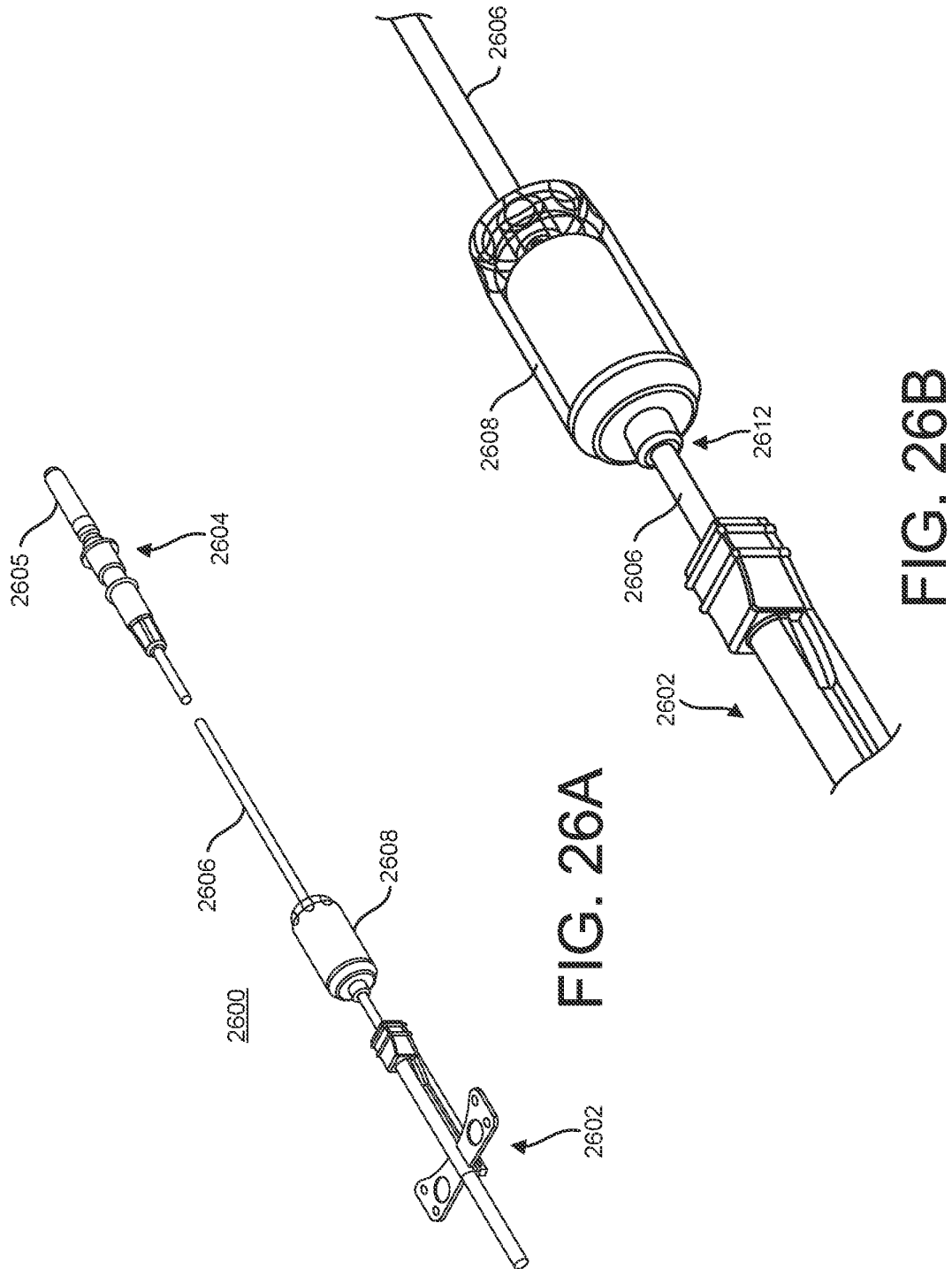
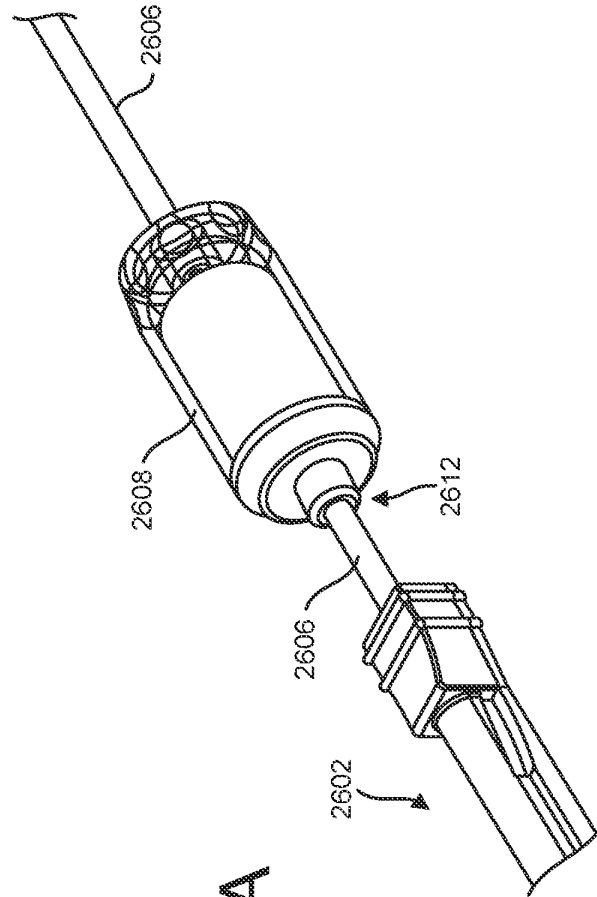
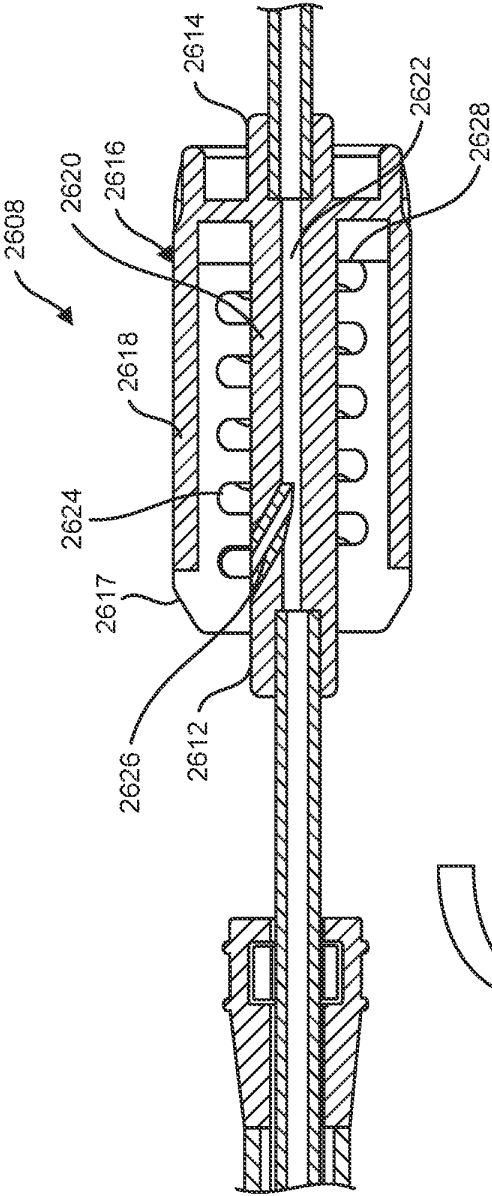
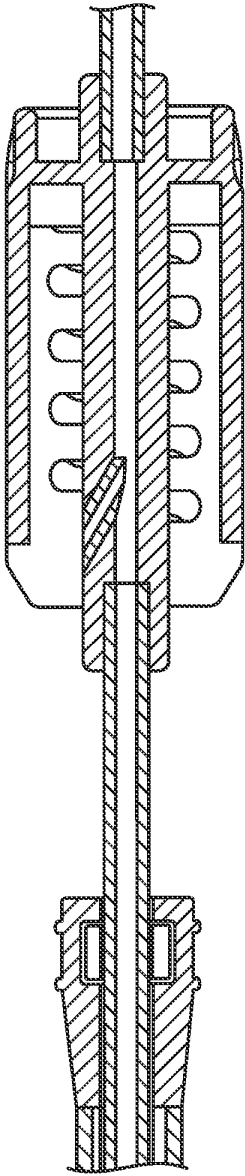


FIG. 25D





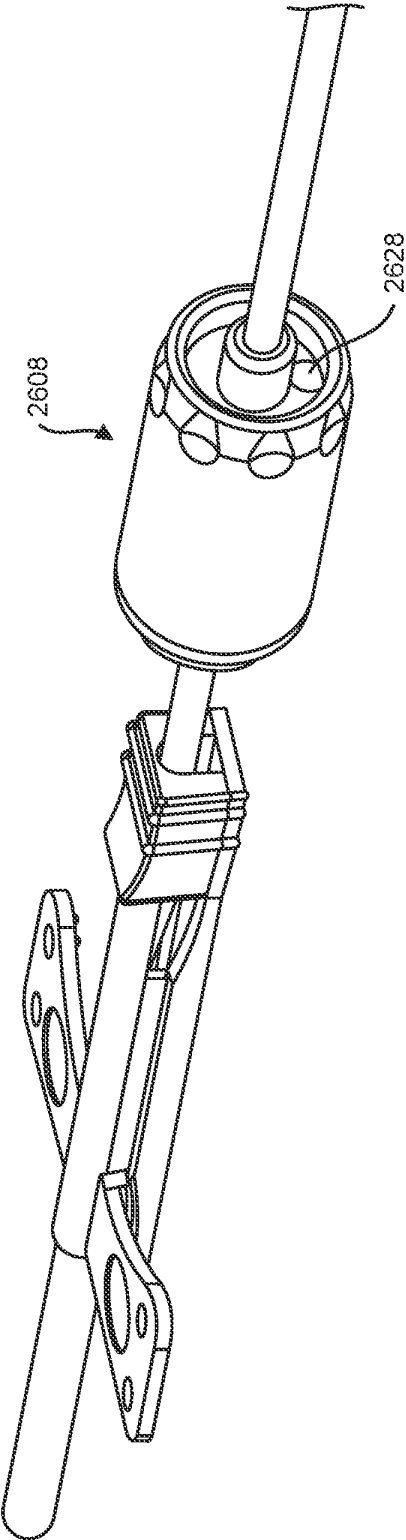
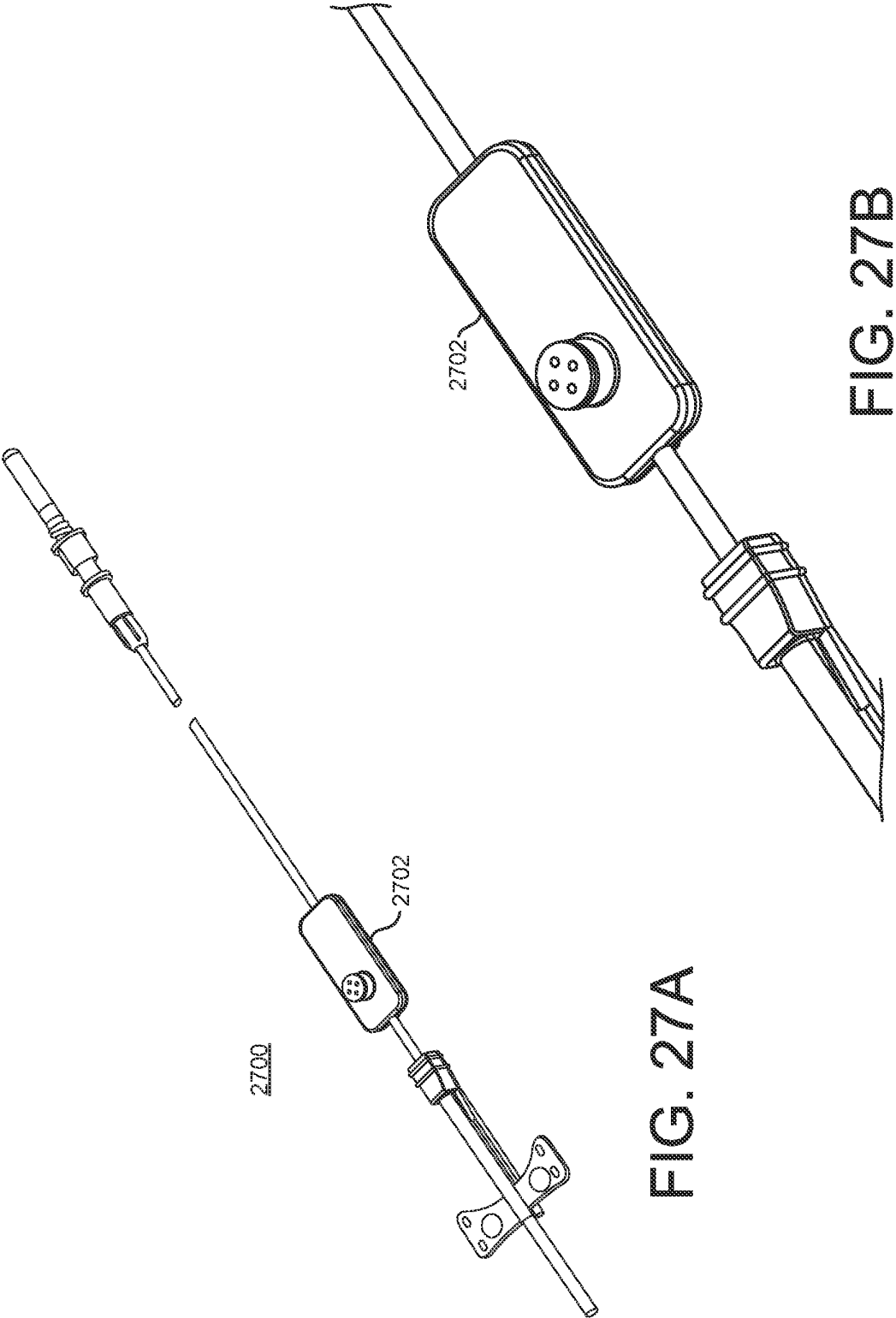


FIG. 26E



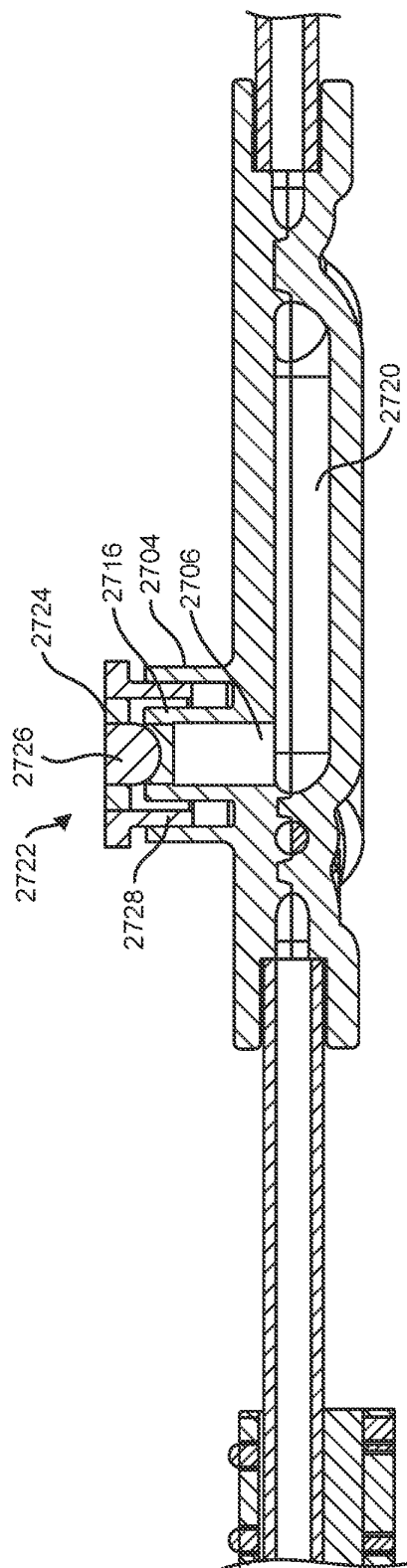


FIG. 27C

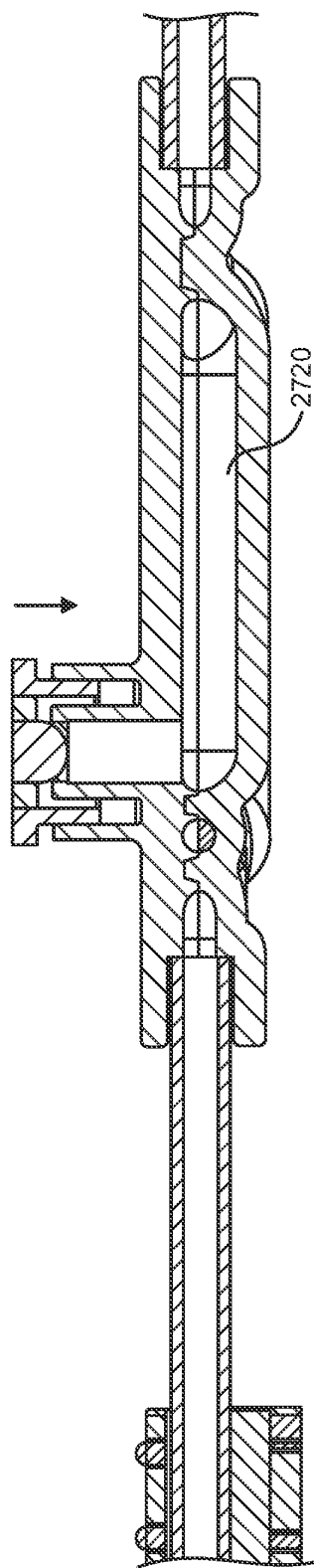
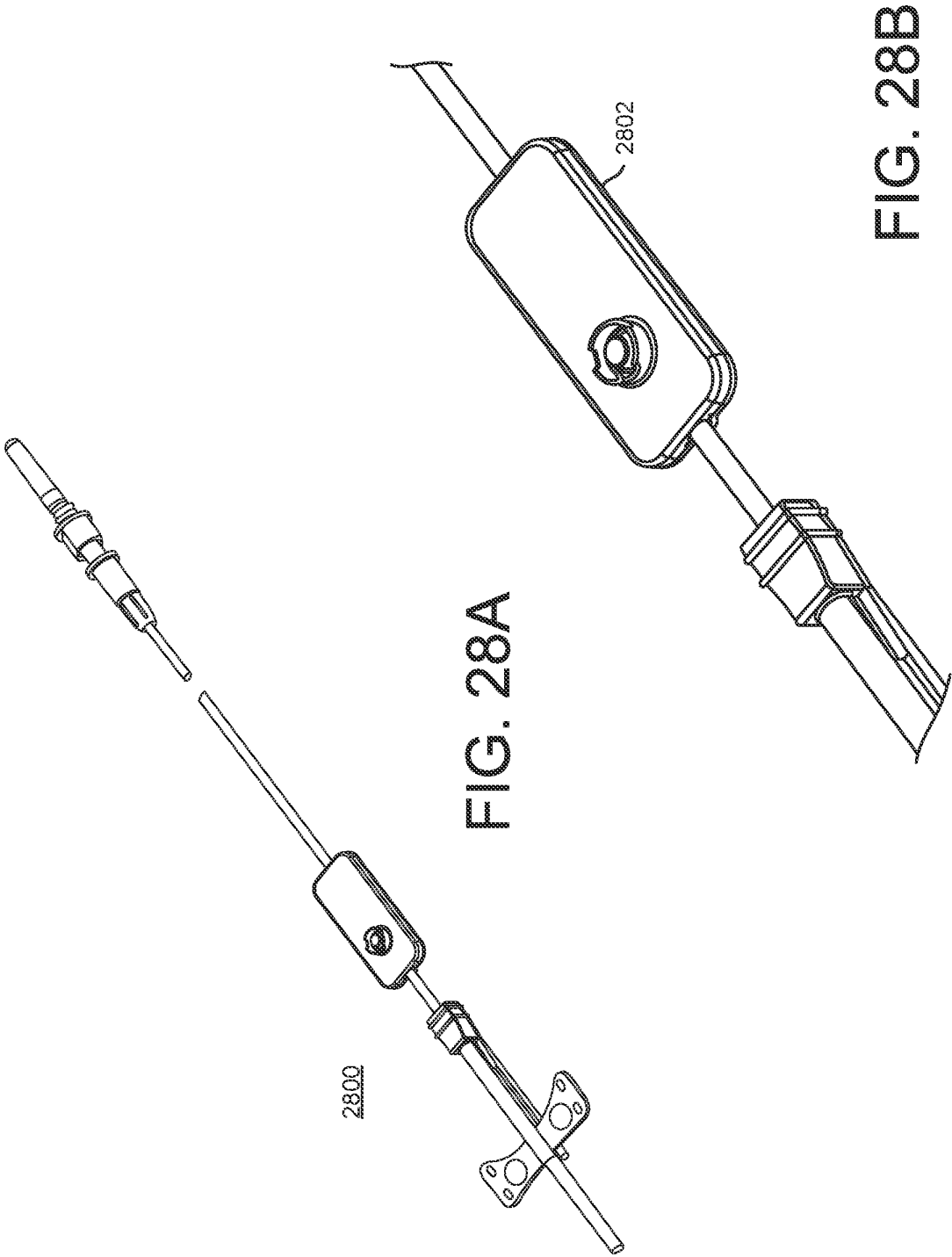


FIG. 27D



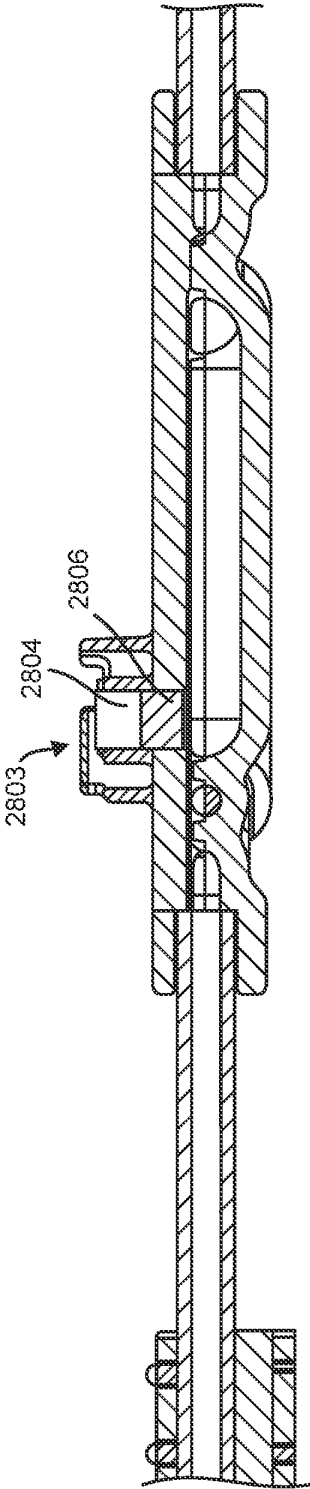


FIG. 28C

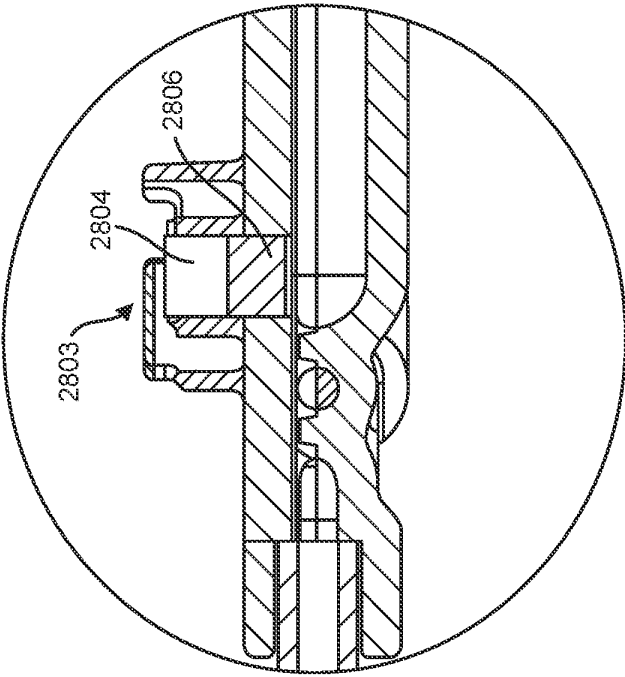


FIG. 28D

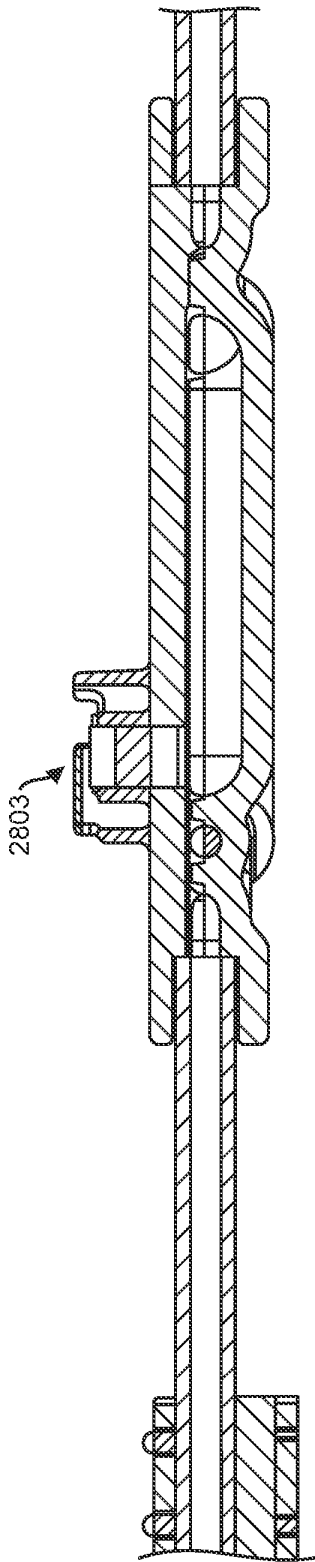


FIG. 28E

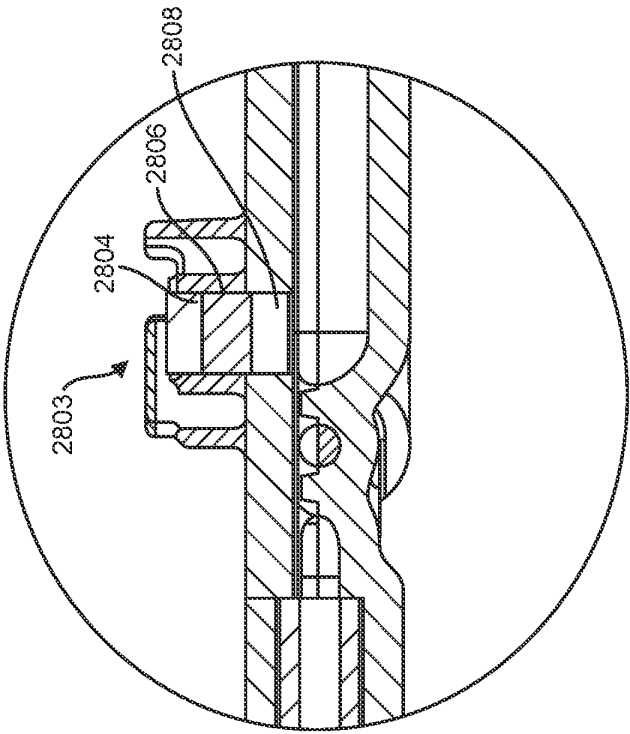
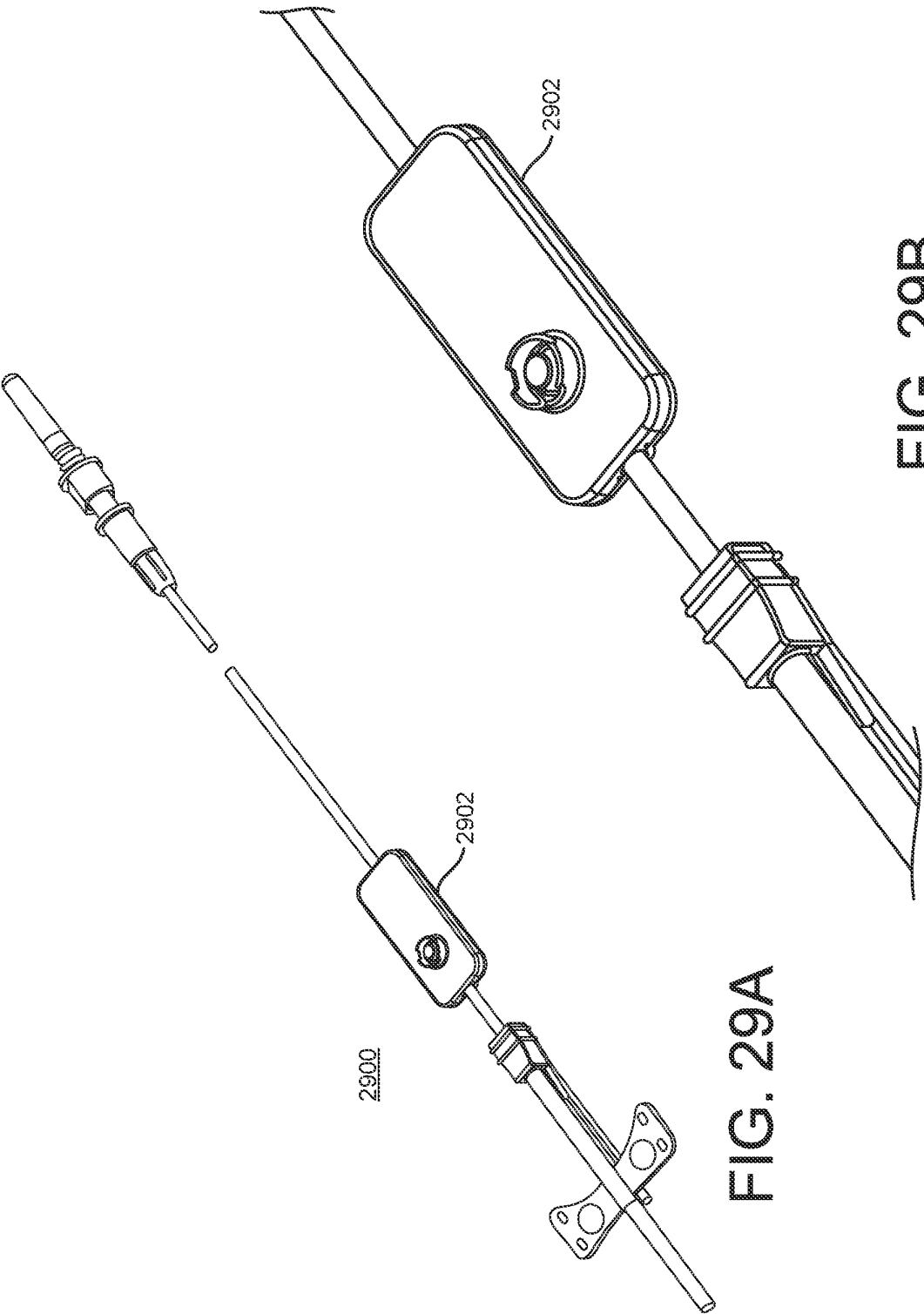


FIG. 28F



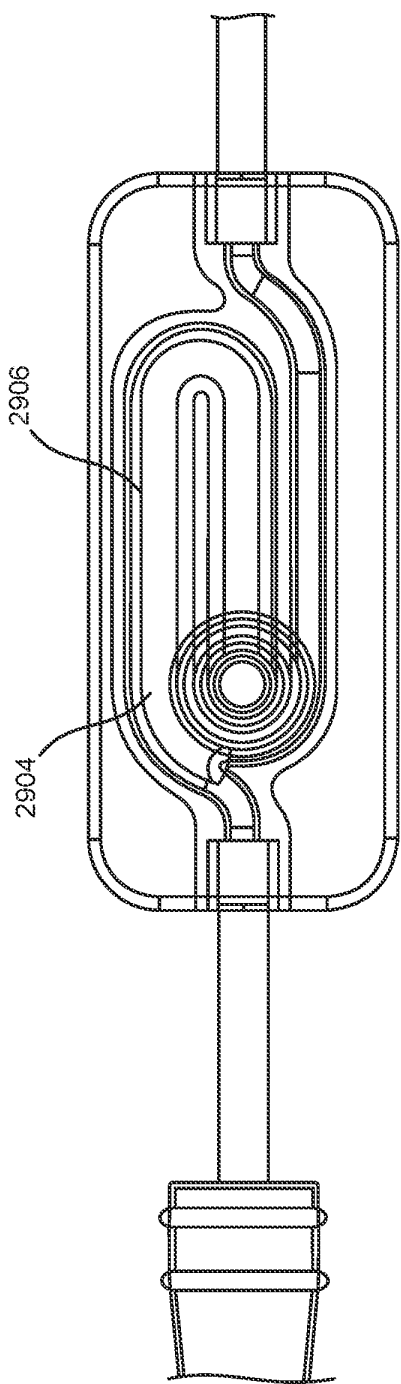


FIG. 29C

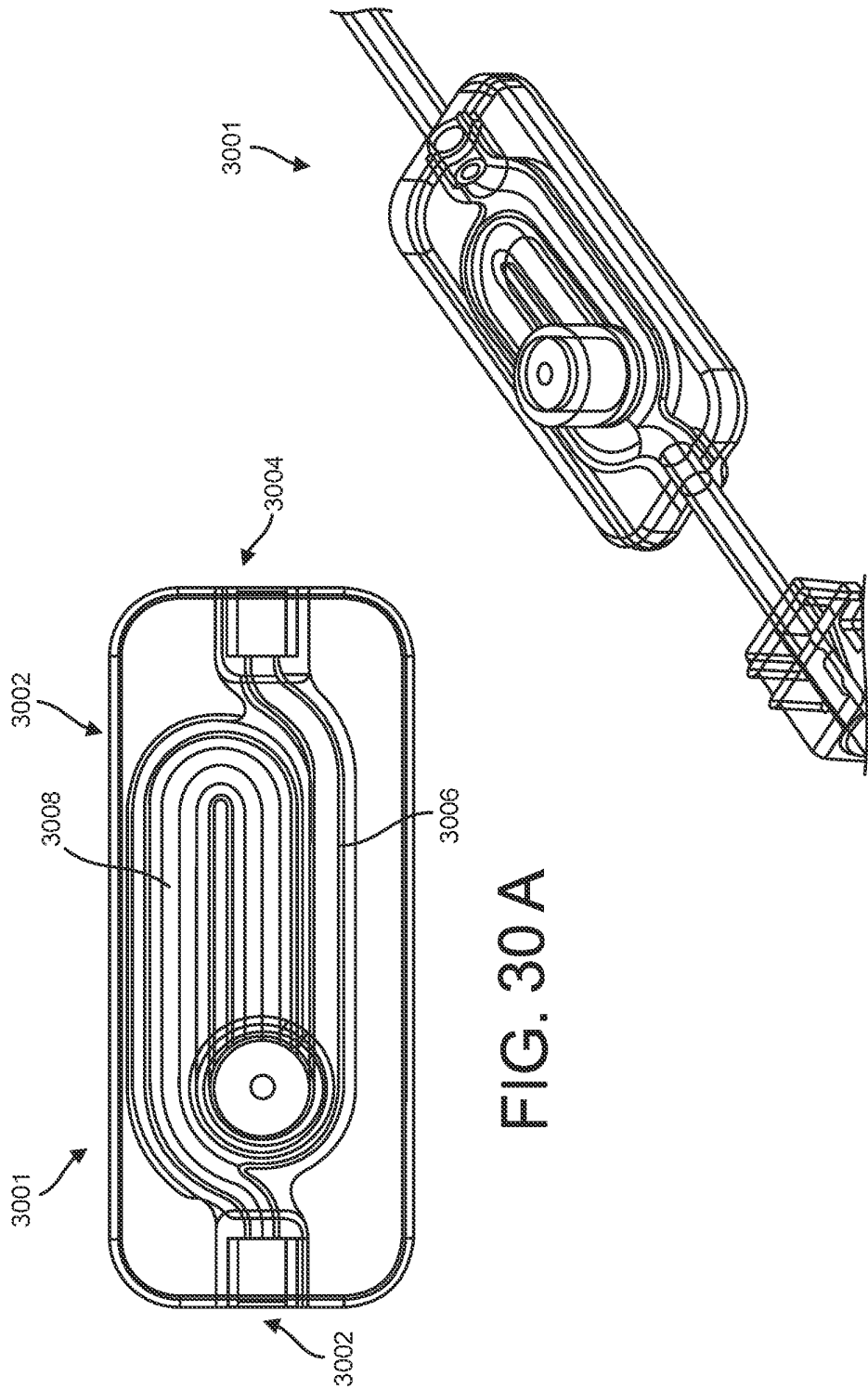


FIG. 30 A

FIG. 30B

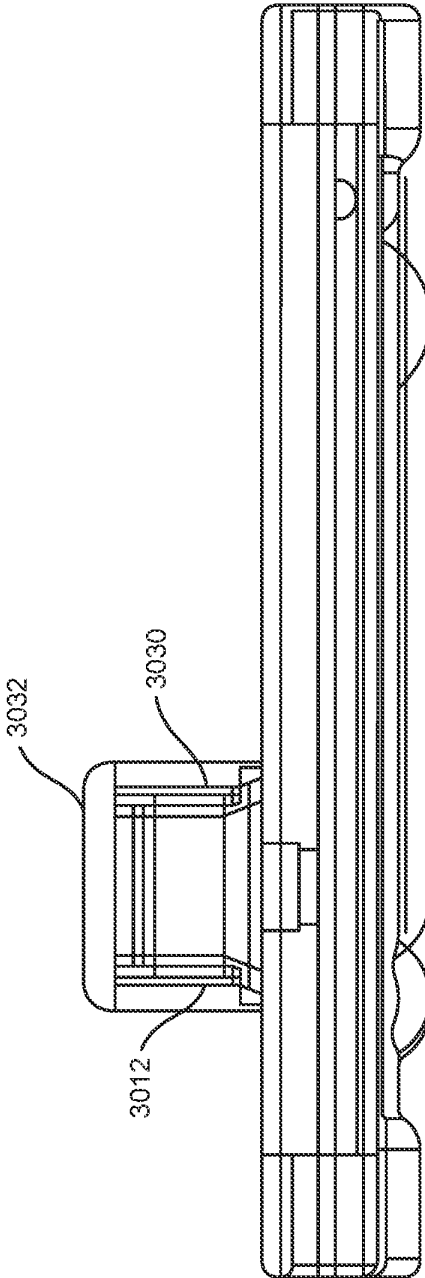


FIG. 30C

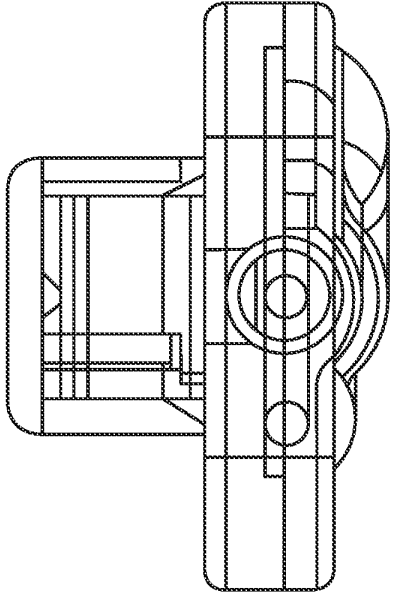
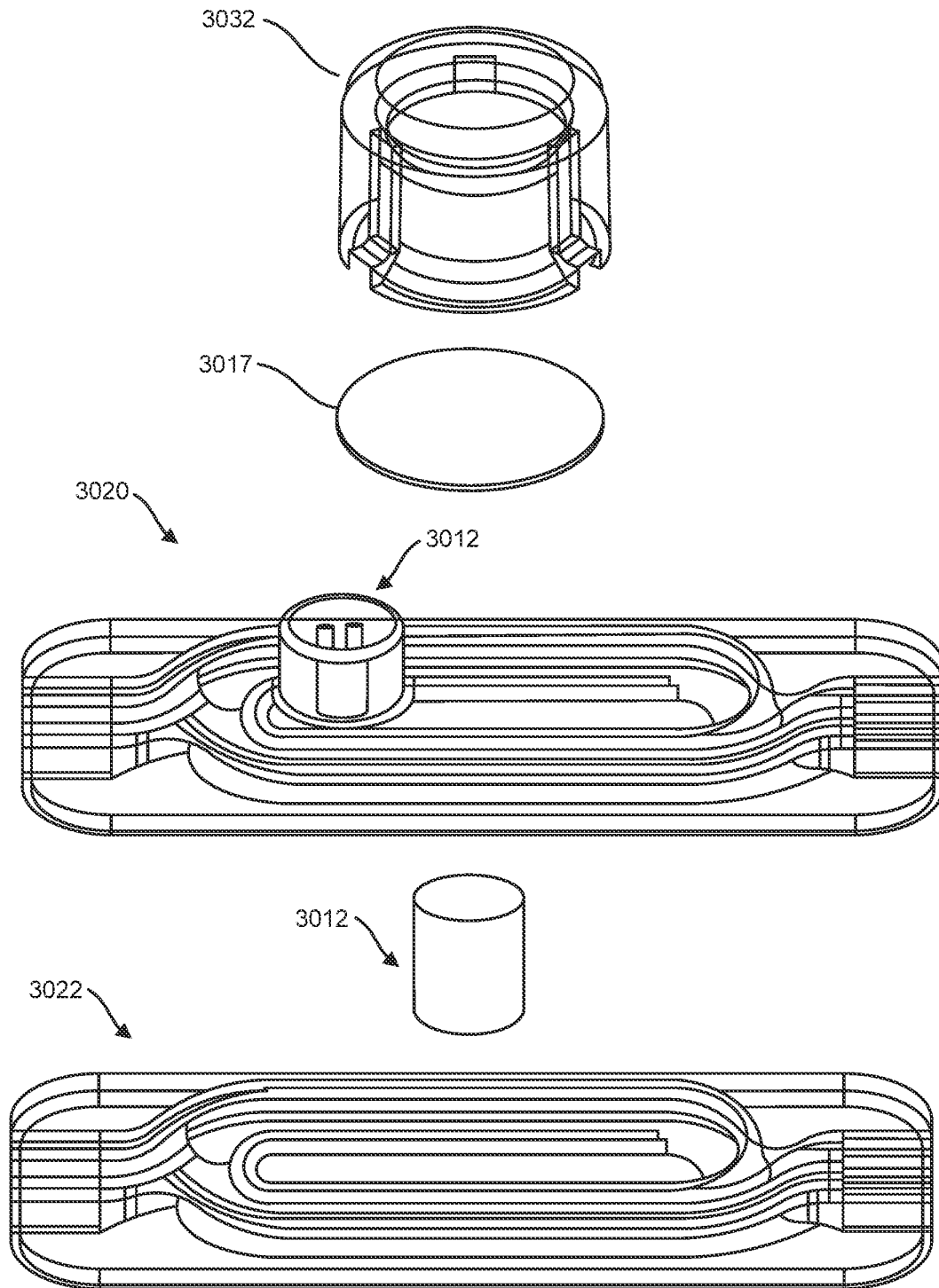


FIG. 30D

**FIG. 30E**

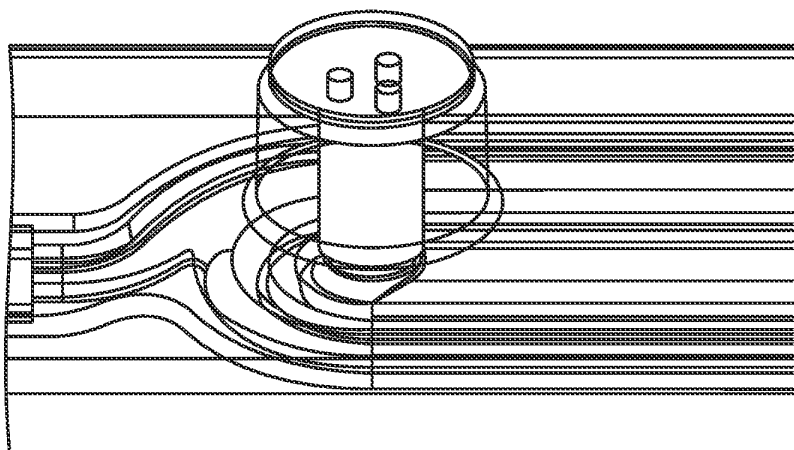


FIG. 30F

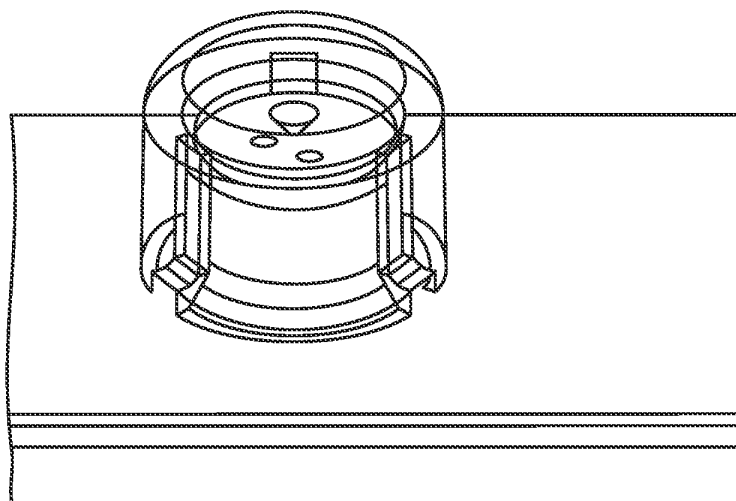


FIG. 30G



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17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420
27500	7590	10/04/2023		
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)			EXAMINER	
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			3791	
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			10/04/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 05/16/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 1 is objected to because of the following informalities: the phrase "blood" in lines 8 and 10 should be amended to read –the blood--. Appropriate correction is required.

4. Claim 1 is objected to because of the following informalities: the phrase "the junction being sized" in lines 7-8 should be amended to read –wherein the junction being sized--. Appropriate correction is required.

5. Claim 2 is objected to because of the following informalities: the phrase "blood" in line 3 should be amended to read –the blood--. Appropriate correction is required.

6. Claim 11 is objected to because of the following informalities: the phrase “an curved channel” in line 2 should be amended to read –the curved channel--.

Appropriate correction is required.

7. Claim 12 is objected to because of the following informalities: the phrase “an air permeable blood barrier” in line 2 should be amended to read –the air permeable blood barrier--. Appropriate correction is required.

8. Claim 13 is objected to because of the following informalities: the phrase “the chamber” in line 9 should be amended to read –wherein the chamber--. Appropriate correction is required.

9. Claim 13 is objected to because of the following informalities: the phrase “bodily fluid” in lines 9-10, 12 and 13 should be amended to read –the bodily fluid--.

Appropriate correction is required.

10. Claim 13 is objected to because of the following informalities: the phrase “from the inlet to bypass the chamber” in line 13 should be amended to read –to be directed from the inlet to bypass the chamber--. Appropriate correction is required.

11. Claim 16 is objected to because of the following informalities: the phrase “bodily fluid” in line 3 should be amended to read –the bodily fluid--. Appropriate correction is required.

Claim Interpretation

12. The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

- (A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;
- (B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g.,

“means for”) or another linking word or phrase, such as “configured to” or “so that”; and

- (C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step”) in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word “means,” but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

Limitation “junction” in claims 1, 6 and 13, the claims does not recite enough structure that corresponds to the claimed “junction”, the specification disclose (junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A-17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608, par.0109) which can be interpreted as the structure that corresponds to the claimed “junction”.

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the

claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

13. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

14. Claim 1 recites the limitation "the patient" in line 2. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 6 recites the limitation "the blood control device" in line 2. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 6 recites the limitation "the sequestration chamber" in line 10. There is insufficient antecedent basis for this limitation in the claim. Examiner respectfully notes that the phrase "the sequestration chamber" is also recite in claim 7.

17. Claim 8 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 9 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

19. The statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a statutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of

activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used.

Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1-20 are non-provisionally rejected on the ground of statutory double patenting as being unpatentable over claims 1-20 of U.S Patent Application No.11311219, claims 1-16 of U.S Patent Application No. 9820682, claims 1-23 of U.S Patent Application No.10143412, and claims 1-26 of U.S Patent Application No.11185266.

Also, claim 1-20 are provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-20 of U.S pending Application No.17/730118, and claims 1-18 and 20 of U.S pending Application No.17/094692.

Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent applications, pending applications and the instance application are claiming a common subject matter including: a blood sample device comprising; an inlet, an outlet; a chamber having a vent that includes an air permeable blood barrier; a sampling channel; and a junction connected between the inlet, the

chamber and the sampling channel, wherein the junction being sized and configured such that a first portion of blood conveyed from the patient flows into the chamber to displace air therein through the air permeable blood barrier, and such that a second portion of blood is allowed to bypass the chamber and the first portion of blood at least temporarily contained therein to be directed into the sampling channel toward the outlet.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and

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/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

<i>Notice of References Cited</i>	Application/Control No. 17/538,990		Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA		Art Unit 3791	Page 1 of 4

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	Examiner MAY A ABOUELELA		Art Unit 3791	Page 2 of 4

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17538990
	Filing Date	2021-11-30
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

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EXAMINER SIGNATURE

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(Not for submission under 37 CFR 1.99)

Application Number	17538990
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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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	Filing Date	2021-11-30
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17538990
Filing Date	2021-11-30
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

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49	Barnard, Dorothy R., et al. "Fibronectin (cold insoluble globulin) in the neonate," The Journal of Pediatrics, Vol. 102, Issue 3, March 1983, Pages 453-455.
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If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	07/05/2023
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17538990
Filing Date	2021-11-30
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Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 04/20/2023
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER

ABOUELELA, MAY A

ART UNIT PAPER NUMBER

3791

DATE MAILED: 04/20/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/094,692	11/10/2020	Bobby E. ROGERS	069366-0572169_KUR4C01US	8012

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH ONE-WAY AIR VALVE AND AIR-PERMEABLE BLOOD BARRIER WITH CLOSURE MECHANISM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	07/20/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 04/20/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/094,692	11/10/2020	Bobby E. ROGERS	069366-0572169_KUR4C01US	8012

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH ONE-WAY AIR VALVE AND AIR-PERMEABLE BLOOD BARRIER WITH CLOSURE MECHANISM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	07/20/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-573000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via Patent Center or EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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17/094,692	11/10/2020	Bobby E. ROGERS	069366-0572169_KUR4C01US	8012
27500	7590	04/20/2023	EXAMINER	
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)			ABOUELELA, MAY A	
ATTENTION: DOCKETING DEPARTMENT			ART UNIT	
P.O BOX 10500			PAPER NUMBER	
McLean, VA 22102			3791	

DATE MAILED: 04/20/2023

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/094,692	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 04/04/2023.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are See Continuation Sheet. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☐ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☐ Other _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.	

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	
--	--

Continuation of 3. The allowed claim(s) is/are: 1,3-8,10-14,16-18 and 20-47

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 04/10/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Allowable Subject Matter

3. Claims 1, 3-8, 10-14, 16-18 and 20-47 are allowed.
4. The following is an examiner's statement of reasons for allowance: the most pertinent art Cuppy et al (US 5,749,857) teaches a blood sampling device, comprising inlet and outlet port, a chamber connected to the inlet port; a sampling channel connected to the outlet; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

The prior art failed to teach, disclose and/or fairly suggest the chamber connected with the inlet port via a junction, and the sampling channel having a proximal end connected with the inlet port via the junction and a distal end connected to the outlet port, the sampling channel being configured to convey subsequent portions of blood to the outlet port after the first portion of blood has entered the chamber.

The other pertinent prior art Patton et al (US 2008/0145933) teaches the chamber connected with the inlet port via a junction, and the sampling channel having a

proximal end connected with the inlet port via the junction and a distal end connected to the outlet port, the sampling channel being configured to convey subsequent portions of blood to the outlet port after the first portion of blood has entered the chamber, but failed to teach and/or suggest a housing that houses and defines the inlet port, the junction, the outlet port, the chamber, and the sampling channel.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is

available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17094692
	Filing Date	2020-11-10
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572169_KUR4C01US

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Examiner Name	ABOUELELA, MAY A
Attorney Docket Number	069366-0572169_KUR4C01US

1	Weinbaum, Fredric I., et al. "Doing it right the first time: quality improvement and the contaminant blood culture." Journal of Clinical Microbiology 35.3 (1997): 563-565.
2	Weinstein, Melvin P. "Blood culture contamination: persisting problems and partial progress." Journal of clinical microbiology 41.6 (2003): 2275-2278.
3	Weinstein, Melvin P. "Current blood culture methods and systems: clinical concepts, technology, and interpretation of results." Clinical infectious diseases 23.1 (1996): 40-46.
4	Weinstein, Melvin P., et al. "The clinical significance of positive blood cultures in the 1990s: a prospective comprehensive evaluation of the microbiology, epidemiology, and outcome of bacteremia and fungemia in adults." Clinical Infectious Diseases 24.4 (1997): 584-602.
5	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.
6	Zimmon, David S. et al. "Effect of portal venous blood flow diversion on portal pressure." The Journal of Clinical Investigation 65.6 (1980): 1388-1397.

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	04/11/2023
--------------------	-------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
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Examiner Name	ABOUELELA, MAY A
Attorney Docket Number	069366-0572169_KUR4C01US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-04-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)

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	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572169_KUR4C01US

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	3382865		1968-05-14	WORRALL JR ASHTON L	
	2	3494352		1970-02-10	RUSSO RONALD D	
	3	3604410		1971-09-14	WHITACRE GARY L	
	4	3648684		1972-03-14	BARNWELL CLEORA W	
	5	3817240		1974-06-18	AYRES W	
	6	3835835		1974-09-17	THOMPSON R	
	7	3848579		1974-11-19	VILLA REAL A	
	8	3859998		1975-01-14	THOMAS JOSEPH JOHN	

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9	3945380	1976-03-23	DABNEY WILLIAM C
10	4056101	1977-11-01	GEISSLER ULRICH C
11	4150089	1979-04-17	LINET MICHAEL S
12	4193400	1980-03-18	LOVELESS JAMES C
13	4257416	1981-03-24	PRAGER DAVID
14	4349035	1982-09-14	THOMAS JOSEPH J
15	4373535	1983-02-15	MARTELL MICHAEL D
16	4416290	1983-11-22	LUTKOWSKI LAWRENCE
17	4673386	1987-06-16	GORDON MARK G
18	4690154	1987-09-01	WOODFORD TIMOTHY
19	4813433	1989-03-21	DOWNEY JOHN M

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20	4904240	1990-02-27	HOOVER ROCKLIN L
21	4980297	1990-12-25	HAYNES JOHN L
22	5045185	1991-09-03	OHNAKA YUKIHIRO
23	5097842	1992-03-24	BONN GINA B
24	5100394	1992-03-31	DUDAR THOMAS E
25	5135489	1992-08-04	JEPSON STEVEN C
26	5200325	1993-04-06	BLATT JOEL M
27	5401262	1995-03-28	KARWOSKI THEODORE
28	5417673	1995-05-23	GORDON MARK G
29	5431811	1995-07-11	TUSINI ANDREA
30	5432084	1995-07-11	BRUBAKER DANIEL B

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31	5439450	1995-08-08	HAEDT LORI E
32	5632906	1997-05-27	SHIDA NOBORU
33	5691486	1997-11-25	BEHRINGER BRUCE E
34	5772608	1998-06-30	DHAS V VARAPRABHU
35	5811658	1998-09-22	VAN DRIEL MICHAEL R
36	5865803	1999-02-02	MAJOR MIKLOS
37	5873841	1999-02-23	BRANNON JAMES K
38	5972294	1999-10-26	SMITH JOHN L
39	5980830	1999-11-09	SAVAGE DOUGLAS ROBERT
40	6013037	2000-01-11	BRANNON JAMES K
41	6106509	2000-08-22	LOUBSER PAUL G

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43	6224561		2001-05-01	SWENDSON DAVID L	
44	6506182		2003-01-14	ESTABROOK BRIAN K	
45	6599474		2003-07-29	EVTODIENKO VLADIMIR	
46	6626884		2003-09-30	DILLON JAGMOHANBIR SINGH	
47	6638252		2003-10-28	MOULTON WILLIAM G	
48	6695004		2004-02-24	RAYBUCK JOHN L	
49	6733433		2004-05-11	FELL CLAUDE	
50	6736783		2004-05-18	BLAKE KEVIN R	
51	6843775		2005-01-18	HYUN DONGCHUL D	
52	6860871		2005-03-01	KURACINA THOMAS C	

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54	6913580		2005-07-05	STONE BENJAMIN CURTIS	
55	6945948		2005-09-20	BAINBRIDGE MARLENE	
56	7052603		2006-05-30	SCHICK KARL G	
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60	7461671		2008-12-09	EHWALD RUDOLF	
61	7479131		2009-01-20	MATHIAS JEAN-MARIE	
62	7666166		2010-02-23	EMMERT MICHAEL	
63	8070725		2011-12-06	CHRISTENSEN KELLY D	

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65	8377040	2013-02-19	BURKHOLZ JONATHAN KARL
66	8574203	2013-11-05	STOUT MARTY L
67	8827958	2014-09-09	BIERMAN STEVEN F
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69	10010282	2018-07-03	ROGERS BOBBY E
70	10143412	2018-12-04	ROGERS BOBBY E
71	10827964	2020-11-10	ROGERS BOBBY E
72	11185266	2021-11-30	ROGERS BOBBY E
73	11213232	2022-01-04	VOSEVIC MILAN
74	11311219	2022-04-26	ROGERS BOBBY E

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	1	20010044615		2001-11-22	AMANO YOSHIKAZU	
	2	20030082074		2003-05-01	JURIK FRANKLIN A	
	3	20030185707		2003-10-02	IWAKI YOSHIHIDE	
	4	20030208151		2003-11-06	KRAUS MENACHEM	
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	6	20050005635		2005-01-13	LE METAIS MARC	
	7	20050007524		2005-01-13	LUO FANG-CHEN	
	8	20050161112		2005-07-28	EHWALD RUDOLF	
	9	20050245885		2005-11-03	BROWN LEROY	

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11	20070119508	2007-05-31	WEST RICHARD L
12	20090227953	2009-09-10	TAN CHEE LEONG
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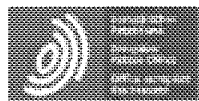
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Bibliographic data: EP0448795 (A2) — 1991-10-02

Compartmental body fluid collection tube.

Inventor(s): DUFRESNE CHRISTOPHER M [US] ± (DUFRESNE, CHRISTOPHER M)

Applicant(s): BECTON DICKINSON CO [US] ± (BECTON DICKINSON AND COMPANY)

Classification: - international: A61B5/15; A61B5/154; B01L3/14; (IPC1-7): B01L3/14
- cooperative: A61B5/15003 (EP); A61B5/150251 (EP); A61B5/150351 (EP); A61B5/150389 (EP); A61B5/150473 (EP); A61B5/150732 (EP); A61B5/154 (EP); B01L3/5082 (EP)

Application number: EP19900123434 19901206 Global Dossier

Priority number(s): US19900501214 19900329

Also published as: EP0448795 (A3) AU627387 (B2) AU6803590 (A) CA2031411 (A1) FI911489 (A) more

Abstract of EP0448795 (A2)

A compartmented body fluid specimen collection tube (10) is provided which allows the user to select a size compartment (14,16) depending upon the quantity of specimen required. Thus, the tube of the invention may be of the standard size which is much easier for the user to handle than very small tubes when taking a blood sample, but a selected size compartment (14,16) is available. The manufacturer of the tube itself may use a single mold for making tubes accommodating differing required specimen quantities, and, thereafter the vendor may select either size compartment (14,16) for imparting a vacuum and the other processing required into a final product. The invention allows the use of a single standard size laboratory equipment array for processing collected specimens of varying quantities, as well as a single standard stopper (28). Finally, reduced vacuum application or "partial draw" tubes are avoided, thus eliminating the problem of unpredictable specimen draw response because of varying atmospheric pressures at different locations of use.



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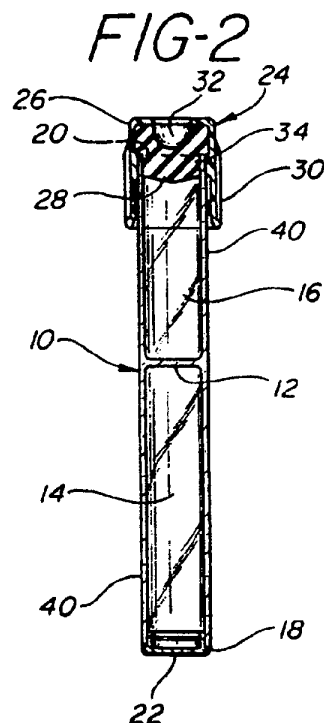
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(54) **Compartmental body fluid collection tube.**

(57) A compartmented body fluid specimen collection tube is provided which allows the user to select a size compartment depending upon the quantity of specimen required. Thus, the tube of the invention may be of the standard size which is much easier for the user to handle than very small tubes when taking a blood sample, but a selected size compartment is available. The manufacturer of the tube itself may use a single mold for making tubes accommodating differing required specimen quantities, and, thereafter the vendor may select either size compartment for imparting a vacuum and the other processing required into a final product. The invention allows the use of a single standard size laboratory equipment array for processing collected specimens of varying quantities, as well as a single standard stopper. Finally, reduced vacuum application or "partial draw" tubes are avoided, thus eliminating the problem of unpredictable specimen draw response because of varying atmospheric pressures at different locations of use.



EP 0 448 795 A2

BACKGROUND AND STATEMENT OF THE INVENTION

This invention relates to body fluid collection tubes for collecting a body fluid specimen from a patient for subsequent examination in a laboratory. More particularly, this invention relates to a blood collection tube for taking such specimens in which the tube has imparted thereto an internal vacuum with the vacuum being utilized for drawing the blood specimen from the vein of a patient.

Attempts have been made to overcome the problem of proliferation of a number of tubes for taking a plurality of specimens from a single venous entry into a patient. For example, Japanese Patent Application No. 62-51238, filed March 6, 1987 teaches a device in which a tube is divided axially into two chambers for taking two blood specimens simultaneously. However, there is no recognition for arranging different size compartments for taking different separate specimens of different size to accommodate subsequent laboratory testing of those specimens.

Other prior art arrangements, such as that taught in U.S. Patent 3,894,951, for example, provide for compartmentalized blood collection tubes in which the compartments have fluid connections for subsequent separation of a single blood sample into separate components.

In taking such specimens, differing quantities or volumes of specimens are required for certain applications. For this reason, larger and smaller tubes are manufactured for this purpose. As an alternative to making larger and smaller tubes, so-called "partial draw" tubes are provided in which the vacuum imparted to the tube is varied in order to accommodate differing quantities of specimen as required. All of these variations increase the cost of collecting blood specimens, and when it is understood that literally billions of such tubes are used and discarded after a single use each year the costs become substantial for medical applications.

This invention overcomes this problem by using a conventionally sized tube of, for example, 6cc in volume and incorporates an integral divider substantially centrally of the length of the tube to provide two compartments of differing size. Such compartments may be, for example, 2cc and 3cc. Thus, the manufacturer, rather than having to use two separate molds and two separate production lines, may manufacture a single tube having a selection of a 2cc and a 3cc compartment or chamber. Thereafter, the user or vendor may utilize or select one of the sizes of compartment and impart a vacuum thereto and place a stopper in the open end of the compartment size selected. The remaining compartment or chamber not being uti-

lized for this particular series of tubes has a plug for closing the open end of the non-utilized chamber or compartment.

Conventional blood collection tubes have only one chamber, and volume in those conventional tubes is varied by using either larger or smaller diameter tubes, taller or shorter length tubes or varying the degree of vacuum imparted. As will be understood by practitioners-in-the-art, larger and smaller diameter tubes require specific dimensioned stoppers for accommodating those various sizes. Moreover, taller and shorter tubes require different packaging to accommodate tube length. If an accommodation is made to utilizing only a single size tube and imparting a partial vacuum for subsequent use in which only a small quantity of specimen is required in relatively large tubes, there is inconsistent draw over different areas of use because of differing atmospheric pressure gradients.

Finally, the users of tubes of different length and diameter must have varying size equipment, such as centrifuges, tube racks and like supporting arrangements to accommodate the varying sizes of tubes being utilized for collecting differing quantities of body fluid specimens for different applications.

With this invention, by contrast, a single size tube, as noted above is utilized. For this reason, the user, in the sometimes tense environment of taking a blood specimen from an individual, has a relatively large tube for handling during the collection activity. Nevertheless the tube has a smaller compartment; for accommodating the actual size specimen required. Moreover, because only a single size tube relative to diameter is being utilized with the invention here, a single stopper size is required rather than a plurality of stopper sizes of differing diameters to accommodate differing diametered tubes. This reduces manufacturing requirements as well as storage requirements for such a variety of stopper sizes.

Moreover, because of the large size tubes having small compartmentalized areas, no "partial draw" vacuum applications are required. This eliminates the problem of inconsistency depending upon the atmospheric pressure gradients over many areas of use of such tubes. Finally, because of the uniformity of size of the tube, the hospital or clinical laboratory only needs to have one size equipment necessary for handling the tubes of a standard size.

A further feature of the invention may be the use of both compartments of a single tube by the phlebotomist. That is, the vendor or manufacturer of the tubes may, for example, impart vacuum to both a 3cc and a 2cc compartment or chamber in a single tube and place stoppers for sealing and

maintaining the vacuum. Thereafter, the phlebotomist, in requiring two separate blood sample volumes for different tests subsequently can first draw blood into one chamber followed by inversion of the tube and collection of blood into the second chamber. Two blood samples would then be contained in a single tube for subsequent examination in the clinical laboratory, and with only one venous entry.

Other objects and advantages of this invention will be apparent from the following description, the accompanying drawings and the appended claims.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is longitudinal sectional view of the compartmentalized blood collection tube of the invention;

Fig. 2 is a longitudinal sectional view of one embodiment of the invention wherein a vacuum has been imparted to the smaller chamber or compartment of the tube of the invention and showing the sealing stopper arrangement for such a tube, together with a plug for the unused chamber;

Fig. 3 is a longitudinal sectional view of the tube of the invention reversed in its application from that shown in Fig. 2;

Fig. 4 is an enlarged partial cross-sectional view of one open end of the tube of the invention showing the mating configuration of a sealing plug applied to the open end for closing off the non-utilized chamber or compartment of the tube of the invention;

Fig. 5 is a longitudinal sectional view of a blood sample tube holder for taking a blood sample from a vein of a patient with the tube of the invention inserted therein; and

Fig. 6 is a longitudinal sectional view of a tube similar to that shown in Fig. 1, but both chambers being closed with a stopper closure for use in evacuating two chambers for collecting two specimens sequentially.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, Fig. 1 illustrates the invention in the form of a conventionally sized blood collection tube compartmentalized in its formation to provide two chambers or compartments of differing size to accommodate differing blood sample requirements.

In Fig. 1, the device 10 is an elongated tube with walls 40 and having open ends 18, 20 at each end thereof. As can be seen in Fig. 1, tube 10 is divided by a wall 12 into compartments or chambers 14 and 16. Also, as will be seen in Fig. 1, chamber 14 is larger than chamber 16. For example, in a 6cc tube, chamber 14 may be, for exam-

ple, 3cc in volume while chamber 16 may be 2cc in volume.

It will be understood that the volume amounts may be varied as use requirements dictate. Tube 10 may be comprised of a thermoplastic resin material, for example, formed in a mold to provide wall 12 integrally joined to wall 40 of tube 10.

Referring now to Fig. 2, tube 10 is shown in a prepared form for use by a vendor. In this case, the smaller dimensioned chamber 16 has had, for example, a vacuum applied thereto with a subsequent insertion of a stopper assembly 24 for maintaining the vacuum in chamber 16. The assembly 24 includes a rubber stopper for closing the open end, 20 of the tube, assembly 10. That is, the outer surface of lower portion of stopper 28 seals against the internal surface of walls 40 of the upper end of tube 10. The assembly 24 includes a plastic cap 26 connected to and surrounding elastomer stopper 28. This serves to accommodate removal of stopper 28 in a simple fashion, when required, to obtain access to the collected sample in chamber 16.

Stopper 28 includes a well 32 formed in the top surface thereof which has the purpose of reducing the vertical extent of stopper 28 in the center portion thereof to provide a diaphragm 34 of vertically smaller dimension through stopper 28 for receiving a needle such as needle 52 and the point 54 thereof, as shown in Fig. 5. The plastic portion 26 of stopper 24 assembly includes outer ridges 34 to provide an easier grip of the assembly 24 for removal thereof from the evacuated chamber 16, when required.

Referring to Fig. 4, the open end 18 of chamber 14, which in this case is not being utilized for fluid collection includes a plug 22 for stabilizing the open end 18 of the tube assembly 10 for subsequent use of the tube or for storing the tube prior to use.

In Fig. 4, an enlarged view of the open end 18 or 20 is shown to accommodate the snap-fit arrangement of plug 22 in the open end 18 or 20 of chamber 14 or 16, as the case may be, when they are not being utilized in a particular tube 10 assembly. That is, the lower end of wall 40 may include an annular indentation 36 for receiving in snap-fit engagement an annular abutment, 38 on plug 22.

Referring now to Fig. 3, a tube 10 is shown reversed from the Fig. 2 showing for accommodating use of the 3cc and/or larger compartment 14 as desired by the user. In this case, stopper assembly 24 closes the open end 18 rather than 20, while the open end 20 is closed with a plug 22. It will be understood by practitioners-in-the-art that both compartments or chambers 14, 16 may be utilized in a single tube 10 by imparting a vacuum to both chambers and using a stopper closure assembly

24 for closing both open ends 18 and 20. In such cases, a plug 22 is not utilized.

Such an arrangement is shown in Fig. 6 wherein a tube 60 similar to tube 10 is shown with chambers 64, 66 divided by wall 62. Tube 60 includes two open ends 68 and 70. In this case, a stopper assembly 24 is applied to both open ends after application of vacuum to chambers 64, 68, respectively. As discussed above, in such an application, the user collects two different volumes of specimen from a patient as required for subsequent testing purposes.

In use, the assembly 10 of the invention is inserted into a blood collection needle holder such as 42 shown in Fig. 5. Holders 42, for example, include at the closed end thereof a hub 46 with internal screw threads 48 for accommodating the screw threads of a needle holder hub 50. Thus, a plurality of needle holder hubs 50 may be, sequentially, screwed into hub 46 of needle holder 42 for repeated use. The needle 52 includes a sharpened end 56 which is inserted into the vein of a patient for collecting a blood specimen.

Subsequent to insertion of the needle 56 into the vein of a patient, the laboratory technician, doctor or nurse inserts the tube assembly 10 into the blood collection holder 42 at the open end 43 thereof. In doing so, the technician holds onto the holder 42 utilizing the flange 44. Subsequently, the tube 10 is moved forward toward the closed end of the holder 42 until such time as the negative pressure needle point 54 passes through stopper 28. When this happens, access to the vacuum in chamber 16 takes place and the vacuum draws blood from the patient's vein through the needle 52 into chamber 16.

As will be understood by practitioners-in-the-art, the smaller chamber 16 may be, for example, of a volume of 2ccs which is all that is required for certain subsequent examinations of the specimen in the lab. A tube such as tube 60 shown in Fig. 6 may be used in holder 42 instead of tube 10. With such an arrangement, the double-ended needle assembly would include a sealing valve sleeve well known in the art so that the tube 60 may be pulled off needle point 54, and reversed for inserting the needle point 54 into the subsequent stopper 28 without blood loss, for collecting a second blood sample in chamber 66, for example.

Alternatively, the technician may use a standard size blood collection container and collect a subsequent larger blood sample, as required from the single insertion of point 56 of needle 52 in the patient's vein all as will be understood by the practitioner-in-the-art.

The blood collection tube of the invention may be comprised, preferably, from a clear molded thermoplastic material such as polyethylene, for

example, or glass. Other materials which may be used, as will be appreciated by practitioners-in-the-art include various other thermoplastics such as polypropylene, polyethylene terephthalate, and polyvinyl chloride.

The evacuated chambers utilized for collection in the device of the invention here may have incorporated therein materials for reaction with the specimen being collected for providing a proper response to the collected specimen for subsequent examination in the clinical laboratory. The stopper may be comprised of an elastomer appropriate for providing the sealing required to maintain the imparted vacuum in the chamber selected for subsequent use by the laboratory technician. The plastic cover portion 26 of stopper assembly 24 may be comprised of polyethylene or other thermoplastic which may be molded into the proper shape for the assembly of the invention.

Whereas, as discussed above, specific embodiments of associated stoppers and caps have been shown, it should be understood that it is within the purview of this invention to provide other forms of closures for blood collection tubes of the kind discussed herein.

It will be understood that the invention here is most appropriate for medical applications because of the substantial reduced cost in accommodating a variety of different requirements for a body fluid specimen collection, and for reducing the number of molds required for providing an assembly which is nevertheless, much easier to handle than the miniaturized collection tubes presently being utilized for small volume specimen collection. Moreover, the arrangement herein eliminates the need for the application of "partial draw" tubes and the inconsistency apparent with the use of such partial draw tubes.

While the forms of apparatus herein described constitute preferred embodiments of the invention, it is to be understood that the invention is not limited to these precise forms of apparatus and that changes may be made therein without departing from the scope of the invention which is defined in the appended claims.

Claims

1. A blood collection tube; comprising
 - (a) a tube body;
 - (b) said tube body comprised of walls formed as a cylinder to define a tube body chamber;
 - (c) said tube body chamber having a first open end at one end of said tube body chamber and a second open end at the end of said tube body chamber opposite said first open end;

- (d) a divider wall positioned between said first and second open ends;
 (e) said divider wall dividing said tube body chamber into a first and a second compartment; and
 (f) said divider wall being formed integrally as one piece with said cylindrical tube body walls. 5
2. The blood collection tube of Claim 1, further comprising 10
 (a) said first and second compartments being of different volume capacity.
3. The blood collection tube of Claim 1 further comprising 15
 (a) a stopper closing one of said first and second open ends; and
 (b) a plug closing the other of said open ends not closed by said stopper. 20
4. The blood collection tube of Claim 3, further comprising 25
 (a) said compartment with the open end closed by said stopper being evacuated.
5. The blood collection tube of Claim 3, further comprising said stopper being comprised of 30
 (a) a first elastomeric portion inserted into said open end in sealing engagement therewith;
 (b) a plastic portion fitted over and surrounding said elastomeric portion;
 (c) said plastic portion encompassing said tubular walls adjacent said open end into which said stopper is inserted; 35
 (d) the top of said plastic portion having an opening adjacent the axis thereof for providing needle access to said elastomeric portion; and 40
 (e) cooperating abutment means on said elastomeric portion and said plastic portion for holding said elastomeric portion and said plastic portion together. 45
6. The blood collection tube of Claim 3, further comprising 50
 (a) said tube walls and said divider wall are comprised of a material selected from the group consisting of polyethylene, polypropylene, polyethylene terephthalate, polyvinyl chloride and glass.
7. A blood collection tube; comprising 55
 (a) a tube body;
 (b) said tube body comprised of walls formed as a cylinder to define a tube body chamber;
- (c) said tube body chamber having a first open end at one end of said tube body chamber and a second open end at the end of said tube body chamber opposite said first open end;
 (d) a divider wall positioned between said first and second open ends;
 (e) said divider wall dividing said tube body chamber into a first and a second compartment;
 (f) said divider wall being formed integrally as one piece with said cylindrical tube body walls;
 (g) said first and second compartments being of different volume capacity;
 (h) a first stopper closing said first open end; and
 (i) a second stopper closing said second open end.
8. The blood collection tube of Claim 7, further comprising
 (a) both said first and said second compartments being evacuated.
9. The blood collection tube of Claim 7, further comprising each of said first and second stoppers comprised of
 (a) a first elastomeric portion inserted into said open end in sealing engagement therewith;
 (b) a plastic portion fitted over and surrounding said elastomeric portion;
 (c) said plastic portion encompassing said tubular walls adjacent said open end into which said stopper is inserted;
 (d) the top of said plastic portion having an opening adjacent the axis thereof for providing needle access to said elastomeric portion; and
 (e) cooperating abutment means on said elastomeric portion and said plastic portion for holding said elastomeric portion and said plastic portion together.
10. The blood collection tube of Claim 7, further comprising
 (a) said tube walls and said divider wall are comprised of a material selected from the group consisting of polyethylene, polypropylene, polyethylene terephthalate, polyvinyl chloride and glass.

FIG-1

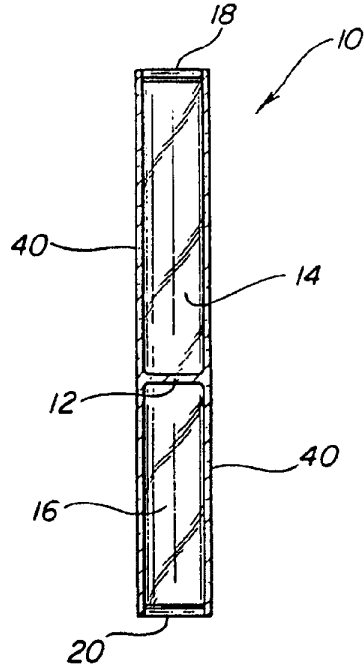


FIG-2

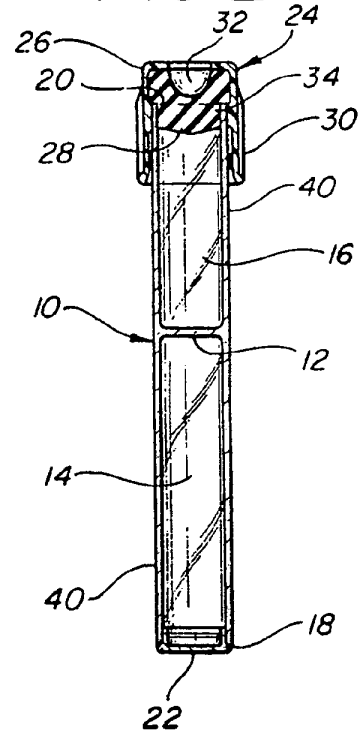


FIG-3

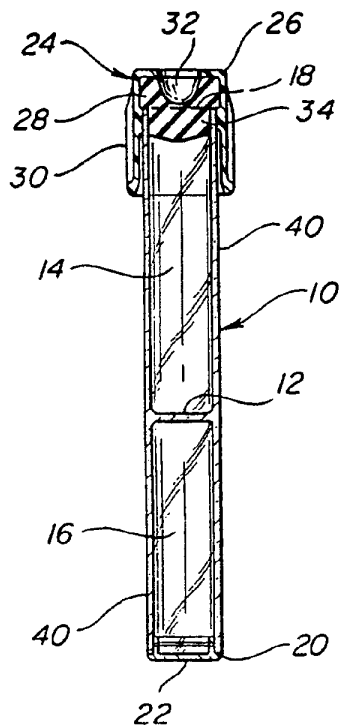


FIG-4

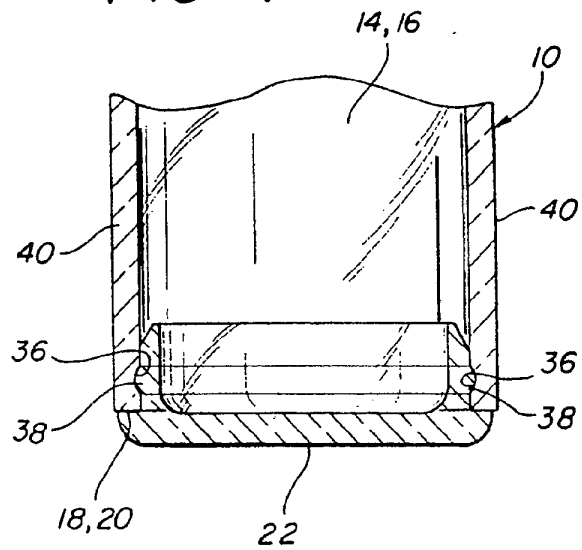


FIG-5

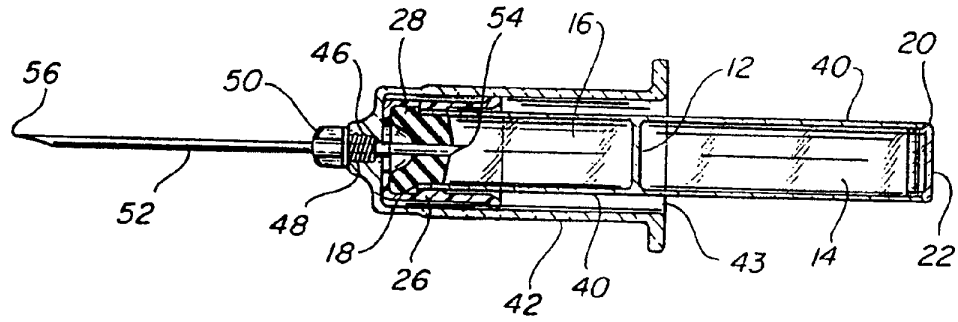
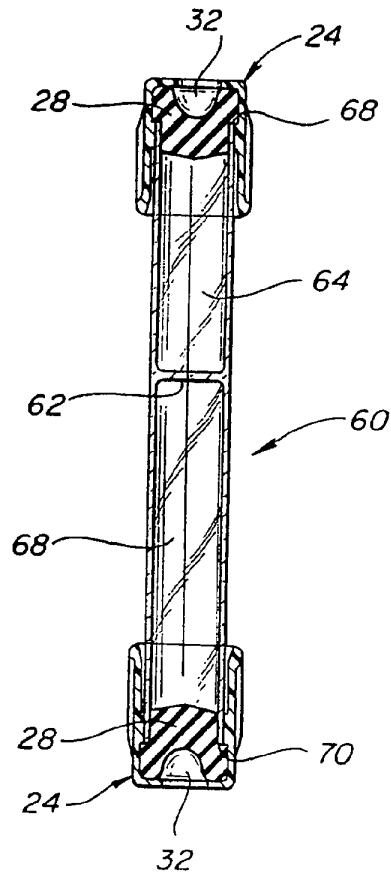
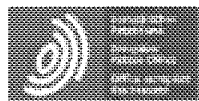


FIG-6





Espacenet

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Medical device used for collecting biological samples

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Abstract of CN104107054 (A)

The invention relates to a biological fluid sampling device used for collecting a blood sample from an independent vascular access device and discharging a part of the collected sample to a point-of-care testing device used for analysis. The biological fluid sampling device comprises a body surrounding a storage device with an internal volume for receiving an enough amount of blood used for diagnosis and test. The sampling device comprises an access pipe cavity extending from the distal end of the body and providing fluid communication between the independent vascular access device and the storage device, a flow-out pipe cavity in fluid communication with the storage device and a detachable discharge cover attached to the flow-out pipe cavity and comprising a vent hole for gas communication between the storage device and the

ambient air. In addition, a plurality of sampling and transfer devices are provided for obtaining samples from people under test and transferring the samples to the point-of-care testing device.



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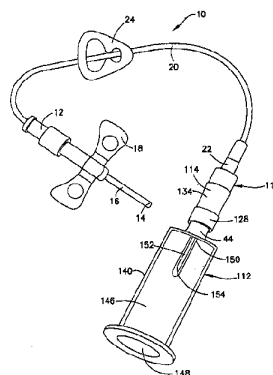
权利要求书2页 说明书8页 附图12页

(54) 发明名称

用于收集生物样品的医学装置

(57) 摘要

本发明涉及一种生物流体取样装置,其用于从单独血管通路装置收集血液样品及排出一部分收集的样品至用于分析的即时检验装置。该生物流体取样装置包括包围储存器的主体。该储存器具有足以容纳足够量的用于诊断检验的血液的内部容积。该取样装置还包括:通路管腔,其自主体的远端延伸,在单独血管通路装置与储存器之间建立流体连通;流出管腔,其也与储存器流体连通;可移除式排出盖,其附接至流出管腔,并且包括在储存器及环境空气之间气体连通的透气口。此外,还提供了数个取样及转移装置,用于从受验者获取样品并且将样品转移至即时检验装置。



1. 一种生物流体取样装置,其能够与单独的血管通路装置接合,并包括:
壳体,其包围生物流体储存器,该储存器限定一内部;
通路管腔,其自壳体的一部分延伸,并且在单独的血管通路装置与储存器的内部之间建立流体连通;
流出管腔,其自壳体的一部分延伸,并且具有第二端以及设置成与储存器的内部流体连通的第一端;以及
排气盖,其可移除地安置在流出管腔的第二端上,并包括在储存器的内部及周围环境之间气体连通的透气口。
2. 根据权利要求1所述的生物流体取样装置,其还包括至少部分地包围通路管腔的鲁尔锁。
3. 根据权利要求1所述的生物流体取样装置,其中,排气盖包括用于插入至流出管腔内的鲁尔锁。
4. 根据权利要求3所述的生物流体取样装置,其中,排气盖包括紧固件,用于将排气盖的一部分可移除地连接至壳体的一部分。
5. 根据权利要求1所述的生物流体取样装置,其中,储存器的内部构造成在其内接收流体样品。
6. 根据权利要求5所述的生物流体取样装置,其中,壳体包括可压缩部,其中,对可压缩部的压缩将使流体样品通过通路管腔从储存器的内部排出。
7. 根据权利要求1所述的生物流体取样装置,其中,通路管腔安置在壳体的远端,流出管腔安置在壳体的近端。
8. 根据权利要求1所述的生物流体取样装置,其中,储存器含有样品稳定剂。
9. 根据权利要求8所述的生物流体取样装置,其中,壳体具有与特定样品稳定剂相对应的可视标识。
10. 根据权利要求9所述的生物流体取样装置,其中,可视标识为特定的颜色。
11. 根据权利要求1所述的生物流体取样装置,其中,排气口包括多孔塞、渗透膜及小排气孔中的至少之一。
12. 一种生物流体取样及收集组件,其包括:
生物流体取样装置,其包括:
壳体,其包围生物流体储存器,该储存器限定一内部;
通路管腔,其自壳体的一部分延伸,并且在储存器的内部与单独的血管通路装置之间建立流体连通;和
流出管腔,其自壳体的一部分延伸,并且具有第二端以及设置成与储存器的内部流体连通的第一端;以及
样品收集装置,其包括:
接头,用于进入样品容器的内部,并在生物流体储存器及样品容器的内部之间建立流体连通,从而允许储存器的内部与样品容器的内部之间的流体连通;以及
限流器,其与接头结合,并且可从打开位置转换至关闭位置,其中,在打开位置时生物流体储存器和样品容器内部之间容许流体连通,在关闭位置时生物流体储存器与样品容器内部流体隔离。

13. 根据权利要求 12 所述的生物流体取样及收集组件,其中,生物流体储存器容纳流体,并且其中,当限流器处在打开位置时,流体从生物流体储存器流至样品容器的内部。

14. 根据权利要求 12 所述的生物流体取样及收集组件,其中,当样品容器与接头接合时限流器处在打开位置,当将样品容器从接头移除时限流器处在关闭位置。

15. 根据权利要求 12 所述的生物流体取样及收集组件,其还包括可移除地布置在流出管腔的第二端上的排气盖,该排气盖包括在储存器的内部与周围环境之间气体连通的透气口。

16. 根据权利要求 12 所述的生物流体取样及收集组件,其中,样品容器为真空容器。

17. 根据权利要求 12 所述的生物流体取样及收集组件,其还包括与通路管腔流体连通的单独血管通路装置。

18. 根据权利要求 17 所述的生物流体取样及收集组件,其还包括在单独血管通路装置与生物流体取样装置之间连接的接头。

19. 根据权利要求 18 所述的生物流体取样及收集组件,其中,接头包括:

壳体;

主管腔,其被包围在壳体内,具有主流出端口;

侧端口,其包括自主管腔延伸并且与主管腔流体连通的侧管腔;以及

阀,其能够从第一位置转换至第二位置,其中在第一位置处允许流体通过主管腔流动同时阻止流体通过侧管腔流动,在第二位置处允许流体通过主管腔及侧管腔二者流动。

20. 根据权利要求 19 所述的生物流体取样及收集组件,其中,通过从侧端口插入管状构件至侧管腔内,将阀从第一位置转换至第二位置。

用于收集生物样品的医学装置

技术领域

[0001] 本发明涉及适用于与血管通路装置一起使用、适用于收集生物样品以用在即时检验中、以及适用于填充样品收集容器以用在常规实验室检验中的装置、组件和系统。

背景技术

[0002] 血液取样是一种常见的医疗过程,包括从患者至少取出一滴血。血液样品通常通过手指针刺、足跟针刺或者静脉穿刺的办法取自住院、家庭护理以及急诊室的患者。一旦被采集,可分析血液样品以获得医学上有用的信息,包括化学成分、血液学、凝血等。

[0003] 血液检验可确定患者的生理生化状态,例如疾病、矿物质含量、药物有效性以及器官功能。血液检验可在临床实验室进行或者在患者附近即时检验。即时血液检验的一个示例是患者血糖水平的常规检验,其包括通过手指针刺提取血液以及机械地收集血液进入诊断板卡。之后,诊断板卡分析血液样品并且向临床医生提供患者的血糖水平读数。可使用其他分析血气电解质水平、锂水平及离子钙水平的装置。一些其他的即时检验设备可确定急性冠脉综合征(ACS)和深静脉血栓/肺栓塞(DVT/PE)的标记物。

[0004] 尽管即时检验和诊断有了快速的发展,但是血液取样技术相对仍保持无改变。通常,通过采用附接至针或者导管组件近端的皮下针头或者真空管来抽取血液样品。在一些情况下,临床医生采用插入导管中的针和注射器从患者经由插入的导管抽血而自导管组件收集血液。这些过程使用针和真空管作为中间装置,通常在检验前从该中间装置抽取收集的血液样品。因此,上述程序是装置密集型的,即在血液样品的获得、准备和检验的过程中使用多个装置。每种额外的装置增加了检验过程的时间和成本。因此,所期望的是获得一种为即时检验提供血液的简化装置。此外,由于即时检验常常补充有其他的常规实验室检验,因此也期望获得能用于收集常规实验室检验用的血液样品和收集即时检验用的第二份样品的血液取样和收集组件。通过本发明的装置、组件和系统能实现上述特性。

发明内容

[0005] 鉴于现有技术中的上述缺点,本文中提供了用于即时检验的生物流体取样装置、用于收集流体样品的血管外系统以及其使用方法。通过下面结合附图的详述,本发明的其他详情和优点将会被理解。

[0006] 根据本发明的实施例,生物流体取样装置(如血液取样装置)包括壳体以及通路管腔,其中,该壳体包围限定一内部的生物流体储存器,该通路管腔自壳体的一部分延伸并且在单独血管通路装置与储存器的内部之间建立流体连通。该生物流体取样装置也包括自壳体的一部分延伸的流出管腔,该流出管腔具有第二端以及设置成与储存器的内部流体连通的第一端。该生物流体取样装置还包括可移除地安置在流出管腔的第二端上的排气盖,该排气盖包括在储存器的内部与周围环境之间气体连通的透气口。

[0007] 在某些构型中,该生物流体取样装置也包括至少部分地包围通路管腔的鲁尔锁。排气盖可包括用于插入流出管腔中的鲁尔锁。排气盖也可包括用于将排气盖的一部分可移

除地连接至壳体的一部分的紧固件。储存器的内部可构造成在其中接收流体样品。壳体也可包括可压缩部,并且对可压缩部压缩可使流体样品通过通路管腔从储存器的内部排出。

[0008] 在某些构型中,通路管腔布置在壳体的远端,流出管腔布置在壳体的近端。储存器也可含有样品稳定剂。在其他的实施例中,壳体可具有与特定的样品稳定剂相对应的可视标识。该可视标识可以是特定的颜色。可选择地,排气口可包括多孔塞、渗透膜及小排气孔中的至少之一。

[0009] 根据本发明的另一个实施例,生物流体取样及收集组件(例如血液取样及收集组件)可包括生物流体取样装置。该生物流体取样装置包括壳体及通路管腔,其中,壳体包围限定一内部的生物流体储存器,通路管腔自壳体的一部分延伸并且在储存器的内部与单独血管通路装置之间建立流体连通。该生物流体取样装置也可包括流出管腔,该流出管腔自壳体的一部分延伸,并且具有第二端以及设置成与储存器的内部流体连通的第一端。该组件也可包括样品收集装置,该样品收集装置包括接头,接头用于进入样品容器的内部并在生物流体储存器及样品容器的内部之间建立流体连通。这样就允许储存器的内部与样品容器的内部之间的流体连通。该样品收集装置也可包括与接头接合的限流器。该限流器可从打开位置转换至关闭位置,其中,在打开位置时生物流体储存器与样品容器的内部之间流体连通,在关闭位置时生物流体储存器与样品容器的内部流体隔离。

[0010] 在某些构型中,生物流体储存器容纳流体,并且当限流器处在打开位置时,流体从生物流体储存器流至样品容器的内部。当样品容器与接头接合时限流器处在打开位置,当将样品容器从接头移除时限流器处在关闭位置。

[0011] 在其他构型中,该生物流体取样及收集组件还包括可移除地布置在流出管腔的第二端上的排气盖。该排气盖包括在储存器的内部与周围环境之间气体连通的透气口。样品容器可为真空容器。该组件还可包括与通路管腔流体连通的单独血管通路装置。

[0012] 在其他构型中,该生物流体取样及收集组件包括在单独血管通路装置与生物流体取样装置之间连接的接头。该接头可包括壳体、主管腔、侧端口以及阀,其中,主管腔包围在壳体内并具有主流出端口,侧端口包括自主管腔延伸并且与主管腔流体连通的侧管腔,阀可从第一位置转换至第二位置,在第一位置处允许流体流经主管腔同时阻止流体流经侧管腔,在第二位置处允许流体流经主管腔及侧管腔二者。通过从侧端口插入管状构件至侧管腔内,将阀从第一位置转换至第二位置。

附图说明

[0013] 进行以下说明以使本领域的技术人员能够制造和使用为实现本发明而构思的所描述的实施例。然而,对于本领域的技术人员而言,各种修改、等同物、变化和替代例将仍然是显而易见的。修改、等同物、变化和替代例中的任一及全部都旨在涵盖在本发明的精神和范围内。

[0014] 图1是根据本发明的一个实施例的生物流体取样装置、样品容器收集装置以及单独血管通路装置的透视图。

[0015] 图2是图1的包括排气盖的生物流体取样装置的透视图。

[0016] 图3是图1的生物流体取样装置的透视图,其中,将排气盖从装置的主体拆卸。

[0017] 图4是图1的生物流体取样装置的透视剖面图,其中,将排气盖从装置的主体拆

卸。

[0018] 图 5 是根据本发明的另一实施例的包括生物流体取样装置和含样品收集容器的样品容器收集装置的组件的透视图。

[0019] 图 6 是图 5 的组件的剖面透视图。

[0020] 图 7 是图 5 的剖面透视图,从组件移除了样品收集容器。

[0021] 图 8 是根据本发明的又一实施例的包括生物流体取样装置、样品容器收集装置、侧端口连接器及单独血管通路装置的系统的透视图。

[0022] 图 9 是图 8 的组件的透视图,其中,侧端口、取样装置和收集装置彼此拆开。

[0023] 图 10 是图 8 的侧端口、取样装置和收集装置的侧视图。

[0024] 图 11 是图 8 的侧端口的剖视图。

[0025] 图 12 是图 8 的侧端口的剖视图,其中,取样装置自该侧端口延伸。

[0026] 图 13 是根据本发明的另一实施例的包括两个生物流体取样装置、侧端口连接器以及连接至侧端口装置的单独血管通路装置的系统的透视图。

[0027] 图 14 是根据本发明一实施例使用者将生物流体从图 1 的的取样装置分送至检验设备的示意性透视图。

具体实施方式

[0028] 为便于理解本发明,附图和描述说明了本发明的优选实施例,并且通过附图和描述使得本发明、本发明不同结构及构型的实施例、操作的方法以及许多优点可被理解和领会。

[0029] 为了后面的描述,术语“上”、“下”、“右”、“左”、“竖直的”、“水平的”、“顶”、“底”、“横向的”、“纵向的”及其衍生词将指的是本发明在附图中的定向。然而,应当理解,除了相反地特指之处之外,该发明可为替代的变例及步骤顺序。也应当理解,在附图中示出的及在以下的说明书中描述的特定装置和方法仅为本发明的示例性实施例。因此,与文中公开的实施例相关的特定尺寸及其他物理特性不应被认为是限制性的。

[0030] 本发明涉及一种生物流体取样装置,例如血液取样装置 110,用于收集血液样品以用于即时检验和分析。血样取样装置 110 构造为较大的血管外系统 10 的一部分,并且构造为从单独的血管通路装置 12 接收流体样品。图 1 描述了示例性的血管外系统。该系统包括血液取样装置 110、样品容器收集装置 112 以及血管通路装置 12。血管通路装置 12 可包括多个在现有技术中已知的构件,例如血管内针 14、套在针之上的导管 16、针遮蔽结构 18 以及末端为鲁尔通路接头 22 或者端口的一体化延伸管 20。

[0031] 示例性的血管通路装置包括直通且带端口的(ported)静脉内导管(如 AUTOGUARD™ 遮蔽式导管,可从 Becton, Dickinson, and Company 商购获得)、一体化的外周静脉内导管、翼状针套件以及血液收集套件。IV 通路套件(例如可从 Becton, Dickinson, and Company 商购获得的 BD NEXIVA™ 封闭式静脉内(IV)导管系统)也可用来形成封闭式通路系统。类似的,包封式鲁尔接头端口(例如也可从 Becton, Dickinson, and Company 商购获得的 BD Q-SYTE™ 鲁尔通路分式隔膜)可用于完全包封介于取样装置 110 和血管通路装置 12 之间的鲁尔通路接头 22。替代地,在没有诸如延伸管 20 的额外构件的情况下,取样装置 110 可直接地连接至静脉内导管座,以减少构件的数量并且简化收集及取样的过程。

[0032] 血管通路装置 12 还可包括限流器（如夹具 24），从而在取样装置 110 和 / 或收集装置 112 从血管外系统 10 移除时，限制血液流经延伸管 20。替代地，鲁尔通路接头 22 可包括一体化的阀或隔膜，在取样装置 110 从血管外系统 10 移除后，该阀或隔膜自动地关闭以限制流体流动。如下文中将更加详细说明的，本发明旨在包括各种模块化构件，根据要被收集的血液样品的类型可组合这些模块化构件以形成多个血管外系统。本发明也旨在，在本发明的范围内提供鲁尔通路接头 22 及取样装置 110 的一体化单元。图 8 及图 13 描述了在本发明的范围内的包括多个血液取样装置和 / 或样品容器收集装置的血管外系统 10 的替代构造。

[0033] 如图 2 所示，血液取样装置 110 包括壳体 114 及可移除的排气式端盖 116，其中，壳体 114 可通过注射成型或者吹塑成型的方法来形成。在一些情况下，血液取样装置 110 可减少从患者抽取诊断用血液样品所需的构件的数量。这是因为，该血液取样装置 110 把执行将血管外系统排气的步骤以及获得血液样品的步骤的能力结合在单一装置中。更加具体地，血液取样装置 110 构造成从血管外系统 10 排气，从而通过延伸管 20 从血管通路装置 12 抽取血液至取样装置 110。也可使用在现有技术中已知的外部动力源（如机动泵）来推动血液经由血管外系统 10 至取样装置 110。血液取样装置 110 也可通过芯吸装置来接收血液，该芯吸装置安置在血液取样装置的远端内，用于抽取血液进入该血液取样装置。如图 4 所示，血液保留在取样装置 110 的储存器 118 中。

[0034] 如下文将更加详细地说明的，一旦将血液取样装置 110 从血管外系统 10 移除，就可将血液从取样装置 110 排出至即时检验装置 30（如图 14 所示），如检验条、载玻片、诊断板卡或其他用于检验和分析的检验装置。检验条、载玻片以及检验板卡是接收血液样品并且检验该血液的一个或多个生理和生化状态的即时检验装置。检验板卡的示例包括可从 Abbot 集团公司商购获得的 **i-STAT®** 检验板卡。诸如 **i-STAT®** 板卡的检验板卡可用于检验各种状况，包括化学物和电解质、血液学、血气浓度、凝血或心脏标志物的存在情况。采用这种板卡的检验结果能很快地提供给临床医生。

[0035] 参考图 2-4，现将更加详细的描述生物取样装置的结构。生物取样装置 110 的壳体 114 包括狭窄管状部 120，该管状部 120 具有构造成与单独的血管通路装置 12 建立流体连通的通路管腔 122。例如，该狭窄管状部 120 可为公鲁尔锁定连接器 124，适于插入血管通路装置 12 的母鲁尔通路接头 22。储存器 118 被包围在壳体 114 内，并且包括足以容纳足够用于诊断检验的血液的内部容积，例如，该内部容积为大致 0.1ml 至大致 0.4ml。由于不同的血液检验需要不同量的血液，因此在一些实施例中，储存器 118 的尺寸设定成能保留特定检验或特定数量的检验所需的血液量。储存器 118 可具有各种样品稳定剂，例如血液保藏剂、试剂或抗凝剂（例如肝素），以保存血液并且保证血液用于某些预期血液检验的有效性。可选择地，血液取样装置 110 的壳体 114 可设置为特定的颜色，以告知使用者取样装置 110 的储存器 118 含有血液保藏化学制剂。不具有保藏剂的血液取样装置可为一不同的壳体颜色，以告知使用者血液取样装置不含有该化学制剂。

[0036] 储存器 118 与通路管腔 122 及流出管腔 126 流体连通，流出管腔 126 相对于通路管腔 122 布置在壳体 114 的另一端。流出管腔 126 可由如螺纹端口 128 的连接结构包围。如图 2-4 描述的实施例中示出的，螺纹端口 128 及流出管腔 126 连接至可移除式端盖 116。

[0037] 可移除式端盖 116 构造成附接至螺纹端口 128，并且包括贯穿端盖 116 的一部分延

伸的内通路 130, 该内通路 130 与流出管腔 126 及储存器 118 流体连通。内通路 130 设置有透气孔 132, 其允许气体通过但是阻止流体 (如血液) 通过。透气孔 132 可包括能提供上述特性的各种结构, 例如多孔塞、渗透膜和 / 或含有多个小排气孔的结构。透气孔 132 可包括由玻璃、聚对苯二甲酸乙二醇酯 (PET)、微纤维材料和 / 或其他由高密度聚乙烯纤维制成的合成材料的组合形成的透气部。透气孔 132 可为疏水的或者亲水的。可选择地, 透气孔 132 可包括多层不同的材料, 以使得透气孔 132 为疏水的且透气的。

[0038] 当在取样装置 110 中收集了足够量的用于检验的血液之后, 将取样装置 110 从血管外系统 10 移除。在如图 1 描述的血管外系统 10 的某些构型中, 在将取样装置 110 移除之前, 可关闭夹具 24 以限制血液进一步流经延伸管 20。替代地, 血管外系统 10 可包括阀或隔膜, 一旦将取样装置 110 移除, 该阀或隔膜自动地限制流体从血管通路装置 12 流动。

[0039] 一旦从血管外系统 10 移除, 血液取样装置 110 构造成从储存器 118 排出至少一部分收集的血液样品。例如, 在优选的且非限制性的实施例中, 血液取样装置 110 包括可压缩部 134。在某些实施例中, 壳体 114 由柔性或半柔性材料制成, 使得整个壳体 114 为可压缩的。替代地, 可压缩部 134 可仅包括在受压时弯曲的壳体 114 的一小部分。可压缩部 134 可包括脊部或者其他的抓握构件 136, 以便于使用者抓握、把持及操纵。在另一非限制性的实施例中, 可压缩部 134 安置在两个基本上刚性的部分之间, 从而当使用者按压该刚性部分时, 可压缩部 134 压缩。在这种构型中, 刚性部分为取样装置 110 提供了结构强度及稳定性。壳体 114 的可压缩部 134 可通过减薄壳体 114 的壁而获得以增加柔性。替代地, 可采用双射成型技术形成壳体 114, 其中, 柔性材料围绕壳体 114 的远端部分包塑成型。在任一情况中, 可压缩部 134 比刚性部分更具有柔性, 并且被构造成朝储存器 118 向内弯曲。

[0040] 在某些构型中, 取样装置 110 被构造成当未被压缩时保留血液, 而在被压缩时排出一定量的血液。照此, 一旦将取样装置 110 从血管外系统 10 移除, 血液自然地保留在血液取样装置 110 的储存器 118 内, 直到可压缩部 134 被临床医生压缩为止。当处在未压缩的位置时, 通过血液对通路管腔 122 周边的表面张力及储存器 118 内的流体压力的结合, 血液被保留在储存器 118 内。相应地, 管状部 120 的纵向长度及通路管腔 122 的周长被选定成使得当压力在一定的范围内时, 血液被保留在储存器 118 内。当储存器 118 的内部容积减少时, 压力增加到超出能够保留血液的范围, 进而使血液通过通路管腔 122 从取样装置 110 流出。血液可被排出到即时检验装置 30, 例如血液检验条、诊断板卡或其他类型的血液检验 / 分析装置上。

[0041] 在取样装置 110 的某些实施例中, 取样装置 110 可包括多个在储存器 118 内的腔室。每个腔室可具有单独且相应的可压缩部 134, 用于分配仅容纳在对应腔室内的流体。这样, 取样装置 110 可容纳用于不同类型检验的各个单独的样品。例如, 各腔室可具有特定检验所需的不同容积。此外, 一些腔室可包括化学制剂、血液保藏剂或特定检验所需的特定试剂。

[0042] 同样需要指出的是, 在取样装置 110 仍然连接至血管外系统 10 时, 取样装置 110 的可压缩部 134 可用于辅助从血管通路装置 12 抽取血液至储存器 118。例如, 使用者可“泵吸”取样装置 110 的可压缩部 134, 以辅助把血液样品抽至储存器 118。

[0043] 参考图 5-7, 在某些构型中, 血液取样装置 110 的可移除式端盖 116 被移除, 替代地, 取样装置 110 经由螺纹端口 128 及流出管腔 126 连接至样品容器收集装置 112。样品

容器收集装置 112 可为真空管收集系统（例如，Vacutainer）。样品容器 138 可为具有可刺穿封盖的真空试管或者其他的合适的医用容器，正如现有技术中已知的。样品容器收集装置 112 构造成通过取样装置 110 在单独的血管通路装置 12 及样品容器 138 之间建立流体连通，使得样品容器 138 可填充血液样品。需要指出的是，当该样品容器为真空管时，血管外系统 10 与该真空管内部之间的压差可辅助抽取流体经由血管外系统 10 进入样品容器 138。充满的样品容器 138 可被送至临床实验室，以进行某些在医疗行业中通常进行的血液检验。

[0044] 样品容器收集装置 112 包括大致圆筒形的主体 140，该主体 140 具有紧固件 142，用于把收集装置 112 连接至取样装置 110 的主体。例如，该收集装置 112 可被构造成通过相应的螺纹盖 144 而附接至取样装置 110 的螺纹端口 128。圆筒形主体 140 限定了内部区域 146，其具有可接收样品容器 138 的开口端 148。填充接头 150 在内部区域 146 内延伸，从位于收集装置 112 基部的螺纹盖 144 延伸进入内部区域 146。填充接头 150 可包括带锋利尖端 154 的细长针插管 152，该尖端 154 用于刺穿样品容器 138 的封盖 139。

[0045] 收集装置 112 被构造成使得样品容器 138 通过内部区域 146 的开口端 148 插入，封盖 139 侧在前，然后与填充接头 150 的针尖 154 接触。针插管 152 的尖端 154 能穿透封盖 139，以进入样品容器 138 的内部。这样，血液能通过取样装置 110 及填充接头 150 从血管通路装置 12 流入样品容器 138 的内部容积，由此填充样品收集容器 138。

[0046] 在某些构型中，诸如隔膜 156 的限流器安置在填充接头 150 的管腔内。当将样品容器 138 附连至收集装置 112 时，隔膜 156 转换到打开位置，以允许流体流过隔膜填充样品容器 138。当将样品容器 138 移除时，隔膜 156 能转换至关闭位置，从而阻挡流体通过针插管 152。需要指出的是，隔膜 156 以类似的方式对上述取样装置 110 的实施例的排气端盖 116 起作用。更加具体地，当隔膜 156 处在打开位置时，在真空管连接至取样装置的情况下，空气能从血管外系统排入至真空管或者样品收集容器，使得在血管外系统 10 内的空气通过针插管 152 从血管外系统 10 排出。当隔膜 156 处在关闭位置时，限制了流体流动及空气流动，从而防止空气从系统排出并且防止血液填充取样装置。实质上，当将接头 150 与血液取样装置连接时，一旦与接头连接，血液取样装置便通过真空管而填充血液。

[0047] 一旦在储存器 118 内保留了足够量的血液，就可将取样装置 110 及连接的收集装置 112 从血管外系统 10 移除。血液可通过取样装置 110 的通路管腔 122 排出，以用于根据上述方法进行检验和分析。正如上述的生物取样装置 110 的情况，储存器 118 及通路管腔 122 被构造成在预定的流体压力范围内保留血液。当使取样装置 110 的可压缩部朝储存器 118 向内弯曲时，储存器 118 内的压力增加，从而导致流体经由通路管腔 122 从取样装置 110 排出。通过关闭的隔膜 156 防止血液经由流出管腔 126 排出。

[0048] 现参考图 8-10，描述血管外系统 10 的另一个实施例，其包括血管通路装置 12，血管通路装置 12 具有流通部 210 及侧端口 212。除了侧端口 212 外，流通部 210 还包括主流出端口 214。如图 8 所示，主流出端口 214 和 / 或侧端口 212 可包括母鲁尔锁连接器，其被构造成接收相应的血液取样装置 110 的狭窄管状部 120。

[0049] 通过主流出端口 214 及侧端口 212 上都包括血液取样装置 110，可收集用于不同类型检验和分析的血液样品。例如，取样装置 110 可被构造成收集不同量的血液。替代地，一个血液取样装置 110 可包括保藏剂或抗凝剂，以改变收集的血液的成分；而第二个取

样装置 110 可不包括任何这种化学成分。在某些实施例中,侧端口 212 可用于在血液取样装置保持连接至接头及血管通路装置时获取血液样品。

[0050] 在一个非限制性的实施例中,不含化学保藏制剂的取样装置 110 可连接至样品容器收集装置 112。在该构型中,通过同样的血管通路装置 12 可同时收集用于即时检验的含保藏剂的血液样品、用于另外的即时检验的不含保藏剂的血液样品、以及容纳在样品容器 138 内用于常规实验室检验的血液样品。不需要额外的刺手指或插入针来从患者获得所需的样品。在某些实施例中,取样装置 110 可具有色码,以便使用者可容易地区分哪个取样装置 110 包括额外的化学保藏制剂以及哪个取样装置 110 不包括额外的化学保藏制剂。

[0051] 参考图 11 及 12,描述了具有流通部 210 及取样装置 110 的血液取样装置 110 的剖面图。流通部 210 包括自主流出端口 214 的鲁尔通路接头 22 延伸的主管腔 216,血液取样装置 110 也包括延伸至侧流出端口 212 的侧管腔 218。该取样装置还可包括内部的可转换阀 220。如图 11 所示,阀 220 构造成使得当其处在不偏压且关闭的位置时,容许流体经由主管腔 216 从鲁尔通路接头 22 流动至主流出端口 214,同时阻止流体经由侧管腔 218 流动至侧端口 212。该构型允许血液直接流至样品容器收集装置 112,使得样品容器 138 可容易地(如果需要的话连续地)填充。如图 12 所示,当取样装置 110 的狭窄管状部 120 及通路管腔 122 被插入至侧端口 212 时,阀 220 转换至第二位置。更加具体地,狭窄管状部 120 与阀 220 的一部分接触,并且把阀 220 推开。当阀 220 被推开时,主管腔 216 与侧管腔 218 之间建立流体连通,由此使通过侧端口 212 插入的取样装置 110 填充用于检验的血液。

[0052] 参考图 13,描述包括主流出端口 214 及侧端口 212 的血管外系统 10 的又一个实施例,其中主流出端口 214 和侧端口 212 都连接至取样装置 110,取样装置 110 上连有端盖 116。取样装置 110 不是如图 8 中所示的那样连接至样品容器收集装置 112。在该构型中,取样装置 110 可被填充并用于不同的检验及分析过程。如上所述,一个取样装置 110 可包括化学保藏制剂,而另一个可不包括化学保藏制剂。取样装置 110 可含有色码,以区分哪个取样装置将用于哪种检验或分析过程。

[0053] 在已经描述了血液取样装置 110、样品容器收集装置 112 的构件以及血管外系统 10 的不同构型后,现描述利用血管外系统 10 收集血液样品的方法。临床医生利用任何已知的确立血管通路的工具(例如针 14、导管 16 或在现有技术中已知的血液收集套件)在患者身上确立血管通路位置。针 14 和/或导管 16 可包括用于将使用者与针 14 遮蔽开的遮蔽结构 18 及其他在现有技术中已知的安全结构。延伸管 20 连接至血管通路装置 12,并且自血管通路位置延伸至具有端口或鲁尔通路接头 22 的管的打开端。鲁尔通路接头 22 可包括阀或隔膜 156,以在鲁尔通路接头 22 未连接至其他装置时防止流体从该血管通路位置流动。替代地,该管可具有如夹具 24 的限流器,可将其手动地从允许流体流动的位置转换至限制流体流动的位置。临床医生可按需转换夹具 24 以进行所需的过程。

[0054] 一旦血管通路装置 12 准备就绪,临床医生可将取样装置 110 的狭窄管状部 120 插入至血管通路装置 12 的母鲁尔通路接头 22,从而在取样装置 110 与血管通路装置 12 之间建立流体连通。在某些构型中,取样装置 110 设置有已经附接的排气端盖 116。当血液抽入至血管外系统 10 时,在该系统内的空气从端盖 116 排出,从而向取样装置 110 抽取血液。替代地,取样装置 110 可设置有附接至其上的样品容器收集装置 112。在该情况下,空气通过取样装置 110 排出,然后通过收集装置 112 的针插管 152 从血管外系统 10 出来。

[0055] 如果将收集装置 112 连接至血管外系统 10, 临床医生将允许血液经由取样装置 110 流入样品容器 138 内。当容器 138 填充了所需量的血液时, 将样品容器 138 从收集装置 112 移除。样品收集容器 138 的移除将引起收集装置 112 的隔膜 156 封闭, 从而阻止血液通过针插管 152 进一步流动。临床医生可将另外的样品容器 138 插入至收集装置 112, 以收集另外的血液样品。一旦填充完所需数量的样品容器 138, 隔膜 156 关闭, 血液收集在取样装置 110 的储存器 118 内。

[0056] 在任一上述的构型中, 下一步骤是将取样装置 110 从血管通路装置 12 移除。在某些构型中, 在将取样装置 110 移除之前, 临床医生必须关闭限流器或夹具 24, 以阻止额外的流体流经延伸管 20。替代地, 母鲁尔通路接头 22 可包括自动关闭型阀或隔膜 156, 该阀或隔膜 156 关闭以阻止流体进一步流经血管外系统 10。当将取样装置 110 从母鲁尔通路接头 22 移除时, 血液通过其相对于通路管腔 122 的内周壁的表面张力而保留在取样装置 110 的储存器 118 内。然后, 临床医生将取样装置 110 移至例如检验条的即时检验装置 30。如图 14 所示, 临床医生压缩取样装置 110, 使可压缩部 134 朝储存器 118 向内弯曲, 由此减少储存器 118 的内部容积并且增加储存器 118 内的流体压力。当达到一定的内部流体压力时, 容纳在储存器 118 内的血液的一部分经由取样装置 110 的通路管腔 122 及狭窄管状部 120 从储存器 118 排出。排出的血液可收集在检验条上或者诊断检验板卡内。然后, 临床医生可采用即时检验装置 30 分析血液样品, 并记录相关结果以进行进一步分析。

[0057] 本血液取样装置 110、血管外系统 10 及其使用方法显著地减少了在采用 IV 或类似血液收集套件创建血管通路之后获得诊断用血液样品所需的构件的数量。如本文中所述, 血液取样装置 110、样品容器收集装置 112 及血管外系统 10 的实施例可用于在创建静脉通路的常规过程中获得、准备及直接检验血液样品。血管外系统 10 也可用于填充标准样品容器 138, 以送至实验室进行常规检验。通过减少过程步骤的数量并减少取样及获得检验结果之间的时长, 这些实施例有利于临床医生的整个血液取样过程。

[0058] 如上所述, 在现有技术中已知各种即时检验装置 30。这类即时检验装置 30 包括检验条、载玻片、诊断板卡、或其他检验及分析的检验装置。检验条、载玻片及诊断板卡是接收血液样品并检验该血液样品的一个或多个生理和生化状态的即时检验装置 30。许多即时检验装置 30 可采用基于板卡的体系结构来分析非常少量的血液, 不需要将样品送至实验室进行分析。从长远来看, 这节约了获得结果的时间, 但是对高度常规化的实验室环境产生了一系列不同的挑战。这类检验板卡的示例包括 Abbot 集团公司的 **i-STAT[®]** 检验板卡。

诸如 **i-STAT[®]** 板卡的检验板卡可用于检验各种状况, 包括化学物和电解质、血液学、血气浓度、凝血或心脏标记物的存在情况。采用所述板卡的检验结果能很快地提供至临床医生。

[0059] 尽管已经基于目前认为是最实用且最优的实施例详细地描述了本发明以作为示例, 但是应当理解, 这些细节仅是为了示例, 本发明不限于所披露的实施例; 相反地, 本发明旨在涵盖在所附权利要求范围和精神内的修改和等同布置。例如, 应当理解, 本发明构思的是在可能的情况下任何一个实施例的一个或多个特征能与任何其他实施例的一个或多个特征组合。

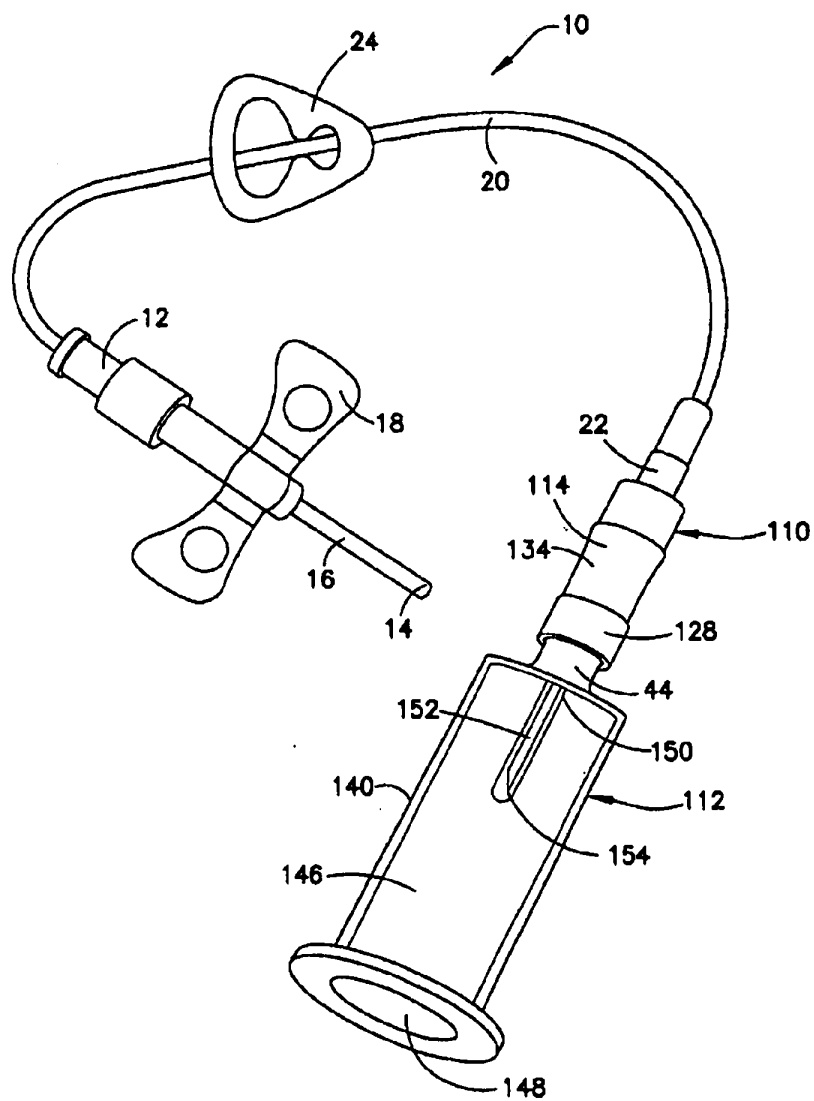


图 1

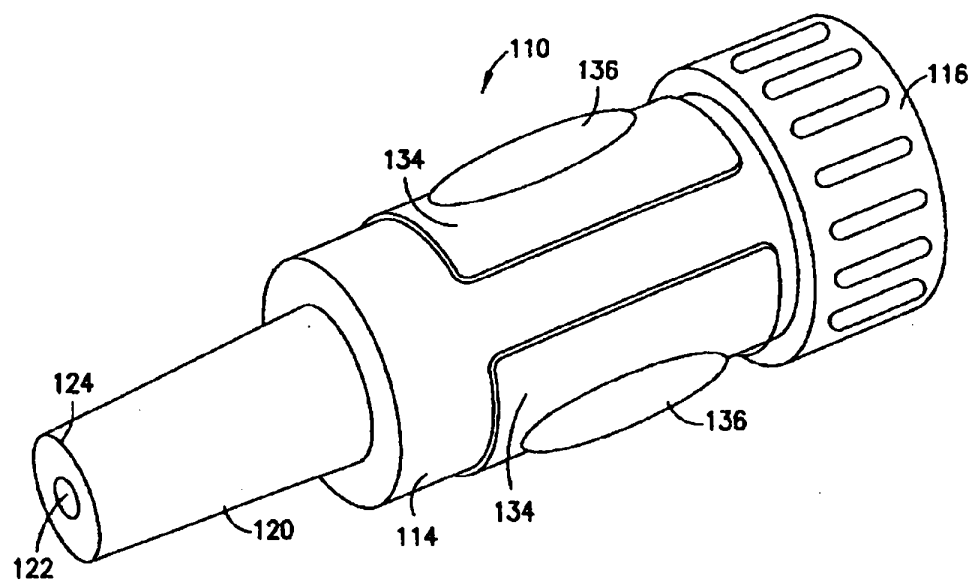


图 2

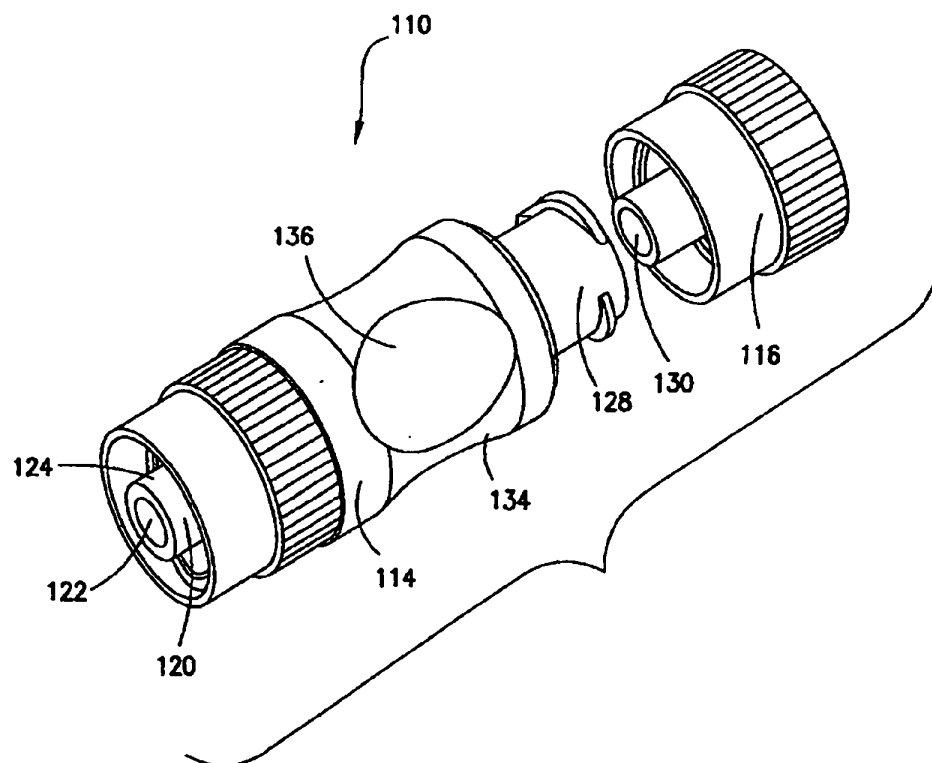


图 3

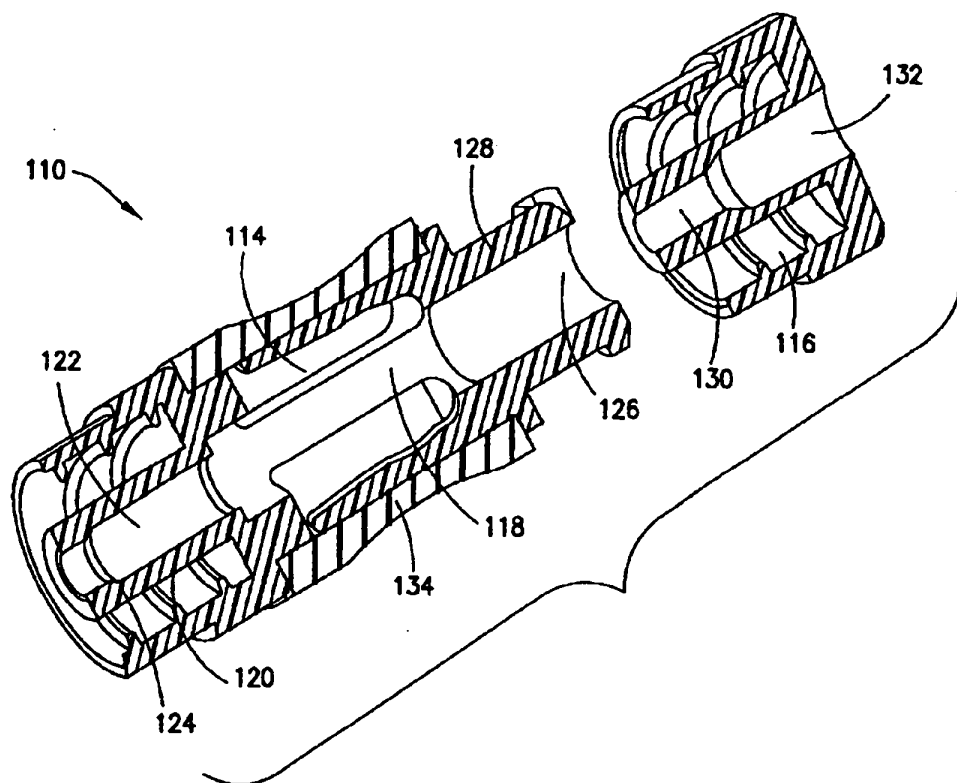


图 4

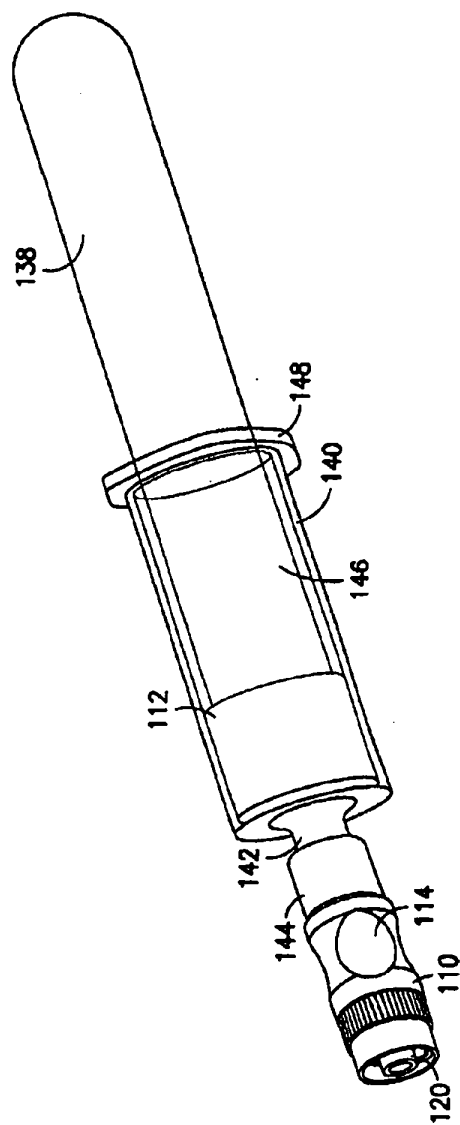


图 5

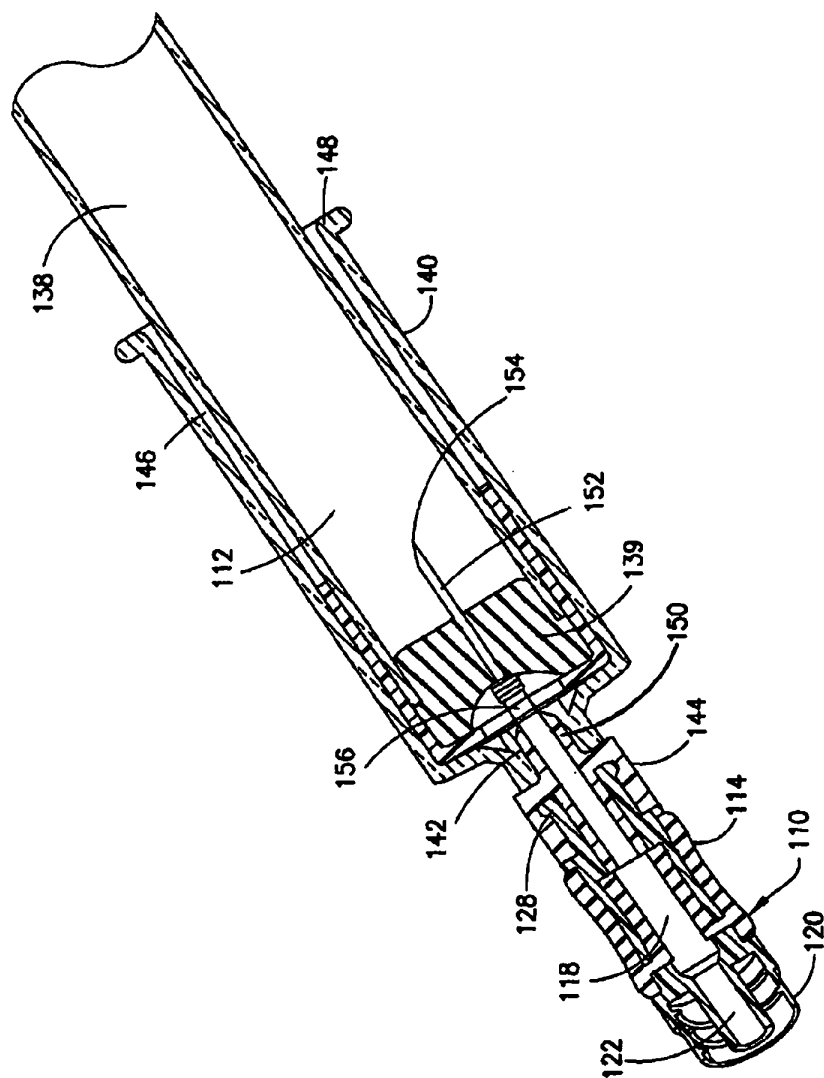


图 6

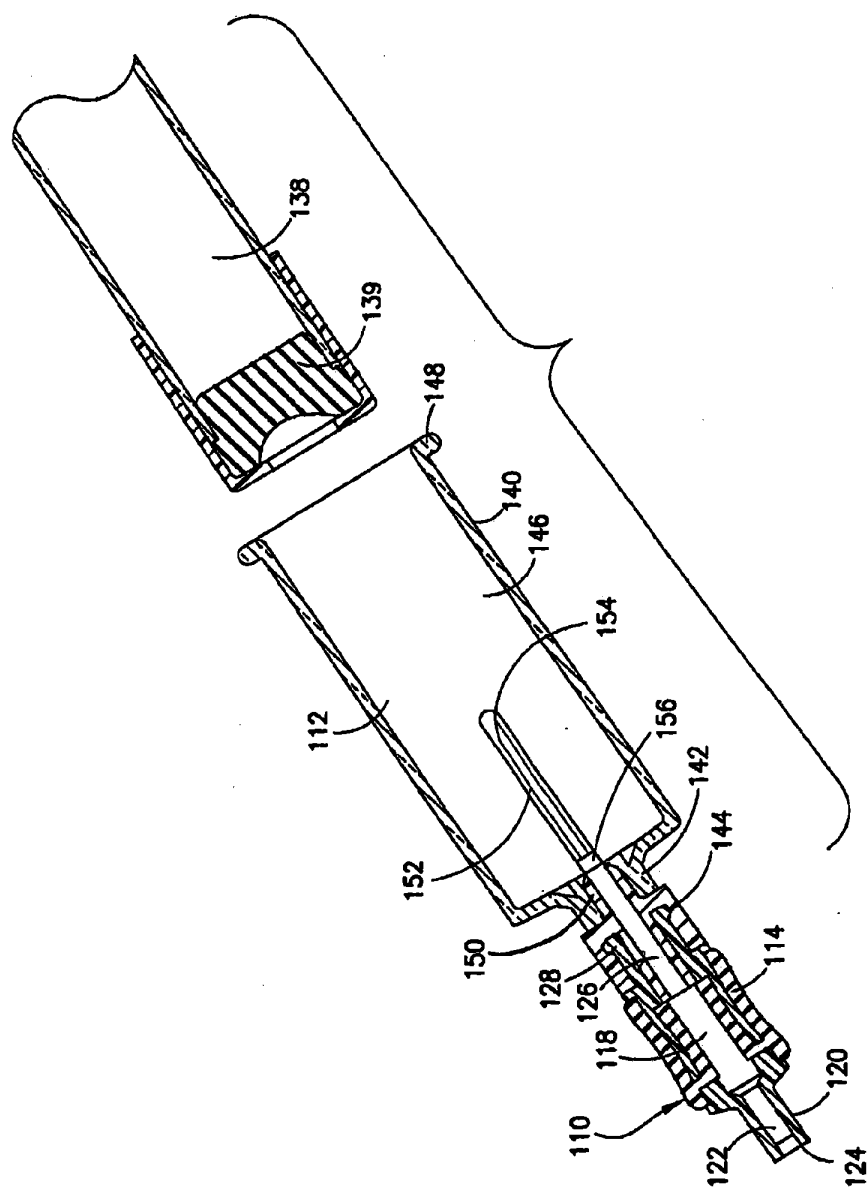


图 7

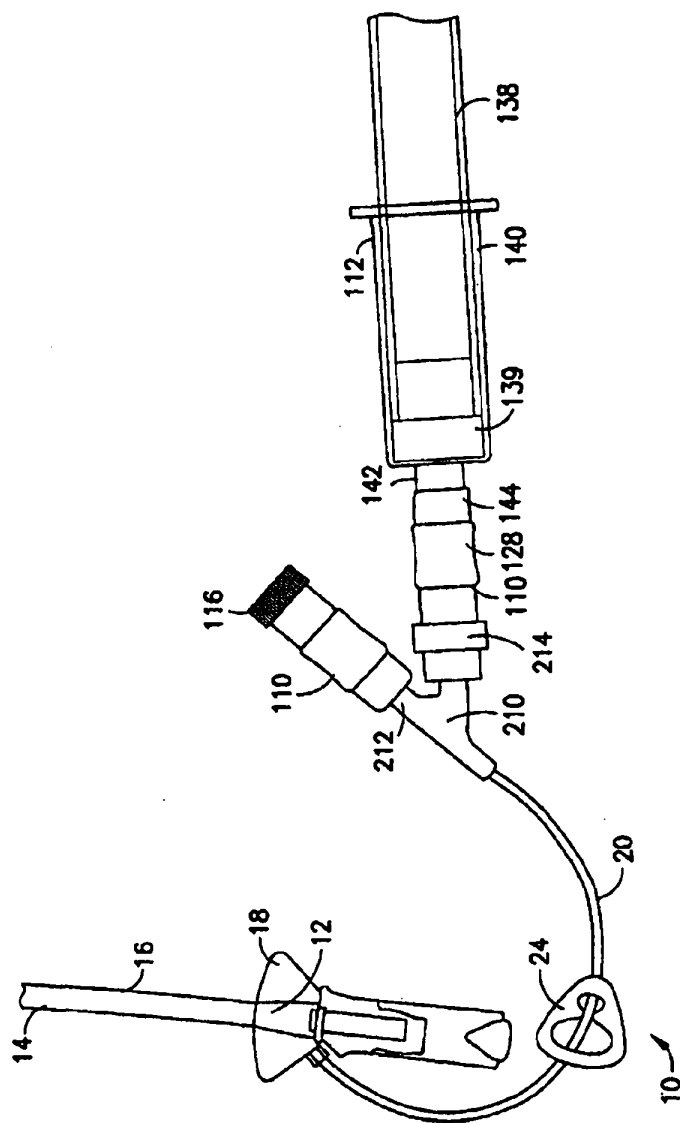


图 8

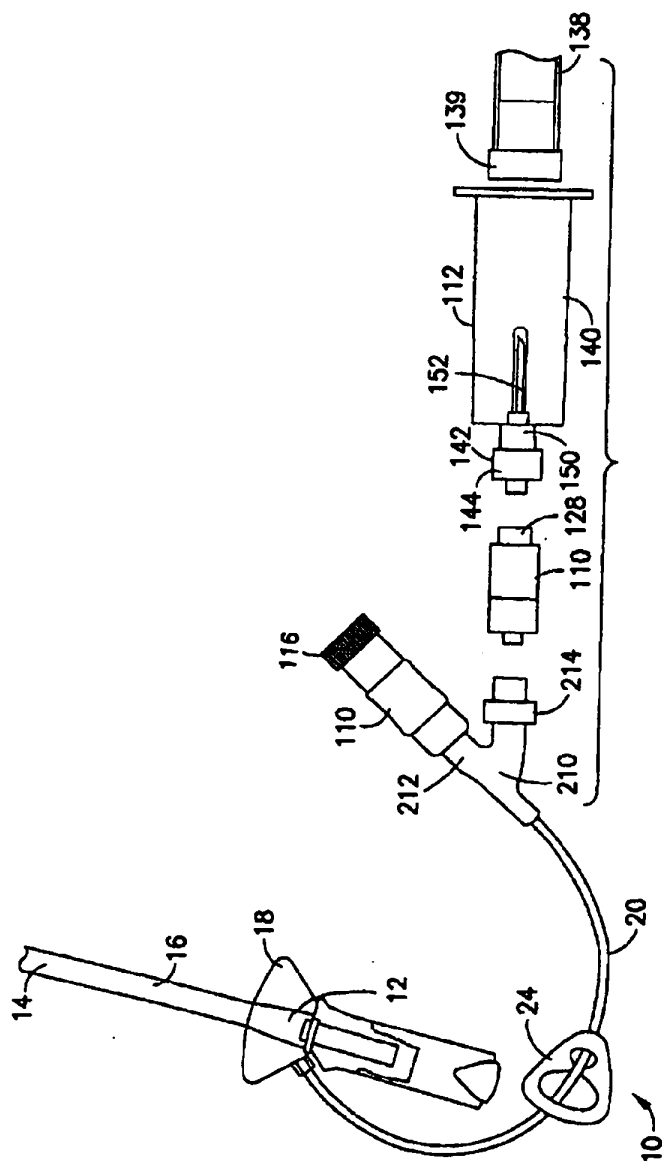


图 9

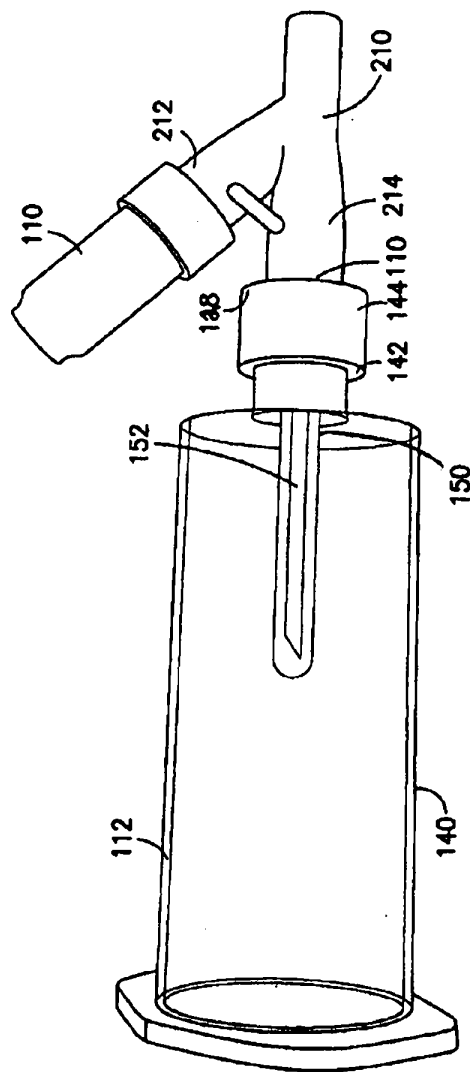


图 10

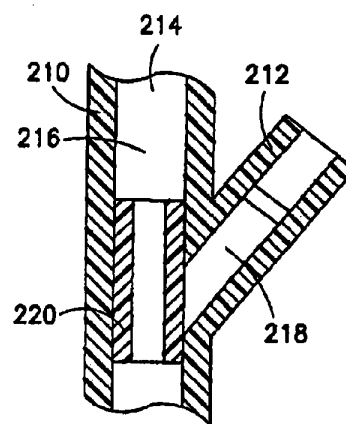


图 11

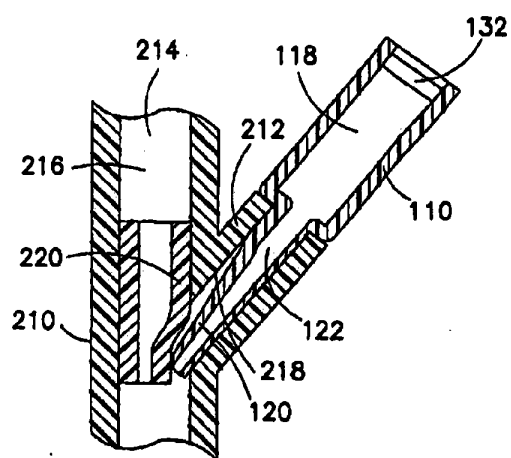


图 12

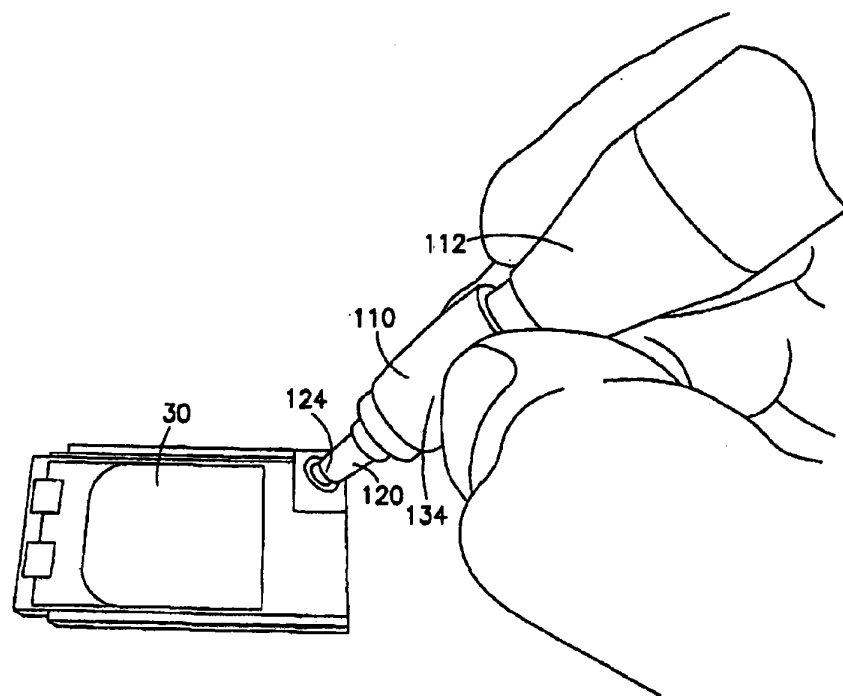


图 14

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membrane

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membrane

basement membrane

basilar membrane

cell membrane

☒ On ☐ Off

Main Entry: **mem·brane** 

Pronunciation: \ˈmem-,brān\

Function: *noun*

Etymology: Middle English, from Latin *membrana* skin, parchment, from *membrum*

Date: 15th century

1 : a thin soft pliable sheet or layer especially of animal or plant origin

2 : a piece of parchment forming part of a roll

— **mem·braned**  \ˈmem-,brānd\ *adjective*

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Pronunciation Symbols

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Merriam-Webster Online. 21 April 2009
<<http://www.merriam-webster.com/dictionary/membrane>>

APA Style

membrane. (2009). In *Merriam-Webster Online Dictionary*.
Retrieved April 21, 2009, from <https://web.archive.org/web/20090422094740/http://www.merriam-webster.com/dictionary/membrane>

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/838,017	04/01/2020	Bobby E. ROGERS	069366-0572158_KUR7001US	1044
27500 7590 04/25/2023 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER PORTILLO, JAIRO H	
			ART UNIT 3791	PAPER NUMBER
			NOTIFICATION DATE 04/25/2023	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

CLAIM INTERPRETATION

The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Use of the word “means” (or “step for”) in a claim with functional language creates a rebuttable presumption that the claim element is to be treated in accordance with 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph). The presumption that 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph) is invoked is rebutted when the function is recited with sufficient structure, material, or acts within the claim itself to entirely perform the recited function.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

- (A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

- (B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g., “means for”) or another linking word or phrase, such as “configured to” or “so that”; and
- (C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step for”) in a claim creates a rebuttable presumption that the claim element is **not** to be treated in accordance with 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph). The presumption that 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph) is not invoked is rebutted when the claim element recites function but fails to recite sufficiently definite structure, material or acts to perform that function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Such claim limitations is/are:

- (Claim 12) “a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film.”
- (Claim 20) “a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film.”

A review of the specification shows that the following appears to be the corresponding structure described in the specification for the 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph limitation:

- (Claim 12) “a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film.”: As identified by the Specification, the following is recognized as the corresponding structure to the piercing member: “The piercing member 704 can include a spike, pin, blade, shard, or the like, and can be held substantially in the center of the opening to the sampling path, as shown in FIG. 9A, by a holding mechanism as shown in FIG. 9B.” Or equivalents thereof.
- (Claim 20) “a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film.”: As identified by the Specification, the following is recognized as the corresponding structure to the piercing member: “The piercing member 704 can include a spike, pin, blade, shard, or the like, and can be held substantially in the center of the opening to the sampling path, as shown in FIG. 9A, by a holding mechanism as shown in FIG. 9B.” Or equivalents thereof.

If applicant wishes to provide explanation or dispute the examiner’s interpretation of the corresponding structure, applicant must identify the corresponding structure with reference to the specification by page and line number, and to the drawing, if any, by reference characters in response to this Office action.

If applicant does not intend to have the claim limitation(s) treated under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may amend the claim(s) so that it/they will clearly not invoke 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, or present a sufficient showing that the claim recites/recite sufficient structure, material, or acts for

performing the claimed function to preclude application of 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

For more information, see MPEP § 2173 *et seq.* and *Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications*, 76 FR 7162, 7167 (Feb. 9, 2011).

Claim Rejections - 35 USC § 102

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-3, 5-8, 10, and 14-17 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by **Rogers et al (US 2017/0020428) (“Rogers”)**.

Regarding Claim 1, while Rogers teaches a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source, a first portion of the fluid sample potentially having contaminants (Abstract, [0124] Figs. 23A and 23B), the fluid sample optimization device comprising:

an inlet configured to connect with the fluid source ([0124] inlet port 2302);

an outlet configured to connect with the fluid collection device ([0124] outlet port 2304);

a sample path connected between the inlet and the outlet ([0124] sample path/sampling channel 2308); and

a contaminant containment reservoir connected between the inlet and the outlet (Figs. 23A and 23B, [0124] sequestration chamber 2306), the contaminant containment reservoir having an air permeable fluid resistor proximate the outlet (Figs. 23A and 23B, hydrophobic plug 2312), the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet ([0124] "A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.).

Regarding Claim 2, Rogers teaches the fluid sample optimization device in accordance with claim 1, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir (*See Claim 1 Rejection*, the tubing of the blood sequestration device 2300 acts as a housing).

Regarding Claim 3, Rogers teaches the fluid sample optimization device in accordance with claim 1, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (*See Claim 1 Rejection*).

Regarding Claim 5, Rogers teaches the fluid sample optimization device in accordance with claim 1, wherein each pressure differential is provided by a vacuum pressure provided by the fluid collection device (*See Claim 1 Rejection*, [0124] “A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there.”).

Regarding Claim 6, Rogers teaches a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source, a first portion of the fluid sample potentially having contaminants (*Abstract*, [0124] Figs. 23A and 23B), the fluid sample optimization device comprising:

an inlet configured to connect with the fluid source ([0124] inlet port 2302);

an outlet configured to connect with the fluid collection device ([0124] outlet port 2304 connected to a blood sample collection device);

a sample path connected between the inlet and the outlet ([0124] sample path/sampling channel 2308), the sample path further having a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path ([0124] valve 2310. Examiner notes that the patent publication has the valve written as 2308, but the language of paragraph [0124] and the Figures heavily imply the valve should be understood as corresponding to reference character 2310); and

a contaminant containment reservoir connected between the inlet and the outlet (Figs. 23A and 23B, [0124] sequestration chamber 2306), the contaminant containment reservoir further having an air permeable fluid resistor proximate the outlet (Figs. 23A and 23B, hydrophobic plug 2312), the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the

fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet ([0124] "A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.).

Regarding Claim 7, Rogers teaches the fluid sample optimization device in accordance with claim 6, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir (*See Claim 6 Rejection*, the tubing of the blood sequestration device 2300 acts as a housing).

Regarding Claim 8, Rogers teaches the fluid sample optimization device in accordance with claim 6, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (*See Claim 6 Rejection*).

Regarding Claim 10, Rogers teaches the fluid sample optimization device in accordance with claim 6, wherein each pressure differential is provided by a vacuum pressure provided by the fluid collection device (*See Claim 1 Rejection*, [0124] "A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial

aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there.).

Regarding Claim 14, Rogers teaches a fluid sample optimization device for optimizing a fluid sample, a first portion of the fluid sample potentially having contaminants, the fluid sample optimization device comprising:

an inlet ([0124] inlet port 2302);

an outlet ([0124] outlet port 2304);

a sample path connected between the inlet and the outlet ([0124] sample path/sampling channel 2308); and

a contaminant containment reservoir connected between the inlet and the outlet (Figs. 23A and 23B, [0124] sequestration chamber 2306), the contaminant containment reservoir having an air permeable fluid resistor proximate the outlet (Figs. 23A and 23B, hydrophobic plug 2312), the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet ([0124] "A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port

2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.).

Regarding Claim 15, Rogers teaches the fluid sample optimization device in accordance with claim 14, wherein the sample path further includes a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path during receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir (*See Claim 14 Rejection*, the valve is a resistive plug).

Regarding Claim 16, Rogers teaches the fluid sample optimization device in accordance with claim 14, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir (*See Claim 14 Rejection*, the tubing of the blood sequestration device 2300 acts as a housing).

Regarding Claim 17, Rogers teaches the fluid sample optimization device in accordance with claim 14, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (*See Claim 14 Rejection*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 4, 9, and 18 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Rogers**.

Regarding Claim 4, while Rogers teaches the fluid sample optimization device in accordance with claim 1, and Rogers teaches in a separate embodiment that a contaminant containment reservoir includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to configure the contaminant containment reservoir of Rogers with a tortuous path as Rogers teaches that a tortuous path has a sealing function ([0065]) which would be useful for containing contaminants.

Regarding Claim 9, while Rogers teaches the fluid sample optimization device in accordance with claim 6, and Rogers teaches in a separate embodiment that a contaminant containment reservoir includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to configure the contaminant containment reservoir of Rogers with a tortuous path as Rogers teaches that a tortuous path has a sealing function ([0065]) which would be useful for containing contaminants.

Regarding Claim 18, while Rogers teaches the fluid sample optimization device in accordance with claim 14, and Rogers teaches in a separate embodiment that a contaminant containment reservoir includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to configure the contaminant containment reservoir of Rogers with a tortuous path as Rogers teaches that a tortuous path has a sealing function ([0065]) which would be useful for containing contaminants.

Claim(s) 11-12 and 19-20 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Rogers** in view of **Davis et al (US 2007/0031283) ("Davis")**.

Regarding Claim 11, while Rogers teaches the fluid sample optimization device in accordance with claim 6, wherein the resistive plug includes a valve (*See Claim 6 Rejection*), Rogers fail to teach the resistive plug includes a film that is pierceable by a first of the subsequent pressure differentials.

However Davis teaches a medical sampling device (Abstract) comprising a valve composition of a film that is pierceable to allow fluid flow ([0278], [0280]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to substitute the pinching valve of Rogers for a needle-pierceable membrane valve of Davis as a simple substitution of one form of controlling fluid flow for another to obtain predictable results of sample optimization by denying the initial aliquot of blood. Further, the pierceable nature of Davis' film would support that it is pierceable by a pressure differential.

Regarding Claim 12, Rogers and Davis teach the fluid sample optimization device in accordance with claim 11, wherein the resistive plug further includes a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film (*See Claim 11 Rejection*, a piercing instrument is configured to pierce the film).

Regarding Claim 19, while Rogers teaches fluid sample optimization device in accordance with claim 15, wherein the resistive plug includes a valve (*See Claim 15 Rejection*), Rogers fail to teach the resistive plug includes a film that is pierceable by a first of the subsequent pressure differentials.

However Davis teaches a medical sampling device (Abstract) comprising a valve composition of a film that is pierceable to allow fluid flow ([0278], [0280]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to substitute the pinching valve of Rogers for a needle-pierceable

membrane valve of Davis as a simple substitution of one form of controlling fluid flow for another to obtain predictable results of sample optimization by denying the initial aliquot of blood. Further, the pierceable nature of Davis' film would support that it is pierceable by a pressure differential.

Regarding Claim 20, Rogers and Davis teach the fluid sample optimization device in accordance with claim 19, wherein the resistive plug further includes a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film (*See Claim 20 Rejection*, a piercing instrument is configured to pierce the film).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAIRO H PORTILLO whose telephone number is (571)272-1073. The examiner can normally be reached M-F 9:00 am - 5:15 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/JAIRO H. PORTILLO/
Examiner
Art Unit 3791

/NATHAN J JENNESS/
Primary Examiner, Art Unit 3792
20 April 2023

<i>Notice of References Cited</i>	Application/Control No. 16/838,017		Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner JAIRO H PORTILLO		Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20070031283-A1	02-2007	Davis; Charles Quentin	A61B5/15087	422/400
*	B	US-20170020428-A1	01-2017	Rogers; Bobby E.	A61B5/15003	1/1
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	Filing Date	2020-04-01
	First Named Inventor	Bobby E. ROGERS
	Art Unit	1798
	Examiner Name	
	Attorney Docket Number	KURIN7US

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20140112841	A1	2014-04-24	Schoen et al.	
	2	20180271425	A1	2018-09-27	Rogers et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button.

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FOREIGN PATENT DOCUMENTS								Remove
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²ⁱ	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	1378602	GB	A	1974-12-27	Ayers		
	2	2019055487	WO	A1	2019-03-21	Magnolia Medical Technologies, Inc.		

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	16838017
Filing Date	2020-04-01
First Named Inventor	Bobby E. ROGERS
Art Unit	1798
Examiner Name	
Attorney Docket Number	KURIN7US

3	2019232196	WO	A1	2019-12-05	Magnolia Medical Technologies, Inc.
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NON-PATENT LITERATURE DOCUMENTS

Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	International Search Report and Written Opinion dated 16 July 2020 for PCT application no. PCT/US2020/026276.	

If you wish to add additional non-patent literature document citation information please click the Add button

Add

EXAMINER SIGNATURE

Examiner Signature	/JAIRO H PORTILLO/	Date Considered	04/19/2023
--------------------	--------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	16838017
Filing Date	2020-04-01
First Named Inventor	Bobby E. ROGERS
Art Unit	1798
Examiner Name	
Attorney Docket Number	KURIN7US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/JSN/	Date (YYYY-MM-DD)	2020-07-31
Name/Print	James S. Nolan	Registration Number	53393

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



21 May 2024

PILLSBURY WINTHROP SHAW PITTMAN, LLP
P.O. BOX 10500
McLean, VA 22102
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By Email Only:

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Docket_ip@pillsburylaw.com

To the attention of Jim Conley

P.K. 26 – First Office Action of:

IL Patent Application No.: 286812
Title: NON-VENTING BODILY FLUID SAMPLE OPTIMIZATION DEVICE AND SYSTEM
Filing Date: 29 September 2021
App. date: 1 April 2020
IL NP of PCT Patent Application No.: PCT/US2020/26276
Applicant(s): KURIN, INC.

Your ref.: 069366-0572161_KUR7N01IL

Our ref.: 1000-020-01

1

Dear Jim:

The Israel Patent Office (ILPO) has issued its first Office Action (substantive examination report) dated 20 May 2024, notifying the Applicant of the beginning of the examination process of the above identified IL Patent Application.

A response to the Office Action should be filed within four months and before 20 September 2024. Monthly extensions (up to four months) are available upon payment of government fees of about \$60 per month. Kindly note that the maximum extension period which can be obtained during substantive examination cannot exceed 12 months.

The examination is based on the following documents:

Description dated 29 September 2021

Claims dated 29 September 2021

Drawings dated 29 September 2021



5250607, רמת-גן, 11 קומה, בית עזר, 14 סילבר, דרך אבא הלל טיבר | info@patents-il.com | 03-9093614 | 03-9326393
+972-3-9326393 | +972-3-9093614 | info@patents-il.com | 14 Abba Hillel Rd. Beit OZ, 11th floor, Ramat Gan 5250607, Israel

www.patents-il.com



The references hereunder relate to the following publications:

D1: US2018271425A1 [KURIN INC [US]] - 27/09/2018

D2: GB1378602A [BECTON DICKINSON CO] - 27/12/1974

D3:US2014112841A1 [BOEHRINGER INGELHEIM MICROPART [DE]] - 24/04/2014

In accordance with details below the following are the examiner's remarks regarding the allowability of the claims:

Defects were found in claims 1-20:

1. Novelty and Inventive Step

1.1. Claims 1-3,5-7,10,14-17 do not define a novel invention as per section 4 of the law, in light of D1, as detailed in the International Search Report.

1.2. Claims 1-20 do not define an invention with an inventive step as per section 5 of the law, in light of D1, D2, D3, as detailed in the International Search Report.

2

Duty of Disclosure

The applicant is hereby reminded that any change in the list of prior art or status of corresponding application (section 18c of the law) regarding oppositions, procedures to cancel corresponding applications / registrations must be reported to the ILPO up to the payment of the allowance fee.

We look forward to receiving your instructions in due course.

Yours sincerely,

Dr. Sarah Presenti, Adv
Katz, Presenti & Co



Submitted herewith

- > The original OA (p.k. 26) in Hebrew.
- > D1, D2, D3
- > Our invoice number 3465

3





European Patent Office
80298 MUNICH
GERMANY

Questions about this communication?
Contact Customer Services at www.epo.org/contact



Thum, Bernhard
Thum & Partner
Thum Mötsch Weickert
Patentanwälte PartG mbB
Siebertstr. 6
81675 München
ALLEMAGNE

Date	28.10.2022
------	------------

Reference KUR-18996-P-EP	Application No./Patent No. 20781928.5 - 1122 / 3948211 PCT/US2020026276
Applicant/Proprietor Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the supplementary European search report (Art. 153(7) EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

Refund of the search fee

If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued shortly (R. 70(2) EPC).



The examination is being carried out on the **following application documents**

Description, Pages

1-28 as published

Claims, Numbers

1-20 as published

Drawings, Sheets

1/16-16/16 as published

Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

- D1 US 2018/271425 A1 (ROGERS BOBBY E [US] ET AL) 27 September 2018 (2018-09-27)
- D2 EP 3 324 845 A1 (KURIN INC [US]) 30 May 2018 (2018-05-30)
- D3 WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05)
- D4 WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 21 March 2019 (2019-03-21)

1. The application does not meet the requirements of Article 84 EPC, because claims 1, 6 and 14 are not clear.

Claims 1, 6 and 14 have been drafted as separate independent claims.

Under Article 84 in combination with Rule 43(2) EPC, an application may contain more than one independent claim in a particular category only if the subject-matter claimed falls within one or more of the exceptional situations set out in paragraph (a), (b) or (c) of Rule 43(2) EPC. However, this is not the case in the present application.

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claims 1, 6 and 14 is not new within the meaning of Article 54(1) and (2) EPC.

2.1 D1 discloses a **fluid sample optimization device** (see fig.23,24, par. [0141]-[0149]: "blood sample optimization system 2400") **for optimizing a fluid sample collected by a fluid collection device from a fluid source, a first portion of the fluid sample potentially having contaminants** (see par. [0141]: "a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered"), **the fluid sample optimization device comprising:**

an inlet ("inlet port 2412") configured to connect with the fluid source;

an outlet ("outlet port 2414") configured to connect with the fluid collection device;

a sample path ("blood sample channel 2422") connected between the inlet and the outlet; and

a contaminant containment reservoir ("blood sequestration chamber 2418 ") connected between the inlet and the outlet, the contaminant containment reservoir having an air permeable fluid resistor ("air permeable blood barrier 2420") proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet (see par. [0148]: "As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position.", "Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.").

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

2.2 D1 discloses a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source (see fig.23,24, par. [0141]-[0149]: "blood sample optimization system 2400"), a first portion of the fluid sample potentially having contaminants (see par. [0141]: "a sampling channel 2308 that

bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered"), the fluid sample optimization device comprising:

an inlet ("inlet port 2412") configured to connect with the fluid source;

an outlet ("outlet port 2414") configured to connect with the fluid collection device;

a sample path ("blood sample channel 2422") connected between the inlet and the outlet, the sample path further having a resistive plug ("apertures 2424") that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path (see par.[0141]: "the inner chamber housing 2419 is in the first position toward the inlet port 2412, such that the one or more apertures 2424 are closed, and the blood sequestration chamber 2418 is in a direct path from the patient needle."); and

a contaminant containment reservoir ("blood sequestration chamber 2418 ") connected between the inlet and the outlet, the contaminant containment reservoir further having an air permeable fluid resistor ("air permeable blood barrier 2420") proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet (see par.[0148]: "As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position.", "Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.").

The subject-matter of claim 6 is therefore not new (Article 54(1) and (2) EPC).

2.3 The subject-matter of claim 14, which comprises for essentially the same features as the subject matter of claim 1, is for essentially the same reasons as those given above (see point 2.1) also not new (Article 54(1) and (2) EPC).

2.4 Furthermore, the documents D2-D3 also disclose all the features of claim 1, 6 and 14. For further details, see the relevant parts thereof as cited in the Search Report.

3. The dependent claims 2 to 5, 7 to 13 and 15 to 20 and seem not to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC in respect of novelty and/or inventive step, defining either features already known from any of D1-D3 or straightforward possibilities from which the person skilled in the art would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

4. Independent claims are not in the two-part form in accordance with Rule 43(1) EPC, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 43(1)(a) EPC) and the remaining features being included in the characterising part (Rule 43(1)(b) EPC).

5. The features of the claims should be provided with reference signs placed in parentheses to increase the intelligibility of the claims (Rule 43(7) EPC). This applies to both the preamble and characterising portion (see Guidelines F-IV, 4.18).

6. The applicant is invited to file new claims which take account of the above comments.

In order to comply with the requirements of Rule 137(4) EPC, the applicant should clearly identify the amendments made, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (see Guidelines H III, 2.1).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed or in documents with tracked changes.

When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and of any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

Datum
Date cf Form 1507
Date

Blatt
Sheet 5
Feuille

Anmelde-Nr:
Application No: 20 781 928.5
Demande n°:

Information on Search Strategy - Pilot phase (see OJ 2015, A86)

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

EP 20 78 1928

TITLE: NON-VENTING BODILY FLUID SAMPLE OPTIMIZATION DEVICE AND SYSTEM**APPLICANT: Kurin, Inc.****IPC CLASSIFICATION: G01N1/10, G01N1/02, A61B5/15, A61B5/154****EXAMINER: Coja, Michael****CONSULTED DATABASES: EPODOC, WPI****CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:****IPC:****CPC: A61B5/15003, A61B5/150213, A61B5/150221, A61B5/150251****FI/F-TERMS:****KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:**



**SUPPLEMENTARY
EUROPEAN SEARCH REPORT**

Application Number
EP 20 78 1928

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2018/271425 A1 (ROGERS BOBBY E [US] ET AL) 27 September 2018 (2018-09-27) * the whole document *	1-20	INV. G01N1/10 G01N1/02 A61B5/15 A61B5/154
X	EP 3 324 845 A1 (KURIN INC [US]) 30 May 2018 (2018-05-30) * paragraph [0104]; figure 23 *	1-20	
X,P	WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05) * paragraphs [0074], [0099], [0120], [0141]; figures 1-14 *	1, 6, 14	
A	WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 21 March 2019 (2019-03-21) * paragraph [1179]; figures 35-37 *	1-20	
			TECHNICAL FIELDS SEARCHED (IPC)
			A61B
The supplementary search report has been based on the last set of claims valid and available at the start of the search.			
Place of search The Hague		Date of completion of the search 20 October 2022	Examiner Coja, Michael
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			
T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

1
EPO FORM 1503 03.82 (F04C04)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 20 78 1928

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

20-10-2022

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2018271425 A1	27-09-2018	US 2018271425 A1	27-09-2018
		US 2021145336 A1	20-05-2021
EP 3324845 A1	30-05-2018	AU 2016297849 A1	22-02-2018
		AU 2021202622 A1	27-05-2021
		CA 2993646 A1	02-02-2017
		EP 3324845 A1	30-05-2018
		EP 3622890 A1	18-03-2020
		IL 257137 A	29-03-2018
		IL 286030 A	31-10-2021
		JP 6643474 B2	12-02-2020
		JP 6734490 B2	05-08-2020
		JP 2018525191 A	06-09-2018
		JP 2020096843 A	25-06-2020
		JP 2020192333 A	03-12-2020
		US 2017020427 A1	26-01-2017
		US 2017020428 A1	26-01-2017
		US 2018289304 A1	11-10-2018
		US 2019159711 A1	30-05-2019
		US 2022079483 A1	17-03-2022
		WO 2017019552 A1	02-02-2017
WO 2019232196 A1	05-12-2019	CA 3101972 A1	05-12-2019
		EP 3801258 A1	14-04-2021
		JP 2021525862 A	27-09-2021
		US 2019365303 A1	05-12-2019
		US 2022151526 A1	19-05-2022
		US 2022151527 A1	19-05-2022
		US 2022304601 A1	29-09-2022
		WO 2019232196 A1	05-12-2019
WO 2019055487 A1	21-03-2019	AU 2018334138 A1	12-03-2020
		CA 3074105 A1	21-03-2019
		CN 111212597 A	29-05-2020
		EP 3681384 A1	22-07-2020
		IL 273025 A	30-04-2020
		JP 2020533045 A	19-11-2020
		US 2019076074 A1	14-03-2019
		US 2022175284 A1	09-06-2022
		WO 2019055487 A1	21-03-2019



Application No.: 20781928.5

The search has started on 19.10.22 (see Notice from the European Patent Office dated 03/2013, OJ EPO 2013, 153).

Receiving Section



רשות המכס



מדינת ישראל
רשות המכס

פ.ק. 26

תאריך: י"ח כסלו תשפ"ב
22/11/2021
מספר: 1000-016-01

לכבוד
כץ, פרזנט ושות'
דרך אבא הלל 14, ת.ד.
רמת גן, מיקוד 52506

א. ג. נ.

הנדון: הודעה על ליקויים בבקשת פטנט מספר 286030

סימוכין: מכתבכם מיום 15/11/2021

לתשומת לבכם: מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ"ז – 1967. מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ"ח – 1968. עליכם להשיב על הודעה זו תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה, עם בקשת הארכה שתוגש יש לשלם אגרה בסך 203.00 ש"ח בעד כל חודש או חלק ממנו. לא יינתנו יותר מארבעה חודשי ארכה בגין כל הודעה על ליקויים וסך כל תקופות הארכה במהלך הבחינה לא יעלה על 12 חודשים בהתאם לכללים שנקבעו בחוזר הרשם 035/2017-פטנטים.

הודעה זו מבוססת על המסמכים הבאים:

שרטוטים מתאריך: 01/09/2021
פרטי הבקשה מתאריך: 01/09/2021
תביעות מתאריך: 01/09/2021

ההפניות בהודעה זו מתייחסות לפרסומים הבאים:

D1: WO 2011162772 A1 [CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]] -
29/12/2011

הסתייעות הבוחן בדוח בינלאומי

מערכת התביעות שבבקשה שבפניי זהה / זהה בחלקה למערכת התביעות בבקשה הבין-לאומית PCT/US/2016/043709 שנבחנה על ידי רשות חיפוש ובחינה בין-לאומית. לאחר עיון בדוח הבין-לאומי ולאור הזהות בתביעות כאמור, החלטתי כי הליקויים שפורטו בדוח הבין-לאומי חלים על הבקשה שבפניי כמפורט בהמשך הודעה זו.

בהתאם למפורט בהמשך הודעה זו להלן סיכום עמדתי לעניין כשירות התביעות לפטנט:

בתביעה/ות מס' 1-4 נמצאו ליקויים.
ראה הנימוקים בהמשך הודעה זו.

בהתאם להוראות תקנה 41 הנני להודיעכם כי נמצאו בבקשה הנ"ל הליקויים המפורטים להלן:





1. בחינת הבקשה מבוססת על ההודעות הבאות:

1.1 הריני להודיעכם כי:

- (א) תאריך הבקשה הנוכחית, שהינה בקשת חלוקה מן הבקשה מס' 257137, הוקדם לתאריך 22/07/2016, שהוא תאריך הבקשה ההורה, וזאת בהתאם לסעיף 24(ג) לחוק;
- (ב) הבקשה הנוכחית זכאית לאותו(ים) תאריך(כל) בכורה אשר עליו(הם) הושתתה הבקשה ההורה.

2. חידוש והתקדמות המצאתית

2.1 תביעה 1 אינה מגדירה אמצאה חדשה כהגדרתה בסעיף 4 לחוק, לאור פרסום: D1.

תביעה 1 שבבקשה שבפניי תואמת לתביעה 17 בבקשה AU2016297849 שנבחנה על ידי IP Australia והופק עבורה דוח בחינה בתאריך 29/04/2020. לאחר עיון בדוח הבחינה האמור ולאור תאימות התביעות, מצאתי כי הליקוי שפורט בנוגע לחוסר חידוש חל גם על התביעות שבפניי לפי חוק הפטנטים הישראלי.

2.2 תביעות 2-4 אינן מגדירות אמצאה שיש בה התקדמות המצאתית כהגדרתה בסעיף 5 לחוק, לאור פרסום: D1.

תביעות 2-4 שבבקשה שבפניי תואמות לתביעות 18-20 בבקשה AU2016297849 שנבחנה על ידי IP Australia והופק עבורה דוח בחינה בתאריך 29/04/2020. לאחר עיון בדוח הבחינה האמור ולאור תאימות התביעות, מצאתי כי הליקוי שפורט בנוגע לחוסר התקדמות המצאתית חל גם על התביעות שבפניי לפי חוק הפטנטים הישראלי.

3. התביעות

3.1 תביעה מס' 1 (התואמת לתביעה 17 בבקשה הבין-לאומית) אינה עונה לדרישות סעיף 13 לחוק ותקנה 20(א)(3) מאחר והיא לא בהירה ו/או תמציתית, כמפורט בדוח הבחינה הבין-לאומי.

חובת המבקש לעדכן את הרשות

תשומת לבכם לסעיף 18 לחוק לעניין חובת המבקש לעדכן את הרשות על כל שינוי שחל ברשימת האסמכתאות או הפרסומים כאמור בסעיף 18(א) לחוק ולסעיף 18ג לחוק בדבר אמצעי האכיפה.

הגשת תיקונים לפירוט במהלך בחינת הבקשה

באם יבוצעו תיקונים בבקשת הפטנט, תשומת לבכם מופנית לתקנה 22(א). יש לשלוח לרשות עותק מלא של חלק הבקשה שבו הוכנסו התיקונים תוך סימונם באופן ברור. יש לסמן תוספות בקו תחתי (כך: דוגמה) והשמטות בקו חוצה (כך: דוגמה). אין להגיש מחדש קבצים שלא תוקנו.

לתשומת לבכם:

(א) בהתאם לתקנות 22(ב) ו-42 במידה שהנכם מתקנים את הפירוט כדי להתגבר על הליקויים בהודעה זו, עליכם לפרט את הליקויים שהתיקונים באים לסלקם, לנמק כיצד תיקון הפירוט מתקן את הליקוי ולגבי תיקון תביעות, כיצד עומד התיקון בתנאי סעיף 13 לחוק.

(ב) בהתאם להוראות חוזר רשם 034/2017-פטנטים, במידה שבחינת הבקשה החלה לאחר 27.03.2017, תיקון





רשות הפטנטים



מדינת ישראל
משרד המשפטים

פירוט בדרך של החלפת האמצאה שנבחנה ואשר לגביה הועלה ליקוי, באמצאה אחרת, בין אם היא הופיעה בתביעות מלכתחילה ובין אם תוארה בלבד, גם אם היא נובעת מהתיאור, אינו מהווה תיקון הליקוי ויביא לשליחת הודעה לפני סירוב.

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

<https://israelpatents.justice.gov.il/#/en/patent-file/details/286030>

ראיון עם בוחן

בהתאם לה.ע. 23.3, המפורסמת באתר הרשות, ניתן לקיים ראיון עם הבוחן באמצעות פגישה במשרדי הרשות או בשיחה טלפונית.

רשות הפטנטים מעודדת קיום של קשר ישיר בין הבוחן למבקש או בא-כוחו באמצעות שירות זה.

קיום ראיון עם בוחן מאפשר לרוב את ייעול וקיצור זמן הבחינה ואף לחיסכון בעלויות בתהליך הבחינה והאישור של בקשה לפטנט.

במסגרת הראיון ניתן לדון עם הבוחן בנושאים הקשורים לתיאור האמצאה והגדרתה, בליקויים שהועלו במהלך הבחינה ואף בתיקונים אפשריים לליקויים אלה.

תיאום הראיון יתבצע ישירות מול הבוחן (פרטי הקשר מופיעים מטה) וילווה בהודעה כתובה של יוזם הראיון שתפרט את הנושאים לדיון ואת הטיעונים העיקריים לגביהם.

לתשומת לבכם, בקשה לקיום ראיון אינה מהווה תשובה להודעת הליקויים כמשמעה בתקנה 42.

השגה בפני הרשם

על פי סעיף 161 לחוק, הנכם רשאים להשיג על החלטתי בפני רשם הפטנטים תוך ארבעה חודשים ממועד משלוח ההודעה.

בכבוד רב

אלברט אקרמן

בוחן פטנטים בכיר

טלפון: 073-3927233

דואר אלקטרוני: albertak@justice.gov.il

ראש צוות: מוריה שלמה לוי



INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18494622
	Filing Date	2023-10-25
	First Named Inventor	Bobby ROGERS
	Art Unit	3791
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0577657_KUR2C05US

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear		
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18494622
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	First Named Inventor	Bobby ROGERS
	Art Unit	3791
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0577657_KUR2C05US

1	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
2	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
3	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
4	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
5	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
6	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18494622
	Filing Date	2023-10-25
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	Art Unit	3791
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0577657_KUR2C05US

CERTIFICATION STATEMENT			
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):			
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).			
OR			
☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).			
☐ See attached certification statement.			
☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.			
☒ A certification statement is not submitted herewith.			
SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474
<p>This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p>			

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/838,017	04/01/2020	Bobby E. ROGERS	069366-0572158_KUR7001US	1044
27500 7590 02/09/2024 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER PORTILLO, JAIRO H	
			ART UNIT 3791	PAPER NUMBER
			NOTIFICATION DATE 02/09/2024	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Advisory Action Before the Filing of an Appeal Brief	Application No. 16/838,017	Applicant(s) ROGERS et al.	
	Examiner JAIRO H PORTILLO	Art Unit 3791	AIA (FITF) Status Yes

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 February 2024 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☒ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires ____ months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires ____ months from the mailing date of the prior Advisory Action or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.

Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because

a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);

b) ☐ They raise the issue of new matter (see NOTE below);

c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): (a) ☒ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____

9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

13. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____

14. ☒ Other: PTO2323, PTO892.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-4, 6-9, 14 and 16-18.

Claim(s) withdrawn from consideration: _____

/J.H.P/ Examiner, Art Unit 3791	/KAYLEE R WILSON/ Primary Examiner, Art Unit 3791
------------------------------------	--

Continuation of 3, 7, and 12. NOTE: Applicant's amendments and arguments, filed 2/1/2024 have been fully considered and are persuasive over the currently cited art. However further search and consideration are required to make a determination on allowability. Examiner will note a newly found reference of Bullington et al (US 2019/0365303) has relevant subject matter in Figs. 9-14 specific to the new claim amendment and Bullington invention is also a device for optimizing a fluid sample with highly relevant subject matter.

<i>Notice of References Cited</i>	Application/Control No. 16/838,017	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner JAIRO H PORTILLO	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS						
*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20190365303-A1	2019-12-05	BULLINGTON; Gregory J.	A61B5/150213	1/1
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
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FOREIGN PATENT DOCUMENTS						
*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS		
*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

AFCP 2.0 Decision

Application No.

16/838,017

Applicant(s)

ROGERS et al.

Examiner

JAIRO H PORTILLO

Art Unit

3791

AIA (FITF) Status

Yes

This is in response to the After Final Consideration Pilot request filed 01 February 2024.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

- ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.
- ☐ A non-broadening amendment to at least one independent claim was not submitted.
- ☐ The request is not the first proper AFCP 2.0 request submitted in response to the most recent final rejection.
- ☐ Other: _____

2. **Proper Request**

A. After final amendment submitted with the request will not be treated under AFCP 2.0.

The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

- ☒ The after final amendment will be treated under pre-pilot procedure.

B. Updated search and/or completed additional consideration.

The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

- ☐ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.
- ☐ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action. See attached interview summary for further details.
- ☐ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.
- ☐ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.
- ☐ 5. Other: _____

Examiner Note: Please attach an interview summary when necessary as described above.

Application No. 16/838,017

Attorney's Docket No.: 069366-0572158_KUR7001US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bobby E. Rogers, et al.

Confirmation No: 1044

Application No.: 16/838,017

Art Unit: 3791

Filed: April 1, 2020

Examiner: Jairo H. Portillo

For: Non-Venting Bodily Fluid Sample Optimization Device And System

Mail Stop AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO FINAL OFFICE ACTION

Dear Examiner Portillo:

This reply is responsive to the Final Office Action mailed January 29, 2024, in the above-referenced matter (hereinafter “the Office Action”). Reconsideration and allowance of the application is requested in view of the following:

Listing of Claims beginning on page 2.

Remarks beginning on page 8.

DO NOT ENTER: /J.H.P/



UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION # 18/494,622	RECEIPT DATE / TIME 07/24/2024 06:21:55 PM Z ET	ATTORNEY DOCKET # 069366-0577657_KUR2C05US
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Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9839	FILED BY	Trent Tercenio
PATENT CENTER #	66505481	AUTHORIZED BY	Benjamin Hudson
CUSTOMER #	27500	FILING DATE	10/25/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Bobby E. ROGERS

Payment Information

PAYMENT METHOD DA / 033975	PAYMENT TRANSACTION ID E20247NI22096463	PAYMENT AUTHORIZED BY Trent Tercenio
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FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
2202	EACH CLAIM IN EXCESS OF 20	40.00	10	400.00
TOTAL AMOUNT:				\$400.00

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C.

371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # **18/494,622** RECEIPT DATE / TIME **07/24/2024 06:21:55 PM Z ET** ATTORNEY DOCKET # **069366-0577657_KUR2C05US**

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BLOOD SAMPLE OPTIMIZATION DEVICE

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CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. ROGERS
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
069366-0577657_KUR2C05US-Preliminary-amendment-APP.TEXT.docx	8	Application body structured text document	36 KB

Warning: Bookmarks were found and have been removed.

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
069366-0577657_KUR2C05US-	00AF77B4EA949F029E9E7261C03A295163B6936CFECD729FF

Preliminary-amendment-
APP.TEXT.docx

E1D620A1E32D18291CF779F8E05D1661BCC6D4DD44AFFB06
893D66549E415CA4254C2FE472FD8E6

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Application No. 18/494,622

Attorney's Docket No.: 069366-0577657_KUR2C05US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bobby E. Rogers, et al.

Confirmation No: 9839

Application No.: 18/494,622

Art Unit: 3791

Filed: October 25, 2023

Examiner: Not yet assigned

For: BLOOD SAMPLE OPTIMIZATION DEVICE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Prior to initial examination on the merits, please amend the above-identified application
as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 8 of this paper.

AMENDMENTS TO THE CLAIMS

Please replace all prior listings of claims with the following listing of claims:

1. (Cancelled)
2. (New) A device comprising:
 - an inlet port for receiving a blood sample;
 - an outlet port;
 - a chamber connected to the inlet port and being configured to collect a first portion of the blood sample, the chamber having a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood sample;
 - a housing, separate from the blood impermeable membrane; and
 - a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port.
3. (New) The device in accordance with claim 2, wherein the blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port.
4. (New) The device in accordance with claim 2, wherein the device is configured such that, when a drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.
5. (New) The device in accordance with claim 2, further comprising a valve configured to initially close off the sampling channel.

6. (New) The device in accordance with claim 2, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.
7. (New) The device in accordance with claim 2, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port.
8. (New) The device in accordance with claim 5, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.
9. (New) The device in accordance with claim 2, wherein the housing defines the inlet port, the sampling channel, and the outlet port.
10. (New) The device in accordance with claim 2, further comprising a patient needle and a sample collection device.
11. (New) The device in accordance with claim 2, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered.
12. (New) The device in accordance with claim 2, wherein the chamber has a volume of less than 1.5 cubic centimeters.
13. (New) A device comprising:

an inlet port for receiving blood;

an outlet port;

a chamber connected to the inlet port and being configured to collect a first portion of the blood, the chamber comprising a flexible blood impermeable membrane that allows the chamber to collect the first portion of the blood; and

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port.

14. (New) The device in accordance with claim 13, wherein the flexible blood impermeable membrane causes the first portion of the blood to back up into the chamber following application of the drawing force applied from the outlet port.

15. (New) The device in accordance with claim 13, wherein the device is configured such that, when a drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a material that is blood impermeable.

16. (New) The device in accordance with claim 13, further comprising a valve configured to initially close off the sampling channel.

17. (New) The device in accordance with claim 13, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.

18. (New) The device in accordance with claim 13, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the

chamber and is further configured such that, upon release, follow-on amounts of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.

19. (New) The device in accordance with claim 16, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.

20. (New) The device in accordance with claim 13, further comprising a patient needle and a sample collection device.

21. (New) The device in accordance with claim 13, the chamber having a volume sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.

22. (New) A device comprising:

an inlet port for receiving a blood;

an outlet port;

a chamber connected to the inlet port, the chamber having a blood impermeable membrane and being configured to collect a first portion of the blood; and

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port.

23. (New) The device in accordance with claim 22, wherein the blood impermeable membrane causes the first portion of the blood to back up into the chamber following application of the drawing force applied from the outlet port.

24. (New) The device in accordance with claim 22, wherein the device is configured such that, when a drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a material that is blood impermeable.
25. (New) The device in accordance with claim 22, further comprising a valve configured to initially close off the sampling channel.
26. (New) The device in accordance with claim 22, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.
27. (New) The device in accordance with claim 22, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the chamber and is further configured such that, upon release, follow-on amounts of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.
28. (New) The device in accordance with claim 25, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.
29. (New) The device in accordance with claim 22, further comprising a patient needle and a sample collection device.
30. (New) The device in accordance with claim 22, the chamber having a volume sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.

31. (New) The device in accordance with claim 22, wherein the chamber has a volume of less than 1.5 cubic centimeters.

REMARKS

By this amendment, Claim 1 has been cancelled without prejudice or disclaimer and claims 2-31 have been added. The claims find support throughout the specification. It is believed no new matter has been added. Upon entry of this amendment, Claims 2-31 are pending.

Prompt and favorable consideration of this amendment is respectfully requested.

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975 (Ref. No. 069366-0577657_KUR2C05US). The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,
PILLSBURY WINTHROP SHAW PITTMAN LLP

Date: July 24, 2024

By: /Ben Hudson/
Benjamin F. Hudson, Ph.D.
Reg. No. 71,474

PO BOX 10500
McLean, Virginia 22102
Telephone: (858) 509-4000
Customer No. 27500

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
--------------------	--

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐

The attached application, or

☒

United States application or PCT international application number 15/140,448

filed on April 27, 2016

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Bobby E. Rogers

Date (Optional): _____

Signature: Bobby E. Rogers

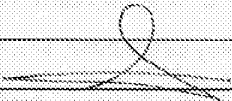
Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1460, Alexandria, VA 22313-1460. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 3.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
<p>As the below named inventor, I hereby declare that:</p> <p>This declaration is directed to: ☐ The attached application, or ☒ United States application or PCT international application number <u>15/140,448</u> filed on <u>April 27, 2016</u></p> <p>The above-identified application was made or authorized to be made by me.</p> <p>I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.</p> <p>I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.</p> <p style="text-align: center;">WARNING:</p> <p>Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.</p> <p>LEGAL NAME OF INVENTOR</p> <p>Inventor: <u>Gino Kang</u> Date (Optional): <u>1/22/2018</u></p> <p>Signature: </p> <p>Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.</p>	

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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LEGAL NAME OF INVENTOR	
Inventor: <u>John Detloff</u> Date (Optional): <u>1-23-18</u> Signature: <u>[Signature]</u>	
Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.	

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UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # **18/494,622** RECEIPT DATE / TIME **07/25/2024 03:09:55 PM Z ET** ATTORNEY DOCKET # **069366-0577657_KUR2C05US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9839	FILED BY	Trent Tercenio
PATENT CENTER #	66521979	FILING DATE	10/25/2023
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. ROGERS
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
069366-0577657_KUR2C05US-Declaration.pdf	3	Oath or Declaration filed	867 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
069366-0577657_KUR2C05US-Declaration.pdf	4AD43A0D0051FF165798AE089ABF7EA36C03DD6021A9A2E96BB9A2ADCB08BF21214575C900480B74B6CC265BAB55FAEC950B4240412C0489957978CC58A845DB

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 18/494,622		Filing Date 10/25/2023		☐ To be Mailed			
ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO											
APPLICATION AS FILED - PART I											
		(Column 1)		(Column 2)							
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A		N/A		N/A					
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A		N/A		N/A					
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A		N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(j))		minus 20 = *				x \$40 =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *				x \$ 192 =					
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))											
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL					
APPLICATION AS AMENDED - PART II											
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	07/24/2024	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 30	Minus	** 20	= 10			x \$ 40 =		400	
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0			x \$ 192 =		0	
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
TOTAL ADD'L FEE										400	
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=			x \$ 0 =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=			x \$ 0 =			
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
TOTAL ADD'L FEE											
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.										Case Resolution Specialist	
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".										/BONNIE L COLE/	
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".											
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.											

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA/82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	18/494,622
Filing Date	October 25, 2023
First Named Inventor	Bobby E. ROGERS
Title	BLOOD SAMPLE OPTIMIZATION DEVICE
Art Unit	3791
Examiner Name	Not Yet Assigned
Attorney Docket Number	069366-0577657_KUR2C05US

SIGNATURE of Applicant or Patent Practitioner

Signature	/Ben Hudson/	Date (Optional)	07-30-2024
Name	Benjamin F. Hudson	Registration Number	71,474
Title (if Applicant is a juristic entity)	Appointed Practitioner		
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.



*Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number

Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)



I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:

27500

OR



I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:



The address associated with the above-mentioned Customer Number

OR



The address associated with Customer Number:

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State

Zip

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I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Kurin, Inc.



Inventor or Joint Inventor (title not required below)



Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)



Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)



Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature

Date (Optional)

Name

Bobby E. Rogers

Title

CEO

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.



Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.52, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # 18/494,622 RECEIPT DATE / TIME 07/30/2024 05:58:44 PM Z ET ATTORNEY DOCKET # 069366-0577657_KUR2C05US

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE Utility - Nonprovisional Application under 35 USC 111(a) PATENT # -
CONFIRMATION # 9839 FILED BY Trent Tercenio
PATENT CENTER # 66584452 FILING DATE 10/25/2023
CUSTOMER # 27500 FIRST NAMED INVENTOR Bobby E. ROGERS
CORRESPONDENCE ADDRESS - AUTHORIZED BY Benjamin Hudson

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
069366-0577657_KUR2C05US-Power-of-Attorney.pdf	2	Power of Attorney	535 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
069366-0577657_KUR2C05US-Power-of-Attorney.pdf	34899C950E7AAC2E64E99C67CC5ABC81E1845A691CA10052423BA20B5B47B03A36789F2876BE1CF9D3CBAC1886C264AAA9E47083B926F6F76695180DB6E7D1FE

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/494,622	10/25/2023	Bobby E. ROGERS	069366-0577657_KUR2C05US

CONFIRMATION NO. 9839

27500

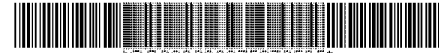
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)

ATTENTION: DOCKETING DEPARTMENT

P.O BOX 10500

McLean, VA 22102

PUBLICATION NOTICE



0000000075970585

Date Mailed: 08/01/2024

Title:BLOOD SAMPLE OPTIMIZATION DEVICE

Publication No.US-2024-0252079-A1

Publication Date:08/01/2024

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be viewed using the USPTO's publicly available Searchable Databases via the Patent Public Search tool at www.uspto.gov. The direct link to access the Patent Public Search tool is currently <https://ppubs.uspto.gov/pubwebapp/static/pages/ppubsbasic.html>.

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Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

TO: Docket_IP@pillsburylaw.com
FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 27500

Thu Aug 01 05:00:20 EDT 2024

Dear Patent Center Customer:

Correspondence Address:

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
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McLean,VIRGINIA,22102
UNITED STATES

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Application	Document	Mailroom Date	Attorney Docket No.
18494622	NTC.PUB	08/01/2024	069366-0577657_KUR2C05US

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/494,622	10/25/2023	Bobby E. ROGERS	069366-0577657_KUR2C05US

CONFIRMATION NO. 9839

27500

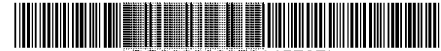
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)

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P.O BOX 10500

McLean, VA 22102

POA ACCEPTANCE LETTER



0000000076145767

Date Mailed: 08/07/2024

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 07/30/2024.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/dtdinh/

TO: Docket_IP@pillsburylaw.com
FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 27500

Wed Aug 07 05:00:08 EDT 2024

Dear Patent Center Customer:

Correspondence Address:

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
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McLean,VIRGINIA,22102
UNITED STATES

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Application	Document	Mailroom Date	Attorney Docket No.
18494622	N570	08/07/2024	069366-0577657_KUR2C05US

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The Patent Center Team



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2280 HV Rijswijk
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Tel: +31 70 340 2040



Carroll, Christopher P.
Burns & Levinson London LLP
4-12 Regent Street, 4th Floor
London SW1Y 4PE
ROYAUME UNI

Questions about this communication?
Contact Customer Services at
www.epo.org/contact

Primary Examiner
Name: Coja, Michael
Tel: +31 70 340 - 9260

Application No. 20 781 928.5 - 1122	Ref. KUR-007EP1	Date 31.07.2024
Applicant Kurin, Inc.		

Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC. One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the Examining Division requesting that you correct this deficiency (R. 137(4) EPC).

In case you withdraw the application within the above-mentioned period, the examination fee will be refunded at a rate of 50% (Art. 11(b) RFees).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).

Registered Letter

EPO Form 2001 11.16AUWF (26.07.2024)



Coja, Michael
Primary Examiner
For the Examining Division

Enclosure(s): 4 page/s reasons (EPO Form 2906)

Datum
Date 31.07.2024
Date

Blatt
Sheet 1
Feuille

Anmelde-Nr:
Application No: 20 781 928.5
Demande n°:

The examination is being carried out on the **following application documents**

Description, Pages

3-28 as published

1, 2, 3b filed in electronic form on 12-05-2023

Claims, Numbers

1-9 filed in electronic form on 12-05-2023

Drawings, Sheets

1/16-16/16 as published

Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

D1 US 2018/271425 A1 (ROGERS BOBBY E [US] ET AL) 27 September 2018 (2018-09-27)

D2 EP 3 324 845 A1 (KURIN INC [US]) 30 May 2018 (2018-05-30)

D3 WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05)

D3 published on 05-12-2019 claims the priority date of 31-05-2018. Its content as filed is therefore considered to be comprised in the state of the art relevant to the question of novelty, pursuant to Article 54(3) EPC. Furthermore, the present application claims a priority date of 01-04-2019, which appears not to be valid since the content of the priority document (US201962827783P, see document filed on 26-10-2020 by the applicant) does not support the subject matter of the present application, in particular the claims as filed. D3 is therefore considered to be comprised in the state of the art, pursuant to Article 54(2) EPC.

1. The amendments filed with the letter dated 12-05-2023 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 123(2) EPC. The amendments concerned are the following:

- In claims 1 and 5, replacing the expression "**A fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source, a first portion of the fluid sample potentially having contaminants**" with the expression "**A device**", which is broader than what is supported by the original description.

- In claims 1 and 5, replacing the expression "**contaminant containment reservoir**" with the expression "**chamber**", which is broader than what is supported by the original description.

- In claim 1, removing the features "**wherein the resistive plug includes a film that is pierceable by a first of the subsequent pressure differentials**" (original claim 11) and "**wherein the resistive plug further includes a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film**" (original claim 11), while these features are clearly essential for solving the technical problem of sequestering a first portion of the fluid sample from a subsequent portion of the fluid sample (see Guidelines H-V.3.1).

- In claim 5, removing the features "**wherein the resistive plug includes a mesh with a dissolvable material that dissolves upon contact with a first of the subsequent portions of the fluid sample**" (original claim 13), while these features are clearly essential for solving the technical problem of sequestering a first portion of the fluid sample from a subsequent portion of the fluid sample (see Guidelines H-V.3.1).

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claims 1, 5 is not new within the meaning of Article 54(1) and (2) EPC.

2.1 D3 discloses **a device** (see fig.8-12, par.[0135]-[0150]) **comprising:**
an inlet (512) configured to connect with a fluid source;
an outlet (516) configured to connect with a fluid collection device;
a sample path (524) connected between the inlet and the outlet, the sample path further having a resistive plug (574) that is configured to inhibit at least a part of a first portion of a fluid sample from entering the sample path;
a chamber (514) connected between the inlet and the outlet, the chamber further having an air permeable fluid resistor (515) proximate the outlet, the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such

that upon receipt of the first portion of the fluid sample in the chamber (see fig.9, par.[0142]), subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet, the resistive plug including a membrane (574) that is pierceable; and a piercing member (578) configured to pierce the membrane (see fig.10, par. [0145]).

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

2.2. D3 discloses **a device (see fig.3, par.[0098]-[0112]) comprising:**
an inlet (312) configured to connect with a fluid source;
an outlet (316) configured to connect with a fluid collection device;
a sample path (324) connected between the inlet and the outlet, the sample path further having a resistive plug (323) that is configured to inhibit at least a part of a first portion of the fluid sample from entering the sample path, the resistive plug including a mesh; and
a chamber (314) connected between the inlet and the outlet, the chamber further having an air permeable fluid resistor (315) proximate the outlet, the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber (see par. [0106]), subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet (see par.[0111]).

The subject-matter of claim 5 is therefore not new (Article 54(1) and (2) EPC).

3. Dependent claims 2-4,6-9 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to novelty and/or inventive step.

3.1 The features of claims 2,7 are merely some straightforward possibilities which the skilled person would select, depending on the circumstances, without exercising inventive skill, in order to solve the problem posed.

3.2 The subject matter of claims 3,8 is already known from D3 (see par.[0021]).

Datum
Date 31.07.2024
Date

Blatt
Sheet 4
Feuille

Anmelde-Nr:
Application No: 20 781 928.5
Demande n°:

3.3 The subject matter of claims 4,9 is already known from D3 (see par.[0108]:"the selectively permeable member 315 is placed in a sealed configuration when transitioned to the second state").

3.4 The subject matter of claim 6 is already known from D3 (see par.[0103]).



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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/494,622	08/26/2024 08:20:36 PM Z ET	069366-0577657_KUR2C05US

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9839	FILED BY	Trent Tercenio
PATENT CENTER #	66923681	FILING DATE	10/25/2023
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. ROGERS
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 5

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
069366-0577657_KUR2C05US-NPL-001.pdf	9	Non Patent Literature	178 KB
069366-0577657_KUR2C05US-NPL-003.pdf	6	Non Patent Literature	221 KB
069366-0577657_KUR2C05US_Transmittal-Letter.pdf	1	Transmittal Letter	493 KB
069366-0577657_KUR2C05US_PTO_IDS-Form.pdf	4	Information Disclosure Statement (IDS) Form (SB08)	1272 KB
069366-0577657_KUR2C05US-NPL-	6	Non Patent Literature	1641 KB

002.pdf

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
069366- 0577657_KUR2C05US-NPL- 001.pdf	E703DE90488B0D02D0CA5D085349A59835B03A3A86E03DEF2 E758BA7BB459B42F85DECC46C2C1F0AB7A8CAC17ED3DEF2 63ED929E7FBF4313095EF86312A0EC32
069366- 0577657_KUR2C05US-NPL- 003.pdf	654A38EFC7808B934872A0AABBA4B5887B365C196C81535FF 08A7097BFBF352B0D6BC624C4730AA16640804BB8DC89ED6 D1D5E95D61ECD1F12A418F5F9BEDA7E
069366- 0577657_KUR2C05US_Trans mittal-Letter.pdf	A92D9484EB9544E0ADA01A0EC14F3812D285A1C5538B00C2 AB5042D1758E3F0B728D554DB28A651692877D305A8CD653F D070793DB1AC10530B2337DE959042D
069366- 0577657_KUR2C05US_PTO_I DS-Form.pdf	4CF22F48B26197B033BB7892E580B30F7948F12FC2A66C465B 3F7B8F8D6BC044E5DD13C11A7ACE629B96F125D4584486927 024CA095664AD1127472B6D487E21
069366- 0577657_KUR2C05US-NPL- 002.pdf	82E1479D3F15F49A563AD9DCC2F593ABF3F1243B10A20F4DB 4AEC21C54E7C159058EC962B4B80A74FCD892D16DE4F6BAB DD150D8C73093B8B0ABFF6323D58ECC

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	18494622
	Filing Date	10/25/2023
	First Named Inventor	Bobby ROGERS
	Art Unit	OPAP
	Client Number	069366
Page 1 of 1	Matter Number	0577657_KUR2C05US

GENERAL
<p>Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.</p> <p>Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention, nor is it intended to constitute an admission that such information is "analogous prior art".</p> <p>In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.</p>

TIMING
<p>In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.</p>

CERTIFICATION STATEMENT
<p>No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).</p>

FEE
<p>No fee is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).</p>

ADDITIONAL COMMENTS

SIGNATURE			
Signature	/Benjamin F. Hudson/	Date	2024-08-26
Name	Benjamin F. Hudson	Registration Number	71,474

21 May 2024

PILLSBURY WINTHROP SHAW PITTMAN, LLP
P.O. BOX 10500
McLean, VA 22102
USA

By Email Only:

james.conley@pillsburylaw.com
benjamin.hudson@pillsburylaw.com
suzanne.simpson@pillsburylaw.com
Docket_ip@pillsburylaw.com

To the attention of Jim Conley

P.K. 26 – First Office Action of:

IL Patent Application No.: 286812
Title: NON-VENTING BODILY FLUID SAMPLE OPTIMIZATION DEVICE AND SYSTEM
Filing Date: 29 September 2021
App. date: 1 April 2020
IL NP of PCT Patent Application No.: PCT/US2020/26276
Applicant(s): KURIN, INC.

Your ref.: 069366-0572161_KUR7N01IL

Our ref.: 1000-020-01

1

Dear Jim:

The Israel Patent Office (ILPO) has issued its first Office Action (substantive examination report) dated 20 May 2024, notifying the Applicant of the beginning of the examination process of the above identified IL Patent Application.

A response to the Office Action should be filed within four months and before 20 September 2024. Monthly extensions (up to four months) are available upon payment of government fees of about \$60 per month. Kindly note that the maximum extension period which can be obtained during substantive examination cannot exceed 12 months.

The examination is based on the following documents:

Description dated 29 September 2021

Claims dated 29 September 2021

Drawings dated 29 September 2021



The references hereunder relate to the following publications:

D1: US2018271425A1 [KURIN INC [US]] - 27/09/2018

D2: GB1378602A [BECTON DICKINSON CO] - 27/12/1974

D3:US2014112841A1 [BOEHRINGER INGELHEIM MICROPART [DE]] - 24/04/2014

In accordance with details below the following are the examiner's remarks regarding the allowability of the claims:

Defects were found in claims 1-20:

1. Novelty and Inventive Step

1.1. Claims 1-3,5-7,10,14-17 do not define a novel invention as per section 4 of the law, in light of D1, as detailed in the International Search Report.

1.2. Claims 1-20 do not define an invention with an inventive step as per section 5 of the law, in light of D1, D2, D3, as detailed in the International Search Report.

2

Duty of Disclosure

The applicant is hereby reminded that any change in the list of prior art or status of corresponding application (section 18c of the law) regarding oppositions, procedures to cancel corresponding applications / registrations must be reported to the ILPO up to the payment of the allowance fee.

We look forward to receiving your instructions in due course.

Yours sincerely,



Dr. Sarah Presenti, Adv
Katz, Presenti & Co



Submitted herewith

- > The original OA (p.k. 26) in Hebrew.
- > D1, D2, D3
- > Our invoice number 3465

3





רשות הפטנטים



מדינת ישראל
משרד המשפטים

פ.ק 26

תאריך: י"ב אייר תשפ"ד

20/05/2024

מספרם: 1000-020-01

לכבוד
כץ, פרזנטי ושות'
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.

הנדון: הודעה על ליקויים בבקשת פטנט מספר 286812

סימוכין: מכתבם מיום 26/12/2022, 19/10/2023

לתשומת לבכם: מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ"ז – 1967. מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ"ח – 1968. עליכם להשיב על הודעה זו תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה, עם בקשת הארכה שתוגש יש לשלם אגרה בסך 226.00 ש"ח בעד כל חודש או חלק ממנו. לא יינתנו יותר מארבעה חודשי ארכה בגין כל הודעה על ליקויים וסך כל תקופות הארכה במהלך הבחינה לא יעלה על 12 חודשים בהתאם לכללים שנקבעו בחוזר הרשם 035/2017-פטנטים.

הודעה זו מבוססת על המסמכים הבאים:

תביעות מתאריך: 29/09/2021

שרטוטים מתאריך: 29/09/2021

פרטי הבקשה מתאריך: 29/09/2021

ההפניות בהודעה זו מתייחסות לפרסומים הבאים:

D1: US2018271425A1 [KURIN INC [US]] - 27/09/2018

D2: GB1378602A [BECTON DICKINSON CO] - 27/12/1974

D3: US2014112841A1 [BOEHRINGER INGELHEIM MICROPART [DE]] - 24/04/2014

בהתאם למפורט בהמשך הודעה זו להלן סיכום עמדותי לעניין כשירות התביעות לפטנט:

בתביעה/ות מס' 1-20 נמצאו ליקויים.

ראה הנימוקים בהמשך הודעה זו.

בהתאם להוראות תקנה 41 הנני להודיעכם כי נמצאו בבקשה הנ"ל הליקויים המפורטים להלן:

1. חידוש והתקדמות המצאתית

1.1 תביעות מס' 1-3,5-7,10,14-17 אינן מגדירות אמצאה חדשה כהגדרתה בסעיף 4 לחוק, לאור פרסומים:

D1, כמפורט בדוח הבחינה הבין-לאומי.





רשות הפטנטים



מדינת ישראל
משרד המשפטים

1.2 תביעות 1-20 אינן מגדירות אמצאה שיש בה התקדמות המצאתית כהגדרתה בסעיף 5 לחוק, לאור פרסום/ים : D1, D2, D3, כמפורט בדוח הבחינה הבין-לאומי.

חובת המבקש לעדכן את הרשות

תשומת לבכם לסעיף 18 לחוק לעניין חובת המבקשת לעדכן את הרשות על כל שינוי שחל ברשימת האסמכתאות או הפרסומים כאמור בסעיף 18(א) לחוק ולסעיף 18ג לחוק בדבר אמצעי האכיפה.

הגשת תיקונים לפירוט במהלך בחינת הבקשה

באם יבוצעו תיקונים בבקשת הפטנט, תשומת לבכם מופנית לתקנה 22(א). יש לשלוח לרשות עותק מלא של חלק הבקשה שבו הוכנסו התיקונים תוך סימונם באופן ברור. יש לסמן תוספות בקו תחתי (כך: דוגמה) והשמטות בקו חוצה (כך: דוגמה). אין להגיש מחדש קבצים שלא תוקנו.

לתשומת לבכם:

א) בהתאם לתקנות 22(ב) ו-42 במידה שהנכם מתקנים את הפירוט כדי להתגבר על הליקויים בהודעה זו, עליכם לפרט את הליקויים שהתיקונים באים לסלק, לנמק כיצד תיקון הפירוט מתקן את הליקוי ולגבי תיקון בתביעות, כיצד עומד התיקון בתנאי סעיף 13 לחוק.

ב) בהתאם להוראות חוזר רשם 034/2017-פטנטים, במידה שבחינת הבקשה החלה לאחר 27.03.2017, תיקון פירוט בדרך של החלפת האמצאה שנבחנה ואשר לגביה הועלה ליקוי, באמצאה אחרת, בין אם היא הופיעה בתביעות מלכתחילה ובין אם תוארה בלבד, גם אם היא נובעת מהתיאור, אינו מהווה תיקון הליקוי ויביא לשליחת ההודעה לפני סירוב.

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

<https://israelpatents.justice.gov.il/#/en/patent-file/details/286812>

ראיון עם בוחן

בהתאם לה.ע. 23.3, המפורסמת באתר הרשות, ניתן לקיים ראיון עם הבוחן באמצעות פגישה במשרדי הרשות, בשיחה טלפונית או בהיוועדות חזותית.

רשות הפטנטים מעודדת קיום של קשר ישיר בין הבוחן למבקש או בא-כוחו באמצעות שירות זה. קיום ראיון עם בוחן מאפשר לרוב את ייעול וקיצור זמן הבחינה ואף לחיסכון בעלויות בתהליך הבחינה והאישור של בקשה לפטנט.

במסגרת הראיון ניתן לדון עם הבוחן בנושאים הקשורים לתיאור האמצאה והגדרתה, בליקויים שהועלו במהלך הבחינה ואף בתיקונים אפשריים לליקויים אלה.

תיאור הראיון יתבצע ישירות מול הבוחן (פרטי הקשר מופיעים מטה) וילווה בהודעה כתובה של יוזם הראיון שתפרט את הנושאים לדיון ואת הטיעונים העיקריים לגביהם.

לתשומת לבכם, בקשה לקיום ראיון אינה מהווה תשובה להודעת הליקויים כמשמעה בתקנה 42.

השגה בפני הרשם

רחוב אגודת ספורט הפועל מס' 1,
הגן הטכנולוגי מלחה בנין מס' 5
ירושלים, מיקוד 9695101
טל': 972-73-3927100 פקס: 972-2-6467774
<https://www.gov.il/he/departments/ilpo>





רשות המכס

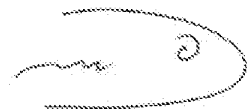


מדינת ישראל
משרד המשפטים

על פי סעיף 161 לחוק, הנכם רשאים להשיג על החלטתי בפני רשם הפטנטים תוך ארבעה חודשים ממועד משלוח ההודעה.

בתקווה לימים שקטים ובטוחים יותר.

בכבוד רב



מתן כוחיי
סגן הממונה על הבוחנים
טלפון : 073-3927255
דואר אלקטרוני : matanc@justice.gov.il



(Translation)

Reference No.: F1729JP01 Letter No.: 327992 Mailing Date: July 9, 2024 1

Notice of Allowance

Application Serial No.: 2021-558648
Drafting Date: July 4, 2024
Examiner: ISONO, Koji 3411 2Q00
Title of the Invention: NON-VENTING BODILY FLUID SAMPLE
OPTIMIZATION DEVICE AND SYSTEM
Number of Claims: 18
Applicant(s): KURIN, INC.
Agent: MURAKOSHI, Satoshi (4 others)

A decision is hereby made to grant patent right to the above identified patent application on the ground that no cause for rejecting the application has been found in the examination.

This is to certify that all the above-referenced items are identical to the JPO's official record.
Certificated: July 8, 2024
Administrative Official of Ministry of Economy, Trade and Industry, AKUTSU, Masamitsu

Note: Applicant must pay Issue Fee within 30 days from the mailing date indicated above.

(Translation)

Reference No.: F1729JP01 Letter No.: 327992 Mailing Date: July 9, 2024 2

- Type of Application: Non-Divisional Application
- Cited References: Yes
- Grace Period under Patent Act Article 30: No
- Amendment to Title of the Invention: No
- Deposit of Biological Material : N/A

(Translation)

Reference No.: F1729JP01 Letter No.: 327992 Mailing Date: July 9, 2024 3/E

Reference Information

Application Serial No.: 2021-558648

- FI

A61B 5/154 200 ,
G01N 1/10 V

- Search Fields (IPC, DB Name):

A61B 5/15-5/157
G01N 1/10

- References Cited :

US Patent Application Publication No.2018/0271425 (US,A1)
International Patent Application Publication No.2019/055487 (WO,A1)

- Non-patent literatures:

(Translation)

Reference No.: F1729JP01 Letter No.: 327992 Mailing Date: July 9, 2024 1

Notice of Allowance

Application Serial No.: 2021-558648
Drafting Date: July 4, 2024
Examiner: ISONO, Koji 3411 2Q00
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- Cited References: Yes
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- Amendment to Title of the Invention: No
- Deposit of Biological Material : N/A

(Translation)

Reference No.: F1729JP01 Letter No.: 327992 Mailing Date: July 9, 2024 3/E

Reference Information

Application Serial No.: 2021-558648

- FI

A61B 5/154 200 ,
G01N 1/10 V

- Search Fields (IPC, DB Name):

A61B 5/15-5/157
G01N 1/10

- References Cited :

US Patent Application Publication No.2018/0271425 (US,A1)
International Patent Application Publication No.2019/055487 (WO,A1)

- Non-patent literatures:

特許査定

特許出願の番号	特願 2 0 2 1 - 5 5 8 6 4 8
起案日	令和 6 年 7 月 4 日
特許庁審査官	磯野 光司 3 4 1 1 2 Q 0 0
発明の名称	非通気性体液サンプル最適化装置及びシステム
請求項の数	1 8
特許出願人	クリン インコーポレイテッド
代理人	村越 智史 (ほか 4 名)

この出願については、拒絶の理由を発見しないから、特許査定をします。

上記はファイルに記録されている事項と相違ないことを認証する。

認証日 令和 6年 7月 8日 経済産業事務官 坪 政光

注意：この書面を受け取った日から 3 0 日以内に特許料の納付が必要です。

- ・出願種別 通常
- ・参考文献 有
- ・特許法第30条適用 無
- ・発明の名称の変更 無

- ・菌寄託

参考情報

特許出願の番号 特願 2 0 2 1 - 5 5 8 6 4 8

・ F I

A 6 1 B 5 / 1 5 4 2 0 0 ,
G 0 1 N 1 / 1 0 V

・ 調査した分野 (I P C , D B 名)

A 6 1 B 5 / 1 5 - 5 / 1 5 7
G 0 1 N 1 / 1 0

・ 参考特許文献

米国特許出願公開第 2 0 1 8 / 0 2 7 1 4 2 5 (U S , A 1)
国際公開第 2 0 1 9 / 0 5 5 4 8 7 (W O , A 1)

・ 参考図書雑誌

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18494622
	Filing Date	2023-10-25
	First Named Inventor	Bobby ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0577657_KUR2C05US

U.S.PATENTS							Remove	
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear		
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If you wish to add additional Foreign Patent Document citation information please click the Add button							Add	
NON-PATENT LITERATURE DOCUMENTS							Remove	
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		18494622
	Filing Date		2023-10-25
	First Named Inventor	Bobby ROGERS	
	Art Unit	OPAP	
	Examiner Name	CENTRAL, DOCKET	
	Attorney Docket Number	069366-0577657_KUR2C05US	

1	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
2	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
3	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18494622
	Filing Date	2023-10-25
	First Named Inventor	Bobby ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0577657_KUR2C05US

CERTIFICATION STATEMENT			
Please see 37 CFR 1.97(e) to make the appropriate selection(s):			
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).			
OR			
☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).			
☐ See attached certification statement.			
☒ A certification statement is not submitted herewith.			
FEE			
☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.			
COPIES			
☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.			
SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.			

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/730,118	04/26/2022	Bobby E. ROGERS	069366-0572186_KUR3C01US	1667
27500 7590 09/23/2024 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER NGUYEN, HUONG Q	
			ART UNIT 3791	PAPER NUMBER
			NOTIFICATION DATE 09/23/2024	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

- (A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;
- (B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g., “means for”) or another linking word or phrase, such as “configured to” or “so that”; and
- (C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step”) in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as

otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No claim elements are interpreted under 112(f).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the junction of Claim 1 (referred to element 3007 in the specification 00160, which is not shown), the vent of Claim 1 (referred to as element 3010 in the spec 00161, which is not shown), and the air vent (Claim 1) must be shown with reference numbers in the claimed embodiment of Figure 30 or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or

"New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "3012" has been used to designate both fulcrum (0166 – published spec) and semi permeable barrier (0166 – published spec). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "3017" and "2\3008" have both been used to designate "the seal" (0166 – published spec), while "3008" has also been used to designate the sequestration chamber (0166 – published spec). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement

Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 1 is objected to because of the following informalities: “insludes” should be “includes.”

~~Appropriate correction is required.~~

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

The recitation of “~~and includes one or more air vents~~” is indefinite because it is unclear if the air vents are part of the wall or the air permeable blood barrier. It is assumed the air vents are part of the wall, however, clarification is requested.

~~Double Patenting~~

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to

examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159.

See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, or 7, 9, 10, 11, 12 of U.S. Patent No. 10827964 in view of Eldridge et al (US Pat No. 4207870).

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a blood sequestration device comprising; an inlet port; an outlet port; a sequestration chamber connected with the inlet port, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents (aperture in claim 3, 10 of Patent), the vent further including a cap that at least partially covers the wall and a one-way seal (flexible sheet, plug in claim 3, 10 of Patent)

abutting (claim 3, 12 of Patent) the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port, and a distal end connected with the outlet port; the sequestration chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

However, the patent doesn't expressly disclose the sequestration chamber connected to the inlet port via a junction. Eldridge et al teach that it is well-known in the art to provide an analogous blood sequestration device comprising inlet port (in hub 10 where cannula 14 is connected Col.2: 50-55), outlet port (cannula 18 in hub 12, Col.2: 50-55), sequestration chamber (28 and 30, Col.2: 63-65), the sequestration chamber connected to the inlet port via a junction (valve 20, Col.2: 57-6), and proximal end of sampling channel (32, Col.3: 52-54) connected to the inlet port via the junction, best seen in Figure 1 and 3, as an effective manner of connecting the inlet port to the sequestration chamber for controlled blood flow in the desired direction. Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the invention of the Patent such that the sequestration chamber is connected to the inlet port via a junction as taught by Eldridge, to provide an effective manner of connecting the two for controlled blood flow in the desired direction.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 8, or 15 of U.S. Patent No. 11311219 (Parent case of instant application) in view of Fischel (US Pub No. 20110306899).

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a blood sequestration device comprising; an inlet port; an outlet port; a sequestration chamber connected with the inlet port via the junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port; the sequestration chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

However, the Patent does not disclose one or more air vents. Fischel teach that it is well-known in the art to provide an analogous blood collection device comprising both an air permeable blood barrier 160 (0043 – “member 160 may be constructed out of any material which is capable of substantially preventing blood from passing through it while permitting air to vent through it”) as well as one or more air vents 336 that leads to ambient, best seen in Figure 16, as an effective configuration for the desired blood flow

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 17/730,118
Art Unit: 3791

Page 12

/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/730,118		Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN		Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS						
*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20110306899-A1	2011-12-15	BROWN; LEROY R.	A61B5/150572	600/581
	B					
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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)

Approved for use through 05/31/2024. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17730118	
	Filing Date		2022-04-26	
	First Named Inventor	Bobby E. ROGERS		
	Art Unit	3791		
	Examiner Name	NGUYEN, HUONG Q		
	Attorney Docket Number	069366-0572186_KUR3C01US		

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17730118
Filing Date	2022-04-26
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572186_KUR3C01US

1	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	☐
2	European Patent Office; Communication pursuant to Article 94(3) EPC, dated Oct. 31, 2018; 11 pages.	☐
3	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	☐
4	Japanese Patent Office, Notice of Reasons for Rejection dated Jun. 15, 2021, Application No. JP 2019-534792, 6 pages.	☐
5	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application No. JP2018-523384, dated Jul. 23, 2019, 5 pages.	☐

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EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/17/2024
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17730118
	Filing Date	2022-04-26
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572186_KUR3C01US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17730118
	Filing Date	2022-04-26
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572186_KUR3C01US

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Application Number	17730118
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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572186_KUR3C01US

1	BD Diagnostics, "Venous Blood Collection, BD Vacutainer Passive Shielding Blood Collection Needle " literature (2005) 2 pages.
2	Barnard, Dorothy R., et al. "Fibronectin (cold insoluble globulin) in the neonate," The Journal of Pediatrics, Vol. 102, Issue 3, March 1983, Pages 453-455.
3	Mayer, G.A. "A Method for the Reliable Determination of Clotting Time in Whole Blood," Canadian Medical Association Journal, June 15, 1955, Vol. 72, Pages 927-929.
4	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.
5	Pall Medical, "Leukotrap Filtration Systems for Whole Blood Derived Platelets, Leukotrap RC PL and Leukotrap PL Systems" literature, (2005) 8 pages.
6	Meissner, George F., et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, Vol. 39, No. 3., pp. 321-323, March 1963.
7	Sheppard, et al., Bacterial Contamination of Platelets for Transfusion: Recent Advances and Issues, LABMEDICINE, Vol. 36, No. 12, Dec. 2005 ("Sheppard 2005").

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EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/17/2024
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

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OR

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-17
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)

Approved for use through 05/31/2024. OMB 0651-0031

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	First Named Inventor	Bobby E. ROGERS		
	Art Unit	3791		
	Examiner Name	NGUYEN, HUONG Q		
	Attorney Docket Number	069366-0572186_KUR3C01US		

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	Filing Date	2022-04-26
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	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572186_KUR3C01US

1	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
2	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
3	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐

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CERTIFICATION STATEMENT

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☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Receipt date: 06/27/2024

17/730,118 - GAU: 3791

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6126643		2000-10-03	VAILLANCOURT VINCENT L	
	2	9764891		2017-09-19	AVILES VICTOR M	
	3	5147329		1992-09-15	BRANNON JAMES K	
	4	5518005		1996-05-21	BRANNON JAMES K	
	5	62845767		2019-05-09	BREWER MICHAEL	
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	1	20150314105		2015-11-05	GASPARYAN LEVON	

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	2	20150359473		2015-12-17	GARRETT CHAD	
	3	20160262677		2016-09-15	EBETSBERGER FRANZ	
	4	20160325085		2016-11-10	CHELAK TODD	
	5	20070031283		2007-02-08	DAVIS CHARLES Q	
	6	20190365303		2019-12-05	BULLINGTON GREGORY J	
	7	20180297303		2018-10-18	SEKIGUCHI TAKUMI	
	8	20190175087		2019-06-13	BULLINGTON GREGORY J	
	9	20210145336		2021-05-20	ROGERS BOBBY E	
	10	20060009713		2006-01-12	FLAHERTY PATRICE	

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	1	S5643474	JP		1981-10-12			☐
	2	1996005875	WO		1996-02-29	BAXTER INT		☒
	3	104107054	CN		2014-10-22	BECTON DICKINSON CO		☒
	4	104981203	CN		2015-10-14	MAGNOLIA MEDICAL TECHNOLOGIES INC		☒
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	1	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	2	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
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Filing Date	2022-04-26
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572186_KUR3C01US

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	Attorney Docket Number	069366-0572186_KUR3C01US

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572186_KUR3C01US

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17730118
	Filing Date	2022-04-26
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572186_KUR3C01US

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	1	S5825146	JP		1983-02-15	BECTON DICKINSON CO		☒
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Examiner Signature	/H Q NGUYEN/	Date Considered	09/17/2024
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-04-23
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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Receipt date: 02/06/2024

17/730,118 - GAU: 3791

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

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	Art Unit	OPAP	
	Examiner Name	CENTRAL, DOCKET	
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	1	4416291		1983-11-22	KAUFMAN JOSEPH		
	2	10299713		2019-05-28	PATTON RICHARD G		
	3	10265007		2019-04-23	BULLINGTON GREGORY		
	4	11395612		2022-07-26	BULLINGTON GREGORY J		
	5	10881343		2021-01-05	BULLINGTON GREGORY J		
	6	10596315		2020-03-24	BULLINGTON GREGORY J		
	7	11660030		2023-05-30	BULLINGTON GREGORY J		
	8	11259727		2022-03-01	BULLINGTON GREGORY J		

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	9	11737693		2023-08-29	BULLINGTON GREGORY J	
	10	11439332		2022-09-13	BULLINGTON GREGORY J	
	11	11589843		2023-02-28	BULLINGTON GREGORY J	
	12	11612340		2023-03-28	BULLINGTON GREGORY J	
	13	11234626		2022-02-01	BULLINGTON GREGORY J	
	14	10624977		2020-04-21	BULLINGTON GREGORY J	
	15	11653863		2023-05-23	BULLINGTON GREGORY J	
	16	11419531		2022-08-23	BULLINGTON GREGORY J	
	17	11786155		2023-10-17	BULLINGTON GREGORY J	
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	1	20220151525		2022-05-19	BULLINGTON GREGORY J	
	2	20220151527		2022-05-19	BULLINGTON GREGORY J	
	3	20200289039		2020-09-17	BULLINGTON GREGORY J	
	4	20210275068		2021-09-09	MIAZGA JAY M	
	5	20220304664		2022-09-29	HAMMER JEREMY	
	6	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	

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	1	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	2	Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.	☐

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-02-06
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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	Art Unit	OPAP	
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	2	20140309558		2014-10-16	FLETCHER GARY D	
	3	20140073990		2014-03-13	HOLMES ELIZABETH A	
	4	20140323911		2014-10-30	SLOAN DEBORAH	
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	1	Office Action (Non-Final Rejection) dated 9/24/2024 for U.S. Application No. 18/783,173 ; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	2	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 17/893,079 ; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-50).	☐
	3	Office Action (Non-Final Rejection) dated 9/23/2024 for U.S. Application No. 17/730,118 ; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-73).	☐
	4	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 18/783,088 ; Attorney Docket No. 069366-0580418_KUR2C06US (pages 1-60).	☐
	5	Office Action (Notice of Deficiencies) dated 10/14//2023 for IL App No. 309380 (pages 1-7).	☐

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FEE			
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☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.			
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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-10-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.			

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240
27500 7590 09/17/2024 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER NGUYEN, HUONG Q	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/19/2024 has been entered.

Claims 1-4, 6-7, and 32-41 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "junction" in **Claims 3-4 and 40-41** must be shown *with element numbers* or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element

(also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

- (A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;
- (B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g., “means for”) or another linking word or phrase, such as “configured to” or “so that”; and
- (C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step”) in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under

35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 40-41 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims recite a junction connecting the inlet port, sampling channel, and the chamber. However, as the instant invention appears to be drawn to the embodiment in Figure 24 and said junction has not been identified in Figure 24 per the drawing objection above, it is unclear that applicant has proper support for the embodiment of Figure 24 with the moving part having a first and second position along with said junction as claimed. If support exists for said junction, applicant is requested to point out portions of the disclosure showing said support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-4, 6-7, 32, 34-38, and 40-41 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Percarpio (US Pat No. 4106497 – cited by applicant).

In regard to Claim 1, Percarpio discloses a device comprising:

an inlet port (corresponding to location of needle 22) for receiving a blood sample, best seen in Figure 3 (Col.2: 58-Col.3: 23);

an outlet port 42, 44 (central passageway, opening -- Col.2: 58-Col.3: 23) – Figure 3;

a chamber (one channel) 92 connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample (“by capturing the blood within the indicator area including channels 92, there is no danger of contamination of blood being collected into chamber 32 and ultimately into an evacuated container through the passageway interconnected with rear needle 50” – Col.4: 16-39) – Figure 3,

the chamber including a material 90 that is air permeable (due to vents) and blood impermeable (“film of water expansible material 90... Three spaced channels 92 are formed in the film to provide air passageways for facilitating venting of the assembly and flow of blood into the indicator area where film 90 is located. The number of channels is a matter of choice. Thereafter, expansion of the film due to contact with the liquid closes channels 92 and locks the blood into the area of the location of the film” – Col.4: 16-39) – Figure 3;

a sampling channel 28 (extends through valve 78) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber – after blood is collected in channel 92 and the water expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube...The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through

the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4; and a housing (defined by hub 26 and adapter 40) that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 3.

2. (Previously Presented) The device in accordance with claim 1, wherein the material is configured to seal upon contact with the first portion of the blood sample (Col.4: 16-39; Col.5: 1-47).

3. (Previously Presented) The device in accordance with claim 1, further comprising a junction 32 connecting the inlet port (corresponding to location of needle 22) and the sampling channel 28 and the chamber 92, best seen in Figure 3.

4. (Previously Presented) The device in accordance with claim 3, wherein the junction 32 is configured to convey the subsequent portion of the blood sample to the outlet port 42, 44 while bypassing the chamber 92 (Col.4: 16-39; Col.5: 1-47).

6. (Previously Presented) The device in accordance with claim 1, wherein the device is configured with a moving part – 78 check valve with flaps 82, 84 – that is movable from a first position (closed) to a second position (open) to allow blood to bypass the chamber 92 and go through the sampling channel 28 – “The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through

the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes” (Col.5: 1-47), best seen in Figure 2 and 4.

7. (Previously Presented) The device in accordance with claim 6, the moving part 78, 82, 84 further configured to move from the first position to the second position after the first portion of blood flows into the chamber 92 – “tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube...The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes” (Col.5: 1-47).

32. (Previously Presented) The device in accordance with claim 6, wherein the moving part 78, 82, 84 is an inner chamber housing, best seen in Figure 3-4.

In regard to Claim 34, Percarpio discloses a device comprising:

- an inlet port (corresponding to location of needle 22) for receiving a blood sample, best seen in Figure 3 (Col.2: 58-Col.3: 23);

- an outlet port 42, 44 (central passageway, opening -- Col.2: 58-Col.3: 23) – Figure 3;

- a chamber (one channel) 92 connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample (“by capturing the blood within the indicator area including channels 92, there is no danger of contamination of blood being

collected into chamber 32 and ultimately into an evacuated container through the passageway interconnected with rear needle 50” – Col.4: 16-39) – Figure 3,

the chamber including an air permeable blood barrier due to vents (“Three spaced channels 92 are formed in the film to provide air passageways for facilitating venting of the assembly and flow of blood into the indicator area where film 90 is located. The number of channels is a matter of choice – Col.4: 16-39) – Figure 3;

a sampling channel 28 (extends through valve 78) connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port – after blood is collected in channel 92 and the water expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube...The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4; and

a housing (defined by hub 26 and adapter 40) that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 3.

35. (Previously Presented) The device in accordance with claim 34, wherein the air permeable blood barrier is configured to seal upon contact with the first portion of the blood sample (Col.4: 16-39; Col.5: 1-47).

36. (Previously Presented) The device in accordance with claim 34, wherein the device is configured with a moving part – 78 check valve with flaps 82, 84 – that is movable from a first position (closed) to a second position (open) to allow blood to bypass the chamber 92 and go through the sampling channel 28 – “The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes” (Col.5: 1-47), best seen in Figure 2 and 4.

37. (Previously Presented) The device in accordance with claim 36, the moving part 78, 82, 84 further configured to move from the first position to the second position after the first portion of blood flows into the chamber 92 -- after blood is collected in channel 92 and the water expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube...The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4.

38. (Previously Presented) The device in accordance with claim 36, wherein the moving part 78, 82, 84 is an inner chamber housing, best seen in Figure 3-4.

40. (Previously Presented) The device in accordance with claim 34, further comprising a junction 32 connecting the inlet port (corresponding to location of needle 22) and the sampling channel 28 and the chamber 92, best seen in Figure 3.

41. (Previously Presented) The device in accordance with claim 40, wherein the junction 32 is configured to convey the subsequent portion of the blood sample to the outlet port 42, 44 while bypassing the chamber 92, best seen in Figure 3-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 33 and 39 is/are rejected under 35 U.S.C. 103 as being unpatentable over Percarpio in view of Kaufman (US Pat No. 4312362).

Percarpio discloses the invention above but do not expressly disclose the device further comprising a locking mechanism configured to maintain the moving part in the first until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Kaufman teach that it is well-known in the art to provide a blood sampling device comprising a locking mechanism that maintain the moving part 26 in the first position (so that hole 48 is free) which allows air to escape (similar to in Percarpio), and then providing force to overcome the locking mechanism to enable movement of the moving part to the second position (to free hole 49), which enables collection of the blood into evacuated tube 16 when said tube is connected also similarly to Percarpio, best seen in Figure 2 and 7 (Col.6: 44-Col.7: 50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention of filing to modify Percarpio such that the device further comprising a locking

mechanism configured to maintain the moving part in the first until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position as taught by Kaufman to effectively maintain the moving part in the first position until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the

examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood

sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air

permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 3, and 20-21 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an

outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 and 8-9 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Response to Arguments

Applicant's arguments with respect to claim(s) above have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

Regarding the Drawing objections and 112(a) rejection, it is submitted that the mention of "a pathway" to the sampling channel 2422 in paragraph 0142 does not necessarily indicate a junction as recited in claims 3-4 and 40-41. As previously noted, Figure 24 does not clearly show said structure, the specification does not describe said structure in relation to said embodiment, and the specific reference to a junction in Figure 17A is not relevant as said figure does not apply to the instant embodiment. Therefore, said objections and rejections are maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

<i>Notice of References Cited</i>	Application/Control No. 17/893,079		Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN		Art Unit 3791	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-4312362-A	1982-01-26	Kaufman; Joseph	A61B5/15003	600/584
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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17893079	
	Filing Date		2022-08-22	
	First Named Inventor	Gino KANG		
	Art Unit	3791		
	Examiner Name	NGUYEN, HUONG Q		
	Attorney Docket Number	069366-0572192_KUR3C02US		

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	1	S5825146	JP		1983-02-15	BECTON DICKINSON CO		☒
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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-04-23
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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1	European Patent Office; Communication pursuant to Article 94(3) EPC, dated Oct. 31, 2018; 11 pages.	☐
2	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	☐
3	Communication Under Rule 71(3) EPC dated Apr. 22, 2020 for EP application No. 17840467.9. 125 pages.	☐
4	Japanese Patent Office, Notice of Reasons for Rejection dated Jun. 15, 2021, Application No. JP 2019-534792, 6 pages.	☐
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6	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application No. JP2018-523384, dated Jul. 23, 2019, 5 pages.	☐

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Receipt date: 06/27/2024

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	1	20150314105		2015-11-05	GASPARYAN LEVON	

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	2	20150359473		2015-12-17	GARRETT CHAD			
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1	S5643474	JP	1981-10-12	TORAY INDUSTRIES	☐
2	1996005875	WO	1996-02-29	BAXTER INT	☒
3	104107054	CN	2014-10-22	BECTON DICKINSON CO	☒
4	104981203	CN	2015-10-14	MAGNOLIA MEDICAL TECHNOLOGIES INC	☒
5	1717280	CN	2006-01-04	SECR DEFENCE	☒
6	2015150742	WO	2015-10-08	UNIV HULL	☒

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	1	Office Action (Non-Final Rejection) dated 04/25/2023 for US App. 16838017 (pages 1-20).	☐
	2	Office Action (Final Rejection) dated 01/29/2024 for US App. 16838017 (pages 1-44).	☐
	3	"Membrane Definition & Meaning," Merriam-Webster, Merriam-Webster, 22 Apr. 2009, www.merriam-webster.com/dictionary/ membrane. (Year: 2009).	☐

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4	Office Action (Advisory Action) dated 02/09/2024 for US App. 16838017 (pages 1-6).	☐
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7	First Office Action (Non-Final Rejection) dated 01/16/2024 for JP App. 2021-558648 (pages 1-6).	☐
8	First Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. 202080000666.0 (pages 1-11).	☐
9	Second Office Action (Non-Final Rejection dated 04/28/2024 for CN App. 202080000666.0 (pages 1-11).	☐
10	European Patent Office, Extended European Search Report for European Patent Application 21818838.1-1122, dated April 22, 2024, 11 pages.	☐
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14	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐

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Attorney Docket Number	069366-0572192_KUR3C02US

15	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
16	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐
17	Advisory Action dated 09/29/2023 for US Application 17893079, pages 1-24.	☐
18	European Patent Office, Examination Report for European Patent Application 22181212.6-1122, dated September 28, 2023, pages 1-5.	☐
19	European Patent Office, Extended European Search Report for European Patent Application 20781928.5-1122 dated October 28, 2022, pages 1-10.	☐
20	Rule 70(a) Communication for European Application No. 20781928.5-1122 dated November 15, 2022, 1 page.	☐
21	International Search Report and Written Opinion dated 19 March 2020 for PCT application no. PCT/US2020/023617. pages.	☐
22	International Search Report and Written Opinion dated 28 September 2021 for PCT application no. PCT/US2021/035294. 7 pages.	☐
23	European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated October 24, 2022, pages 1-10.	☐
24	Australian Patent Office, Australian Examination Report No. 1 for Application No. 2021120 622 dated March 18, 2022, 3 pages.	☐
25	Notice of Allowance mailed 03-01-2023; Attorney Docket No. 069366-0572419_KUR2D01AU. 3 pages.	☐

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17893079
Filing Date	2022-08-22
First Named Inventor	Gino KANG
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572192_KUR3C02US

26	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
27	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
28	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
29	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐
30	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐
31	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
32	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
33	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
34	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
35	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
36	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐

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First Named Inventor	Gino KANG
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572192_KUR3C02US

37	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
38	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
39	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
40	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐
41	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐
42	Office Action (Non-Final Rejection) dated 01/25/2024 for IL App. 302893 (pages 1-3).	☐
43	Notice of Allowance mailed 01-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
44	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
45	Office Action (Non-Final Rejection) dated 10/04/2023 for US App. No. 17538990 (pages 1-47)	☐
46	Notice of Allowance mailed 09-14-2023; Attorney Docket No. 069366-0574152_KUR2D02IL. 90 pages.	☐
47	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐

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First Named Inventor	Gino KANG
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572192_KUR3C02US

48	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
49	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	☐
50	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	☐

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Examiner Signature	/H Q NGUYEN/	Date Considered	09/06/2024
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)

Approved for use through 05/31/2024. OMB 0651-0031

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	Filing Date		2022-08-22	
	First Named Inventor	Gino KANG		
	Art Unit	3791		
	Examiner Name	NGUYEN, HUONG Q		
	Attorney Docket Number	069366-0572192_KUR3C02US		

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1	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
2	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
3	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐

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Examiner Signature	/H Q NGUYEN/	Date Considered	09/06/2024
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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Receipt date: 01/19/2024

17/893,079 - GAU: 3791

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

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	1	4416291		1983-11-22	KAUFMAN JOSEPH		
	2	10299713		2019-05-28	PATTON RICHARD G		
	3	10265007		2019-04-23	BULLINGTON GREGORY		
	4	11395612		2022-07-26	BULLINGTON GREGORY J		
	5	10881343		2021-01-05	BULLINGTON GREGORY J		
	6	10596315		2020-03-24	BULLINGTON GREGORY J		
	7	11660030		2023-05-30	BULLINGTON GREGORY J		
	8	11259727		2022-03-01	BULLINGTON GREGORY J		

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	9	11737693		2023-08-29	BULLINGTON GREGORY J	
	10	11439332		2022-09-13	BULLINGTON GREGORY J	
	11	11589843		2023-02-28	BULLINGTON GREGORY J	
	12	11612340		2023-03-28	BULLINGTON GREGORY J	
	13	11234626		2022-02-01	BULLINGTON GREGORY J	
	14	10624977		2020-04-21	BULLINGTON GREGORY J	
	15	11653863		2023-05-23	BULLINGTON GREGORY J	
	16	11419531		2022-08-23	BULLINGTON GREGORY J	
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	1	20220151525		2022-05-19	BULLINGTON GREGORY J	
	2	20220151527		2022-05-19	BULLINGTON GREGORY J	
	3	20200289039		2020-09-17	BULLINGTON GREGORY J	
	4	20210275068		2021-09-09	MIAZGA JAY M	
	5	20220304664		2022-09-29	HAMMER JEREMY	
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	1	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	2	Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. No. 202080000666.0 (pages 1-28).	☐

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-01-19
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
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8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,088	07/24/2024	Bobby E. ROGERS	069366-0580418_KUR2C06US	2051
27500 7590 09/17/2024 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER ABOUELELA, MAY A	
			ART UNIT 3791	PAPER NUMBER
			NOTIFICATION DATE 09/17/2024	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 08/26/2024. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 11 is objected to because of the following informalities: the phrase “a sample collection device” in line 2 should be amended to read –the blood sample collection device--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1, 6-9, 11, 12, 14, 19-22, 24 and 25 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Patton et al (US 2008/0145933).

As to claims 1 and 14, Patton discloses a device (blood sampling device 500, par.38-40, fig.5) comprising:

an inlet port for receiving a blood sample (inlet/opening connecting needle 508 to input tubing 514, par.38-40, fig.5);

an outlet port (needle 510, fig.5);

a chamber (tubing 516 and reservoir 504, par.38-40, fig.5) comprising a flexible material (flexible material of tubing 516 and reservoir 504), wherein the chamber is connected with the inlet port (516 and 504 are connected to inlet of tubing 514, as best seen in fig.5) and configured to collect a first portion of the blood sample (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, par.40, fig.5) when under a drawing force applied from the outlet port from a blood sample collection device (pre vacuumed effect of vessel 506 withdraws blood, first needle 508 can be inserted into a patient to procure a blood sample. In FIG. 5, the first needle 508 is shown inserted into a vein 520. The second needle 510 is shown inserted into the one or more sample vessels 506 that have been vacuum-sealed. The vacuum in each of the one or more sample vessels 506 causes blood to pass from the vein 520 to the diversion mechanism 512, par.40); and

a sampling channel (tubings 514 and 518 connected with inlet of tubing 214, par.38-40, as best seen in fig.4) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port (which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, ar.38-40, fig.5).

As to claims 6 and 19, Patton discloses the device, further comprising a valve (diversion mechanism 512 having valve 60, par.38-41, fig.5) configured to initially close off the sampling channel (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 7 and 20, Patton discloses the device, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 8 and 21, Patton discloses the device, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at

which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, as best seen from fig.5 the subsequent blood will bypass reservoir 504 and flows straight from inlet of 502 to tubings 514 and 518).

As to claims 9 and 22, Patton discloses the device, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, fig.5).

As to claims 11 and 24, Patton discloses the device, further comprising a patient needle (patient needle 508, par.38-40, fig.5) and a sample collection device (sample vessel 506, par.38-40, fig.5).

As to claims 12 and 25, Patton discloses the device, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (the data suggests that fewer false positive test results for the presence of microbes in blood are obtained over conventional methods when initially-drawn volumes of blood are not used in microbial testing, par.54).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 2-5 and 15-18 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933) in view of Flaherty et al (US 2006/0009713).

As to claims 2-5 and 15-18, Patton discloses the invention substantially above, wherein a housing of the diverting mechanism is separate from a blood impermeable membrane, but failed to explicitly teach a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample, and causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port, and wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

However, Flaherty discloses an analogous blood sampling device, wherein the blood sampling chamber comprises (liquid impenetrable, air-permeable membrane 45, par.39, fig.8-10), wherein blood flows into the blood collection chamber 39, air is displaced from the blood collection chamber 39, through the membrane 45 and air opening or openings 46, respectively. This facilitates the substantially continual and unhindered flow of blood from the patient 106 and into the blood collection chamber 39

to collect the desired quantity of blood into the blood collection chamber 39 (par.40, fig.8-10).

Since blood impermeable membrane is well-known in the art, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to include a blood impermeable membrane in reservoir 504 taught by Patton's invention, as blood impermeable membrane 45 taught by Flaherty's invention to facilitate the continual and unhindered flow of blood from the patient and into the blood collection chamber, as taught by Flaherty's invention (par.40).

6. Claim(s) 13 and 26 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933).

As to claims 13 and 26, Patton discloses the volume of blood withdrawn into the one or more pre-sample reservoirs 504 is at least equal to the collective volumes of the first needle 508, the flexible, sterile input tubing 516, the diversion mechanism 512, and the first sterile output tubing 516 (par.40), but failed to explicitly teach the chamber has a volume of less than 1.5 cubic centimeters. However, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to allow reservoir 504 to collect blood volume less than 1.5 cubic centimeters, since it has been that discovering the optimum value of a result of effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215(CCPA 1980).

Allowable Subject Matter

7. Claims 10 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For

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/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

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*	B	US-4412548-A	1983-11-01	Hoch; Louis	A61B5/150213	600/577
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18/783,088 - GAU: 3791

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	First Named Inventor	Bobby E. ROGERS	
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	3	5972294		1999-10-26	SMITH JOHN L		
	4	6187347		2001-02-13	PATTERSON JAMES A		
	5	6599474		2003-07-29	EVTODIENKO VLADIMIR		
	6	8197420		2012-06-12	PATTON RICHARD G		
	7	8535241		2013-09-17	BULLINGTON GREGORY		
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	9	9155495		2015-10-13	BULLINGTON GREGORY J	
	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
	13	9022951		2015-05-05	BULLINGTON GREGORY	
	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
	16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
	18	9877675		2018-01-30	BAID RISHI	
	19	4444203		1984-04-24	ENGELMAN ALLAN	

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	20	6398743		2002-06-04	HALSETH THOR R	
	21	9022950		2015-05-05	BULLINGTON GREGORY	
	22	4436098		1984-03-13	KAUFMAN JOSEPH	
	23	9138572		2015-09-22	ZEYTOONIAN PAUL	
	24	8568371		2013-10-29	SIOPEs WILLIAM	
	25	8540663		2013-09-24	DAVEY CHRISTOPHER T	
	26	8523826		2013-09-03	LAYTON JR RUSSELL K	
	27	4057050		1977-11-08	SARSTEDT WALTER	
	28	8864684		2014-10-21	BULLINGTON GREGORY J	
	29	5749857		1998-05-12	CUPPY MICHAEL J	
	30	9204864		2015-12-08	BULLINGTON GREGORY J	

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	31	3874367		1975-04-01	AYRES WALDEMAR A	
	32	3886930		1975-06-03	RYAN GEORGE R	
	33	4106497		1978-08-15	PERCARPIO EDWARD P	
	34	4154229		1979-05-15	NUGENT EDWARD L	
	35	4980297		1990-12-25	HAYNES JOHN L	
	36	9820682		2017-11-21	ROGERS BOBBY E	
	37	10010282		2018-07-03	ROGERS BOBBY E	
	38	10143412		2018-12-04	ROGERS BOBBY E	
	39	11185266		2021-11-30	ROGERS BOBBY E	
	40	10827964		2020-11-10	ROGERS BOBBY E	
	41	11311219		2022-04-26	ROGERS BOBBY E	

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	43	3648684		1972-03-14	BARNWELL CLEORA W	
	44	4056101		1977-11-01	GEISSLER ULRICH C	
	45	4416290		1983-11-22	LUTKOWSKI LAWRENCE	
	46	8070725		2011-12-06	CHRISTENSEN KELLY D	
	47	4349035		1982-09-14	THOMAS JOSEPH J	
	48	4813433		1989-03-21	DOWNEY JOHN M	
	49	5401262		1995-03-28	KARWOSKI THEODORE	
	50	3859998		1975-01-14	THOMAS JOSEPH JOHN	
	51	4373535		1983-02-15	MARTELL MICHAEL D	
	52	4690154		1987-09-01	WOODFORD TIMOTHY	

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	53	5097842		1992-03-24	BONN GINA B	
	54	5865803		1999-02-02	MAJOR MIKLOS	
	55	5873841		1999-02-23	BRANNON JAMES K	
	56	6013037		2000-01-11	BRANNON JAMES K	
	57	6913580		2005-07-05	STONE BENJAMIN CURTIS	
	58	11213232		2022-01-04	IVOSEVIC MILAN	
	59	6626884		2003-09-30	DILLON JAGMOHANBIR SINGH	
	60	4904240		1990-02-27	HOOVER ROCKLIN L	
	61	4673386		1987-06-16	GORDON MARK G	
	62	7461671		2008-12-09	EHWALD RUDOLF	
	63	6506182		2003-01-14	ESTABROOK BRIAN K	

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	65	3848579		1974-11-19	VILLA REAL A	
	66	6106509		2000-08-22	LOUBSER PAUL G	
	67	3494352		1970-02-10	RUSO RONALD D	
	68	6224561		2001-05-01	SWENDSON DAVID L	
	69	7055401		2006-06-06	PRYBELLA JOHN R	
	70	5135489		1992-08-04	JEPSON STEVEN C	
	71	5811658		1998-09-22	VAN DRIEL MICHAEL R	
	72	3604410		1971-09-14	WHITACRE GARY L	
	73	5772608		1998-06-30	DHAS V VARAPRABHU	
	74	4150089		1979-04-17	LINET MICHAEL S	

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	76	4193400		1980-03-18	LOVELESS JAMES C	
	77	6843775		2005-01-18	HYUN DONGCHUL D	
	78	7666166		2010-02-23	EMMERT MICHAEL	
	79	7479131		2009-01-20	MATHIAS JEAN-MARIE	
	80	8377040		2013-02-19	BURKHOLZ JONATHAN KARL	
	81	5417673		1995-05-23	GORDON MARK G	
	82	6638252		2003-10-28	MOULTON WILLIAM G	
	83	3945380		1976-03-23	DABNEY WILLIAM C	
	84	5100394		1992-03-31	DUDAR THOMAS E	
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	87	6860871		2005-03-01	KURACINA THOMAS C	
	88	6945948		2005-09-20	BAINBRIDGE MARLENE	
	89	7306736		2007-12-11	COLLINS GREGORY R	
	90	5691486		1997-11-25	BEHRINGER BRUCE E	
	91	5980830		1999-11-09	SAVAGE DOUGLAS ROBERT	
	92	5045185		1991-09-03	OHNAKA YUKIHIRO	
	93	5632906		1997-05-27	ISHIDA NOBORU	
	94	6695004		2004-02-24	RAYBUCK JOHN L	
	95	6733433		2004-05-11	FELL CLAUDE	
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	98	5439450		1995-08-08	HAEDT LORI E	
	99	6905483		2005-06-14	NEWBY C MARK	
	100	5431811		1995-07-11	TUSINI ANDREA	
	101	6736783		2004-05-18	BLAKE KEVIN R	
	102	7052603		2006-05-30	SCHICK KARL G	
	103	3835835		1974-09-17	THOMPSON R	
	104	4416291		1983-11-22	KAUFMAN JOSEPH	
	105	10299713		2019-05-28	PATTON RICHARD G	
	106	10265007		2019-04-23	BULLINGTON GREGORY	
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	109	10596315		2020-03-24	BULLINGTON GREGORY J	
	110	11660030		2023-05-30	BULLINGTON GREGORY J	
	111	11259727		2022-03-01	BULLINGTON GREGORY J	
	112	11737693		2023-08-29	BULLINGTON GREGORY J	
	113	11439332		2022-09-13	BULLINGTON GREGORY J	
	114	11589843		2023-02-28	BULLINGTON GREGORY J	
	115	11612340		2023-03-28	BULLINGTON GREGORY J	
	116	11234626		2022-02-01	BULLINGTON GREGORY J	
	117	10624977		2020-04-21	BULLINGTON GREGORY J	
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	120	11786155		2023-10-17	BULLINGTON GREGORY J	
	121	11789017		2023-10-17	BULLINGTON GREGORY J	
	122	3848581		1974-11-19	CINQUALBRE P	
	123	6126643		2000-10-03	VAILLANCOUERT VINCENT L	
	124	9764891		2017-09-19	AVILES VICTOR M	
	125	5147329		1992-09-15	BRANNON JAMES K	
	126	5518005		1996-05-21	BRANNON JAMES K	
	127	62845767		2019-05-09	BREWER MICHAEL	
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	2	20030082074		2003-05-01	JURIK FRANKLIN A	
	3	20030185707		2003-10-02	IWAKI YOSHIHIDE	
	4	20040116830		2004-06-17	TRUDEAU WILLIAM M	
	5	20090299253		2009-12-03	HURSEY FRANCIS X	
	6	20130158506		2013-06-20	HARRIS ADRIENNE ROSE	
	7	20150246352		2015-09-03	BULLINGTON GREGORY J	
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	13	20180271425		2018-09-27	ROGERS BOBBY E	
	14	20080319346		2008-12-25	CRAWFORD JAMIESON	
	15	20100057004		2010-03-04	CHRISTENSEN KELLY D	
	16	20070088279		2007-04-19	SHUE MING-JENG	
	17	20080145933		2008-06-19	PATTON RICHARD G	
	18	20040054333		2004-03-18	THEEUWES FELIX	
	19	20100010372		2010-01-14	BROWN LEROY R	
	20	20080167577		2008-07-10	WEILBACHER EUGENE E	
	21	20080086085		2008-04-10	BROWN LEROY R	
	22	20070083162		2007-04-12	OREAGAN JAMES	

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	24	20120016266		2012-01-19	BURKHOLZ JONATHAN KARL	
	25	20130317391		2013-11-28	BULLINGTON GREGORY J	
	26	20160174888		2016-06-23	BERTHIER ERWIN	
	27	20050240161		2005-10-27	CRAWFORD JAMIESON W M	
	28	20040147855		2004-07-29	MARSDEN STEWART	
	29	20040073171		2004-04-15	ROGERS BOBBY E	
	30	20050004524		2005-01-06	NEWBY C MARK	
	31	20030105414		2003-06-05	LEONG ALVIN TAN CHEE	
	32	20020004647		2002-01-10	LEONG ALVIN TAN CHEE	
	33	20140155781		2014-06-05	BULLINGTON GREGORY J	

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	37	20170020427		2017-01-26	ROGERS BOBBY E	
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	39	20050007524		2005-01-13	LUO FANG-CHEN	
	40	20140039348		2014-02-06	BULLINGTON GREGORY J	
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	46	20180353117		2018-12-13	BULLINGTON GREGORY J	
	47	20190159711		2019-05-30	ROGERS BOBBY E	
	48	20050245885		2005-11-03	BROWN LEROY	
	49	20110306899		2011-12-15	BROWN LEROY R	
	50	20130116599		2013-05-09	BULLINGTON GREGORY J	
	51	20050273019		2005-12-08	CONWAY HUGH	
	52	20150351678		2015-12-10	BULLINGTON GREGORY	
	53	20220160271		2022-05-26	IVOSEVIC MILAN	
	54	20050161112		2005-07-28	EHWALD RUDOLF	
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	57	20220151525		2022-05-19	BULLINGTON GREGORY J	
	58	20220151527		2022-05-19	BULLINGTON GREGORY J	
	59	20200289039		2020-09-17	BULLINGTON GREGORY J	
	60	20210275068		2021-09-09	MIAZGA JAY M	
	61	20220304664		2022-09-29	HAMMER JEREMY	
	62	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	
	63	20150314105		2015-11-05	GASPARYAN LEVON	
	64	20150359473		2015-12-17	GARRETT CHAD	
	65	20160262677		2016-09-15	EBETSBERGER FRANZ	
	66	20160325085		2016-11-10	CHELAK TODD	

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68	20190365303		2019-12-05	BULLINGTON GREGORY J	
69	20180297303		2018-10-18	SEKIGUCHI TAKUMI	
70	20190175087		2019-06-13	BULLINGTON GREGORY J	
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	5	1378602A	GB		1974-12-27	BECTON DICKINSON CO		☐
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	10	2993646	CA		2017-02-02	KURIN INC		☐
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	16	6643474B2	JP		2020-02-12	クリン インコーポレイ テッド		☒
	17	6734490	JP		2020-08-05	クリン インコーポレイ テッド		☒
	18	2001000424	JP		2001-01-09	NISSHO KK		☒
	19	2012016496A	JP		2012-01-26	TERUMO CORP		☒
	20	2016504075	JP		2016-02-12	マグノリア メディカル テクノロジーズ, イン コーポレイテッド		☒
	21	2019534792A	JP		2019-12-05	ブライメタルズ・テクノ ロジーズ・オーストリ ア・ゲーエムペーハー		☒
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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580418_KUR2C06US

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☒ A certification statement is not submitted herewith.

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☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
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25	First Office Action (Non-Final Rejection) dated 01/16/2024 for JP App. 2021-558648 (pages 1-6).	☐
26	First Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. 202080000666.0 (pages 1-11).	☐
27	Second Office Action (Non-Final Rejection dated 04/28/2024 for CN App. 202080000666.0 (pages 1-11).	☐
28	European Patent Office, Extended European Search Report for European Patent Application 21818838.1-1122, dated April 22, 2024, 11 pages.	☐

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	18783088
Filing Date	2024-07-24
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580418_KUR2C06US

29	Australian Patent Office, Examination Report No. 1 for for Australian Patent Application 2021202622, dated March 18, 2022, 3 pages.	☐
30	Office Action (Final Rejection) dated 08/25/2023 for US Application No. 18113710 (pages 1-50).	☐
31	European Patent Office, Extended European Search Report for European Patent Application 23155927.9-1122, dated July 26, 2023, pages 1-8.	☐
32	Notice of Allowance mailed 04-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
33	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
34	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐
35	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
36	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐
37	Advisory Action dated 09/29/2023 for US Application 17893079, pages 1-24.	☐
38	European Patent Office, Examination Report for European Patent Application 22181212.6-1122, dated September 28, 2023, pages 1-5.	☐
39	European Patent Office, Extended European Search Report for European Patent Application 20781928.5-1122 dated October 28, 2022, pages 1-10.	☐

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Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580418_KUR2C06US

40	Rule 70(a) Communication for European Application No. 20781928.5-1122 dated November 15, 2022, 1 page.	☐
41	International Search Report and Written Opinion dated 19 March 2020 for PCT application no. PCT/US2020/023617. pages.	☐
42	International Search Report and Written Opinion dated 28 September 2021 for PCT application no. PCT/US2021/035294. 7 pages.	☐
43	European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated October 24, 2022, pages 1-10.	☐
44	Australian Patent Office, Australian Examination Report No. 1 for Application No. 2021120 622 dated March 18, 2022, 3 pages.	☐
45	Notice of Allowance mailed 03-01-2023; Attorney Docket No. 069366-0572419_KUR2D01AU. 3 pages.	☐
46	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
47	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
48	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
49	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐
50	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18783088
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	Attorney Docket Number	069366-0580418_KUR2C06US

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	09/16/2024
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
<small>¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.</small>			

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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580418_KUR2C06US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18783088
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580418_KUR2C06US

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Application Number	18783088
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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580418_KUR2C06US

1	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
2	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
3	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
4	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
5	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
6	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
7	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
8	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
9	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
10	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐
11	Office Action (Non-Final Rejection) mailed 04/16/2024 for Application No. 16838017, pages 1-19.	☐

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Filing Date	2024-07-24
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580418_KUR2C06US

12	Second Office Action dated 04/28/2024 for CN Application No. 202080000666.0, pages 1-28.	☐
13	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
14	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
15	European Patent Office, Examination Report for European Patent Application 21818838.1, dated April 22, 2024, pages 1-11.	☐
16	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐
17	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	☐

If you wish to add additional non-patent literature document citation information please click the Add button **EXAMINER SIGNATURE**

Examiner Signature	/MAY A ABOUELELA/	Date Considered	09/16/2024
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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/494,622	10/16/2024 02:59:43 PM Z ET	069366-0577657_KUR2C05US

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9839	FILED BY	Trent Tercenio
PATENT CENTER #	67592279	FILING DATE	10/25/2023
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. ROGERS
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 7

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
069366- 0577657_KUR2C05US_PTO _IDS-Form.pdf	5	Information Disclosure Statement (IDS) Form (SB08)	1272 KB
069366- 0577657_KUR2C05US_Transmittal-Letter.pdf	1	Transmittal Letter	493 KB
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פ.ק 26

תאריך: י"ב תשרי תשפ"ה
14/10/2024
מספרכם: 1000-016-04

To
KATZ, PRESENTI AND CO.
11 Menachem Begin St. Rogovin-Tidhar Tower, 31st Floor Ramat Gan 5268104,

Dear Sir / Madam

Subject: Notice of Deficiencies for Patent Application 309380

Ref: Your letter dated 26/07/2024

Please note: any reference made to the "Law" shall mean the Patent Law 5727 - 1967, and any reference made to the "Regulations" shall mean the Patent Regulations (Office Practice, Rules of Procedure, Documents and Fees) 5728 - 1968. You shall reply to this Notice within four months. However, you are entitled to request an extension. **According to the rules set forth in Commissioner's Circular 035/2017-Patents, a maximum extension of 4 months will be allowed per Notice of Deficiencies, while the total period for all extensions approved during the examination shall not exceed 12 months.** With the filed request for extension, a fee of 226.00 NIS shall be paid per month of extension or part of it.

This Notice is based on the following documents:

Description (Date: 13/12/2023)

Drawings (Date: 13/12/2023)

Claims (Date: 26/07/2024)

Reference is made to the following document/s:

D1: US 2014309558 A1 [BECTON DICKINSON CO [US]] - 16/10/2014

D2: US 2014073990 A1 [THERANOS INC [US]] - 13/03/2014

As detailed below, my decision regarding the allowability of the claims is as follows:

Claim/s 1-26 is/are not allowable according to Section 17(a) of the Law, due to deficiencies.

Please see the reasoning below.

According to **Regulation 41**, I hereby inform you that the application contains the following deficiencies:

1. The examination is based on the following notices:

1.1 I hereby inform you that:



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According to **Section 24(c) of the Law**, the date of the present application, which is a divisional application of application number 300848, is deemed to be the same (22/07/2016) as that of the parent application.

2. **Novelty and Inventive step**

2.1 Claims 1-2,4,6-15,17,19-26 do not meet the requirements of **Section 5 of the Law**, since the subject matter of the claims does not involve an inventive step in view of documents: D1 ,D2.

Independent Claim 1:

D1 discloses a blood sampling device with:

- An inlet port (Fig. 5-6 element 40; [0037])
- An outlet port (Fig. 5-6 elements 45-48; [0038])
- A chamber (Fig. 1; [0037]) connected to the inlet port
- A sampling channel (Fig. 1, element 42; [0037]) connected to the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port

D1 also mentions that the chamber collects an initial portion of blood ([0017]). However, D1 does not explicitly disclose that the chamber collects the first portion "when under a drawing force applied from the outlet port from a blood sample collection device."

In a similar field of endeavour, D2 teaches a blood sampling system where a drawing force from a blood collection device is used to draw blood through the system ([0164,0186,0188]).

It would have been obvious to a person of ordinary skill in the art to modify the device of D1 to use a drawing force from the outlet port as taught by D2. This modification would provide the advantage of using a single force to both collect the initial portion in the chamber and draw the subsequent portion through the sampling channel, simplifying the blood collection process.

Independent Claim 14:

Starting from D1 as the closest prior art, the differences are:

1. The chamber is made of flexible material
2. The chamber collects blood under a drawing force from the outlet port

Regarding difference 1, D2 teaches a blood sampling device with a flexible reservoir for collecting a portion of blood ([0251]). It would have been obvious to use a flexible material





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for the chamber in D1 to allow for visual or tactile indication of when the chamber is filled.
Regarding difference 2, as discussed for claim 1, this would have been obvious in view of D2.

Claims 2 and 15:

D1 disclose a blood impermeable membrane facilitating the chamber collecting the first portion of the blood sample ([0035]).

Claims 4 and 17:

A separate housing is a common feature in medical devices and would have been obvious to include.

Claims 6-9 and 19-22:

Valves for controlling fluid flow are common in the art (see D2: [0043],[0166]).

Claims 10 and 23:

A housing defining the ports and channels is a common feature in medical devices and would have been obvious to include.

Claims 11 and 24:

Including a patient needle and sample collection device would have been obvious for a complete blood sampling system.

Claims 12-13 and 25-26:

None of D1-D4 explicitly disclose the claimed volume ranges. However, optimizing the volume of a sampling chamber is routine experimentation and thus and would have been obvious to include.

Therefore, the subject matter of claims 1-2,4,6-15,17,19-26 lacks inventive step.

2.2 Claims 3,5,16,18 meet the requirements of **Sections 4 and 5 of the Law**, because the invention defined in the claims was not published prior to the application date and it involves an inventive step.

3. The claims

3.1 Claims 1-26 do not meet the requirements of **Section 13(a) of the Law**, since the claimed subject matter is not reasonably supported by the specification.

Independent Claim 1:





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- The specification primarily describes the sequestration chamber filling due to the patient's blood pressure, not a drawing force from the outlet port. While vacuum force is mentioned (paragraph [0046]), it's not the primary mechanism described for filling the sequestration chamber in most embodiments.
- The specification doesn't explicitly describe the chamber as "configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port."

Independent Claim 14:

- While flexible materials are mentioned, the specification doesn't explicitly describe the chamber itself as being made of a flexible material in most embodiments. The primary descriptions involve rigid or semi-rigid housings.
- As with Claim 1, the specification doesn't focus on using a drawing force from the outlet port as the primary mechanism for filling the sequestration chamber.

Claims 2-4,15-17 introduce a "blood impermeable membrane." While the specification describes air permeable blood barriers, it doesn't explicitly use the term "blood impermeable membrane" in the same context.

The volume specification in claims 13 and 26 (less than 1.5 cubic centimeters) is not explicitly supported in the specification, which mentions volumes ranging from less than the volume of the patient needle to 20 times or more of the volume of the patient needle (paragraph [0050]).

Claims 5-12,18-25 is not reasonably supported by the specification due to their dependency on claims 1 and 14, respectively.

3.2 Claims 1-3,13-14,16,26 do not meet the requirements of **Regulation 20(a)(3)**, since the subject matter of the claims is not clear or concise.

Independent Claim 1:

- The term "drawing force" is unclear. It's not immediately evident what constitutes a "drawing force" or how it's applied "from the outlet port."
- The phrase "from a blood sample collection device" is ambiguous. It's not clear if this refers to the drawing force or the outlet port.



Independent Claim 14:

- The relative term "flexible material" is unclear without further definition or context of what kind of flexibility is referred to.
- The "drawing force" issue noted in Claim 1 applies here as well.

Claims 2 and 15 introduce a "blood impermeable membrane" without clear context of its relationship to other elements.

Claims 3 and 16 use the phrase "causes the first portion of the blood sample to back up", which lack clarity.

Claims 13 and 26 specify a volume "less than 1.5 cubic centimeters" without clear context of what this volume refers to.

3.3 Claims 12,25 do not meet the requirements of **Regulation 20(a)(3)**, since the subject matter of the claims is not clear regarding the relative term "sufficient". Please note that the description does not include a clear definition for this term. Therefore, to meet the requirements of **Regulation 20(a)(3)**, this term must be replaced with a clear term, based on a reasonable support by the description of the present application.

Applicant's duty to notify the office according Section 18 of the Law

Please note: according to **Section 18A of the Law**, it is the applicant's duty to notify the Office on any change occurring in the list of citations or publications according to **Section 18(a) of the Law**. Attention is drawn to **Section 18C of the Law** regarding means of enforcement with respect to applicant's duty under **Section 18 of the Law**.

Filing amendments to the specification during examination

If amendments are made to the specification, please refer to **Regulation 22(a)**. A full copy of the amended part of the application must be sent to the Office, in which the amendments are clearly marked. Additions should be underlined (i.e. example) and deletions noted by strikethrough (i.e. ~~example~~). **Parts of the specification that have not been amended should not be resubmitted.**

Please note:

a) According to Regulations 22(b) and 42, if amendments to the specification are made to rectify the deficiencies stated in this Notice, you must specify the deficiencies for which these



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amendments are intended to rectify, explain how the amendments rectify them, and, regarding amendments made to the claims, how they satisfy the requirements of Section 13 of the Law.

b) According to the provisions of Circular 034/2017-Patents, amending the specification by replacing an already examined invention, and for which objection was raised, with another invention, even if it the latter was previously claimed or only described and even if it is supported by the specification as originally filed, will not be considered as overcoming the objection, and it will lead to issuing a Notice before Refusal.

The application documents can be accessed at the following link:

<https://israelpatents.justice.gov.il/#/en/patent-file/details/309380>

Interview with the examiner

According to the Examination Guidelines published on the ILPO's website, an interview may be held with the examiner either at the ILPO or alternatively by telephone or videoconference. The ILPO encourages direct contact using this service between the examiner and the applicant or the representative. Conducting an interview with the examiner generally allows for a streamlined examination process and for cost saving measures throughout the overall process. During the interview, the applicant has the opportunity to explain and clarify the invention and to discuss the objections raised during the examination and the possible amendments that may be made in order to overcome them.

The interviews need to be coordinated directly with the examiner (please see the contact details below), and should include a written notice from the person initiating the interview, specifying the topics to be discussed and the main arguments pertaining to these topics.

Please note that a request for an interview does not constitute a response to a Notice of Deficiencies according to Regulation 42.

Objection before the Commissioner

According to **Section 161 of the Law**, the applicant is entitled to object to my decision before Commissioner within four months from the date of this Notice.

With hope for better, peaceful and safer days ahead.

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Sincerely

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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27500 7590 09/24/2024 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER NGUYEN, HUONG Q	
			ART UNIT 3791	PAPER NUMBER
			NOTIFICATION DATE 09/24/2024	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, valve to close off the sampling channel along with the moving part that moves from a first position to a second position to allow travel to the sampling channel of **Claims 10-12 and 25-27** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

(f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

- (A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

- (B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g., “means for”) or another linking word or phrase, such as “configured to” or “so that”; and
- (C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step”) in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No claim elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-12 and 25-27 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10-12 and 25-27 recite a valve to initially close off the sampling channel. This appears to be disclosed in the embodiment of Figure 23A-E. However, the independent claims recite an embodiment with a moving part configured to be movable from a first position to a

second position to allow the blood sample to flow to the sampling channel (and bypass the chamber), which appears disclosed in the embodiment Figure 24A-D.

However, the embodiment in Figure 23 does not disclose said moving part *in addition* to the valve to allow the bypass as claimed. Therefore, it appears that said claims improperly mix embodiments, which constitutes new matter. However, if an embodiment which contains both structures exists, applicant is requested to point out the portions of the specification disclosing such. Also see Drawing Objection above.

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 12, 22, and 27 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

In regard to Claim 7 and 22, the recitation of blood impermeable membrane causes the first portion of the blood sample “to back up” into the chamber is indefinite because it is unclear what specific meaning or function this is meant to convey. In the rejection that follows it is assumed to be normal fluid flow. Clarification is requested.

In regard to Claim 12 and 27, the recitation of “otherwise close off the outlet” is indefinite because it is unclear what mechanisms are included in said limitation to close off the outlet, which are also supported by the disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-5, 13-20, and 28-30 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Bullington et al (US Pub No. 20140163419).

In regard to Claims 1 and 16, Bullington et al disclose a device comprising:

- an inlet port 405 for receiving a blood sample, best seen in Figure 12 (0081, 0089);
- an outlet port 475 (proximal end of lumen 475), best seen in Figure 13-15 (0085);
- a chamber 480 connected with the inlet port, and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device 451, best seen in Figure 14 (0079, 0091-0092 – “a bodily-fluid is drawn through the port 405, the first lumen 432 defined by the flow control mechanism 430, and the first lumen 406 defined by the diverter 409 and into the fluid reservoir 480. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants”);

a sampling channel 433 connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port, best seen in Figure 15 (0095); and

a moving part 430, 431, 435 (flow control mechanism first member 431 controlled by member 435), moving part also defined by plunger 476 (0084 – Figure 13-15),

configured to be movable from a first position to a second position to allow the blood sample to flow to the sampling channel –

in the first position, moving member 435 rotates first member 431 such that lumen 433 (sampling channel) is fluidically isolated, due to lumen 432 of the flow control mechanism aligned with the inlet port 405, which leads through lumen 406 in diverter 409 and into chamber 480 – thus the inlet port 405 is in fluid communication with the chamber 480, best seen in Figure 14 (0081, 0092);

in the second position, moving member 435 rotates first member 431 such that lumen 433 is aligned with inlet port 405 such that “a desired amount of bodily-fluid is drawn through the port 405, the second lumen 433 of the flow control mechanism 430, the second lumen 407 of the diverter 409, and the lumen 475 [defining the outlet port] defined by the shunt tube 471 and into the second reservoir 490. Moreover, the bodily-fluid disposed within the second reservoir 490 is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the first reservoir 480,” best seen in Figure 15 (0082, 0083, 0095, 0097) – thus creates a pathway from the inlet port 405 to the outlet port 475.

2, 17. The device in accordance with claim 1, wherein the first position allows the collection of the first portion of the blood sample in the chamber 480, best seen in Figure 14.

3, 18. The device in accordance with claim 1, wherein the moving part 430, 431, 435 is configured to move from the first position to the second position after the first portion of the blood sample flows into the chamber 480 – sample flow into the chamber 480 occurs first, best seen in Figure 14, followed by moving member 435 rotating first member 431 such that lumen 433 is aligned with inlet port 405 is aligned with the outlet port 475, into second reservoir 490, best seen in Figure 15 (0082, 0083, 0095, 0097).

4, 19. The device in accordance with claim 1, the device further comprising a locking mechanism 474 configured to maintain the moving part 476 in the first position (Figure 14) until the chamber 480 is filled with the first portion of the blood sample – protrusion 474 enables proximal movement of plunger 476 to create chamber 480 for the first portion of the blood sample, best seen in Figure 13-14 (0085, 0091, 0096).

5, 20. The device in accordance with claim 1, wherein the moving part 430, 431, 476 is an inner chamber housing, best seen in Figure 13-15.

13, 28. The device in accordance with claim 1, further comprising a patient needle – “a user can engage the transfer device 400 to couple the port 405 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle, a cannula assembly, a trocar (which in some cases is used to insert a catheter into a patient), or the like” (0089) and

a sample collection device – “with the desired amount of bodily-fluid disposed within the second fluid reservoir 490, the transfer device 400 can be removed from the portion of the patient and disposed above or in a container (e.g., a vial, a test tube, a petri dish, a culture medium, a test apparatus, or the like) such that a portion of the second amount of bodily-fluid can be tested” (0099).

14, 29. The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (0092).

15, 30. The device in accordance with claim 1, wherein the chamber 480 has a volume of less than 1.5 cubic centimeters, e.g. 0.1 mL (0094).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 6-12 and 21-27 is/are rejected under 35 U.S.C. 103 as being unpatentable over Bullington et al as applied to claim 1 above, and further in view of Percarpio (US Pat No. 4106497 – cited by applicant).

In regard to Claims 6-9 and 21-24, Bullington et al disclose the invention above but do not expressly disclose a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a

chamber to collect a first portion of the blood sample (indicator area), and a sampling channel 28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a housing 40, 56 separate from the blood impermeable membrane 90, best seen in Figure 3-4, as an effective configuration for the location of said blood impermeable membrane.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the of filing to modify Bullington et al to include a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port as taught by Percarpio by enabling necessary venting of air from the device during the desired flow of blood such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber in the manner taught by Bullington et al to contact a material that is blood impermeable to enable the venting of air, wherein the blood impermeable membrane is separate from the housing, as taught by Percarpio as an effective configuration for said blood impermeable membrane.

In regard to Claims 10-12 and 25-27, Bullington et al disclose the invention above but do not expressly disclose a valve configured to initially close off the sampling channel.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a chamber to collect a first portion of the blood sample (indicator area), and a sampling channel

28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a valve 78 (check valve) that is configured to initially close off access to the outlet until the first portion of the blood sample is in the chamber, best seen in Figure 3, and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port, best seen in Figure 4 (Col.3: 61-Col.4: 15, 64-Col.5: 47). Percarpio also teach the valve is configured to pinch, shunt, bend or otherwise close off the outlet before the first portion of the blood sample is collected in the chamber, best seen in Figure 3-4 (Col.3: 61-Col.4: 15, 64-Col.5: 47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Bullington et al to include a valve to pinch, shunt, bend or otherwise close off the outlet in the manner above as taught by Percarpio to effectively seal off the outlet before the blood is properly in the chamber of Bullington et al, wherein it would have been obvious to a skilled artisan to place the valve such that it closes off the sampling channel and not just the outlet, to effectively block the flow of blood upstream before it reaches the outlet, prior to being drawn into the chamber as taught by Bullington et al, as well as Percarpio.

Also see 112 rejection above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/H.Q.N/
Examiner, Art Unit 3791

Application/Control Number: 18/783,173
Art Unit: 3791

Page 15

/RENE T TOWA/
Primary Examiner, Art Unit 3791

<i>Notice of References Cited</i>	Application/Control No. 18/783,173		Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN		Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS						
*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20140163419-A1	2014-06-12	Bullington; Gregory J.	A61B5/153	600/575
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	Filing Date		2024-07-24	
	First Named Inventor	Bobby E. ROGERS		
	Art Unit	OPAP		
	Examiner Name	DOCKET CENTRAL		
	Attorney Docket Number	069366-0580420_KUR3C03US		

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	3	1717280	CN		2006-01-04	SECR DEFENCE		☒

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	4	2015150742	WO		2015-10-08	UNIV HULL		☒
	5	0448795	EP		1991-02-10			☒

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	Meissner, George F. , et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, vol. 39, No. 3., pp. 321-323, Mar. 1963.	☐
	2	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	3	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	4	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
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8	Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.	☐
9	Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. No. 202080000666.0 (pages 1-28).	☐
10	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
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	Attorney Docket Number	069366-0580420_KUR3C03US

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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2	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
3	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
4	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
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17	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	☐
18	Pall Medical, "Leukotrap Filtration Systems for Whole Blood Derived Platelets, Leukotrap RC PL and Leukotrap PL Systems" literature, (2005) 8 pages.	☐

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☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Receipt date: 08/26/2024

18/783,173 - GAU: 3791

Doc code: IDS

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PTO/SB/08a (01-22)

Approved for use through 05/31/2024. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		18783173
	Filing Date		2024-07-24
	First Named Inventor	Bobby E. ROGERS	
	Art Unit	OPAP	
	Examiner Name	DOCKET CENTRAL	
	Attorney Docket Number	069366-0580420_KUR3C03US	

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	2	5432084		1995-07-11	BRUBAKER DANIEL B		
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	5	6599474		2003-07-29	EVTODIENKO VLADIMIR		
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	7	8535241		2013-09-17	BULLINGTON GREGORY		
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	9	9155495		2015-10-13	BULLINGTON GREGORY J	
	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
	13	9022951		2015-05-05	BULLINGTON GREGORY	
	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
	16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
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	21	9022950		2015-05-05	BULLINGTON GREGORY	
	22	4436098		1984-03-13	KAUFMAN JOSEPH	
	23	9138572		2015-09-22	ZEYTOONIAN PAUL	
	24	8568371		2013-10-29	SIOPEs WILLIAM	
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	32	3886930		1975-06-03	RYAN GEORGE R	
	33	4106497		1978-08-15	PERCARPIO EDWARD P	
	34	4154229		1979-05-15	NUGENT EDWARD L	
	35	4980297		1990-12-25	HAYNES JOHN L	
	36	9820682		2017-11-21	ROGERS BOBBY E	
	37	10010282		2018-07-03	ROGERS BOBBY E	
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	39	11185266		2021-11-30	ROGERS BOBBY E	
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	43	3648684		1972-03-14	BARNWELL CLEORA W	
	44	4056101		1977-11-01	GEISSLER ULRICH C	
	45	4416290		1983-11-22	LUTKOWSKI LAWRENCE	
	46	8070725		2011-12-06	CHRISTENSEN KELLY D	
	47	4349035		1982-09-14	THOMAS JOSEPH J	
	48	4813433		1989-03-21	DOWNEY JOHN M	
	49	5401262		1995-03-28	KARWOSKI THEODORE	
	50	3859998		1975-01-14	THOMAS JOSEPH JOHN	
	51	4373535		1983-02-15	MARTELL MICHAEL D	
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	54	5865803		1999-02-02	MAJOR MIKLOS	
	55	5873841		1999-02-23	BRANNON JAMES K	
	56	6013037		2000-01-11	BRANNON JAMES K	
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	58	11213232		2022-01-04	IVOSEVIC MILAN	
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	61	4673386		1987-06-16	GORDON MARK G	
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	65	3848579		1974-11-19	VILLA REAL A	
	66	6106509		2000-08-22	LOUBSER PAUL G	
	67	3494352		1970-02-10	RUSO RONALD D	
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	70	5135489		1992-08-04	JEPSON STEVEN C	
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	73	5772608		1998-06-30	DHAS V VARAPRABHU	
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	77	6843775		2005-01-18	HYUN DONGCHUL D	
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	79	7479131		2009-01-20	MATHIAS JEAN-MARIE	
	80	8377040		2013-02-19	BURKHOLZ JONATHAN KARL	
	81	5417673		1995-05-23	GORDON MARK G	
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	84	5100394		1992-03-31	DUDAR THOMAS E	
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	88	6945948		2005-09-20	BAINBRIDGE MARLENE	
	89	7306736		2007-12-11	COLLINS GREGORY R	
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	92	5045185		1991-09-03	OHNAKA YUKIHIRO	
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	94	6695004		2004-02-24	RAYBUCK JOHN L	
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	98	5439450		1995-08-08	HAEDT LORI E	
	99	6905483		2005-06-14	NEWBY C MARK	
	100	5431811		1995-07-11	TUSINI ANDREA	
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	102	7052603		2006-05-30	SCHICK KARL G	
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	105	10299713		2019-05-28	PATTON RICHARD G	
	106	10265007		2019-04-23	BULLINGTON GREGORY	
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	111	11259727		2022-03-01	BULLINGTON GREGORY J	
	112	11737693		2023-08-29	BULLINGTON GREGORY J	
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	120	11786155		2023-10-17	BULLINGTON GREGORY J	
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	125	5147329		1992-09-15	BRANNON JAMES K	
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	2	20030082074		2003-05-01	JURIK FRANKLIN A	
	3	20030185707		2003-10-02	IWAKI YOSHIHIDE	
	4	20040116830		2004-06-17	TRUDEAU WILLIAM M	
	5	20090299253		2009-12-03	HURSEY FRANCIS X	
	6	20130158506		2013-06-20	HARRIS ADRIENNE ROSE	
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	13	20180271425		2018-09-27	ROGERS BOBBY E	
	14	20080319346		2008-12-25	CRAWFORD JAMIESON	
	15	20100057004		2010-03-04	CHRISTENSEN KELLY D	
	16	20070088279		2007-04-19	SHUE MING-JENG	
	17	20080145933		2008-06-19	PATTON RICHARD G	
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	19	20100010372		2010-01-14	BROWN LEROY R	
	20	20080167577		2008-07-10	WEILBACHER EUGENE E	
	21	20080086085		2008-04-10	BROWN LEROY R	
	22	20070083162		2007-04-12	OREAGAN JAMES	

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	24	20120016266		2012-01-19	BURKHOLZ JONATHAN KARL	
	25	20130317391		2013-11-28	BULLINGTON GREGORY J	
	26	20160174888		2016-06-23	BERTHIER ERWIN	
	27	20050240161		2005-10-27	CRAWFORD JAMIESON W M	
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	29	20040073171		2004-04-15	ROGERS BOBBY E	
	30	20050004524		2005-01-06	NEWBY C MARK	
	31	20030105414		2003-06-05	LEONG ALVIN TAN CHEE	
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	35	20090227953		2009-09-10	TAN CHEE LEONG	
	36	20170020428		2017-01-26	ROGERS BOBBY E	
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	38	20050005635		2005-01-13	LE METAIS MARC	
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	46	20180353117		2018-12-13	BULLINGTON GREGORY J	
	47	20190159711		2019-05-30	ROGERS BOBBY E	
	48	20050245885		2005-11-03	BROWN LEROY	
	49	20110306899		2011-12-15	BROWN LEROY R	
	50	20130116599		2013-05-09	BULLINGTON GREGORY J	
	51	20050273019		2005-12-08	CONWAY HUGH	
	52	20150351678		2015-12-10	BULLINGTON GREGORY	
	53	20220160271		2022-05-26	IVOSEVIC MILAN	
	54	20050161112		2005-07-28	EHWALD RUDOLF	
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57	20220151525		2022-05-19	BULLINGTON GREGORY J	
58	20220151527		2022-05-19	BULLINGTON GREGORY J	
59	20200289039		2020-09-17	BULLINGTON GREGORY J	
60	20210275068		2021-09-09	MIAZGA JAY M	
61	20220304664		2022-09-29	HAMMER JEREMY	
62	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	
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**INFORMATION DISCLOSURE
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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580420_KUR3C03US

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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	2593169A1	EP		2013-05-22	BECTON DICKINSON CO		☐
	2	2009131273A	JP		2009-06-18	CSL BEHRING GMBH		☒
	3	2010062734A1	WO		2010-06-03	UNIV MARYLAND		☐

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	26	2017019552A1	WO		2017-02-02	KURIN INC		☐
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	28	S5825146A	JP		1983-02-15	BECTON DICKINSON CO		☒
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	31	5825146B2	JP		2015-12-02	JVC KENWOOD CORP,		☒
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	1	International Search Report and Written Opinion dated Nov. 5, 2015, for PCT application No. PCT/US2015/035870. 6 pages.	☐
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EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/09/2024
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580420_KUR3C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	18494622
	Filing Date	10/25/2023
	First Named Inventor	Bobby ROGERS
	Art Unit	OPAP
	Client Number	069366
Page 1 of 1	Matter Number	0577657_KUR2C05US

GENERAL
<p>Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.</p> <p>Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention, nor is it intended to constitute an admission that such information is "analogous prior art".</p> <p>In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.</p>

TIMING
<p>In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.</p>

CERTIFICATION STATEMENT
<p>No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).</p>

FEE
<p>No fee is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).</p>

ADDITIONAL COMMENTS

SIGNATURE			
Signature	/Benjamin F. Hudson/	Date	2024-10-16
Name	Benjamin F. Hudson	Registration Number	71,474



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/494,622	10/25/2023	Bobby E. ROGERS	069366-0577657_KUR2C05US	9839
27500 7590 12/02/2024 PILLSBURY WINTHROP SHAW PITTMAN LLP (CV) ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER ABOUELELA, MAY A	
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Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 04/23/2024, 06/27/2024, 08/26/2024 and 10/16/2024. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 2 is objected to because of the following informalities: the phrase “an inlet port for receiving a blood sample” in line 2 should be amended to read –an inlet port configured for receiving a blood sample--. Appropriate correction is required.

4. Claim 3 is objected to because of the following informalities: the phrase “cause the first portion of the blood sample” in line 2 should be amended to read –configured to cause the first portion of the blood sample--. Appropriate correction is required.

5. Claim 7 is objected to because of the following informalities: the phrase “follow-on amounts of the blood sample” in lines 3-4 should be amended to read –the subsequent portion of the blood sample--. Appropriate correction is required.

6. Claim 11 is objected to because of the following informalities: the phrase “the chamber having a volume sufficient to collect the first portion of the blood sample” in

lines 1-2 should be amended to read -- the chamber having a volume configured to be sufficient to collect the first portion of the blood sample--. Appropriate correction is required.

7. Claim 13 is objected to because of the following informalities: the phrase “an inlet port for receiving a blood sample” in line 2 should be amended to read –an inlet port configured for receiving a blood sample--. Appropriate correction is required.

8. Claim 14 is objected to because of the following informalities: the phrase “cause the first portion of the blood sample” in line 2 should be amended to read –configured to cause the first portion of the blood sample--. Appropriate correction is required.

9. Claim 18 is objected to because of the following informalities: the phrase “follow-on amounts of the blood” in line 3 should be amended to read –the subsequent portion of the blood--. Appropriate correction is required.

10. Claim 21 is objected to because of the following informalities: the phrase “the chamber having a volume sufficient to collect the first portion of the blood sample” in lines 1-2 should be amended to read -- the chamber having a volume configured to be sufficient to collect the first portion of the blood sample--. Appropriate correction is required.

11. Claim 22 is objected to because of the following informalities: the phrase “an inlet port for receiving a blood sample” in line 2 should be amended to read –an inlet port configured for receiving a blood sample--. Appropriate correction is required.

12. Claim 23 is objected to because of the following informalities: the phrase “cause the first portion of the blood sample” in line 2 should be amended to read –configured to cause the first portion of the blood sample--. Appropriate correction is required.

13. Claim 26 is objected to because of the following informalities: the phrase “follow-on amounts of the blood” in line 3 should be amended to read –the subsequent portion of the blood--. Appropriate correction is required.

14. Claim 30 is objected to because of the following informalities: the phrase “the chamber having a volume sufficient to collect the first portion of the blood sample” in lines 1-2 should be amended to read -- the chamber having a volume configured to be sufficient to collect the first portion of the blood sample--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

15. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 14, 15, 23 and 24 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

16. Claims 4, 15 and 24 recite the limitation "a material blood impermeable" this limitation is not defined by the claims, which renders the claims indefinite. One with ordinary skill in the art would not be able to know if the claimed "material that is blood impermeable" in claims 4, 15 and 24 is the same and/or different than the claimed "blood impermeable membrane" in claims 2, 13 and 22, respectively. The scope of the claim remains indeterminate because of the claimed "a material blood impermeable" in claims 4, 15 and 24.

17. Claim 3 recites the limitation "the drawing force" in line 3. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 14 recites the limitation "the drawing force" in line 3. There is insufficient antecedent basis for this limitation in the claim.

19. Claim 23 recites the limitation "the drawing force" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 2-8 and 10-31 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933) in view of Flaherty et al (US 2006/0009713).

As to claims 2-4, 13-15 and 22-24, Patton discloses a device (blood sampling device 500, par.38-40, fig.5) comprising:
an inlet port for receiving a blood sample (inlet/opening connecting needle 508 to input tubing 514, par.38-40, fig.5);
an outlet port (needle 510, fig.5);
a chamber (tubing 516 and reservoir 504, par.38-40, fig.5) comprising a flexible material (flexible material of tubing 516 and reservoir 504), wherein the chamber is connected with the inlet port (516 and 504 are connected to inlet of tubing 514, as best seen in fig.5) and configured to collect a first portion of the blood sample (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, par.40, fig.5); and
a sampling channel (tubing 514 and 518 connected with inlet of tubing 514, par.38-40, as best seen in fig.4) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port (which point the diversion

mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, ar.38-40, fig.5),

wherein the device is configured such that, when a drawing force applied at the outlet port, the first portion of the blood sample is drawn into the chamber (pre vacuumed effect of vessel 506 withdraws blood, first needle 508 can be inserted into a patient to procure a blood sample. In FIG. 5, the first needle 508 is shown inserted into a vein 520. The second needle 510 is shown inserted into the one or more sample vessels 506 that have been vacuum-sealed. The vacuum in each of the one or more sample vessels 506 causes blood to pass from the vein 520 to the diversion mechanism 512, par.40).

Still, regarding claims 2-4, 13-15 and 22-24, Patton discloses the invention substantially above, wherein a housing of the diverting mechanism is separate from a blood impermeable membrane, but failed to explicitly teach the chamber having a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood sample, and causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port, and wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

However, Flaherty discloses an analogous blood sampling device, wherein the blood sampling chamber comprises (liquid impenetrable, air-permeable membrane 45, par.39, fig.8-10), wherein blood flows into the blood collection chamber 39, air is displaced from the blood collection chamber 39, through the membrane 45 and air opening or openings

46, respectively. This facilitates the substantially continual and unhindered flow of blood from the patient 106 and into the blood collection chamber 39 to collect the desired quantity of blood into the blood collection chamber 39 (par.40, fig.8-10).

Since blood impermeable membrane is well-known in the art, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to include a blood impermeable membrane in reservoir 504 taught by Patton's invention, as blood impermeable membrane 45 taught by Flaherty's invention to facilitate the continual and unhindered flow of blood from the patient and into the blood collection chamber, as taught by Flaherty's invention (par.40).

As to claims 5, 16 and 25, Patton discloses the device, further comprising a valve (diversion mechanism 512 having valve 60, par.38-41, fig.5) configured to initially close off the sampling channel (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 6, 17 and 26, Patton discloses the device, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which

point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 7, 18 and 27, Patton discloses the device, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, as best seen from fig.5 the subsequent blood will bypass reservoir 504 and flows straight from inlet of 502 to tubings 514 and 518).

As to claims 8, 19 and 28, Patton discloses the device, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, fig.5).

As to claims 10, 20 and 29, Patton discloses the device, further comprising a patient needle (patient needle 508, par.38-40, fig.5) and a sample collection device (sample vessel 506, par.38-40, fig.5).

As to claims 11, 21 and 30, Patton discloses the device, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (the data suggests that fewer false positive test results for the presence of microbes in blood are obtained over conventional methods when initially-drawn volumes of blood are not used in microbial testing, par.54).

As to claims 12 and 31, Patton/ Flaherty combination discloses the volume of blood withdrawn into the one or more pre-sample reservoirs 504 is at least equal to the collective volumes of the first needle 508, the flexible, sterile input tubing 516, the diversion mechanism 512, and the first sterile output tubing 516 (par.40), but failed to explicitly teach the chamber has a volume of less than 1.5 cubic centimeters. However, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to allow reservoir 504 to collect blood volume less than 1.5 cubic centimeters, since it has been that discovering the optimum value of a result of effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215(CCPA 1980).

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used.

Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all

requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to

<http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 2-31 are non-provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-15 of U.S Patent Application No. 11,832,944 and are provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-9, 11-22 and 24-26 of pending Application No.18/783088. Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent Application and the instance application are claiming a common subject matter including: a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected to the inlet port and being configured to collect a first portion of the blood sample, the chamber having a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood sample; and a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an

interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

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<i>Search Notes</i> 	Application/Control No. 18/494,622	Applicant(s)/Patent Under Reexamination ROGERS et al.
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CPC - Searched*		
Symbol	Date	Examiner
A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068 OR A61B5/150251	10/16/2024	MA

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
class/subclass search, inventor name search, text search	10/16/2024	MA

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	
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✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	10/16/2024								
	1	-								
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	31	✓								

Bibliographic Data

Application No: 18/494,622

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/

Examiner's Signature

Initials

Title: BLOOD SAMPLE OPTIMIZATION DEVICE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
10/25/2023	600	3791	069366-0577657_KUR2C05US
RULE			

APPLICANTS

Kurin, Inc., San Diego, CA, UNITED STATES

INVENTORS

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Gino KANG, San Diego, CA, UNITED STATES

John DETLOFF, San Diego, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 18113710 02/24/2023 PAT 11832944

18113710 is a CON of 17538990 11/30/2021 PAT 11963769

17538990 is a CON of 16208559 12/04/2018 PAT 11185266

16208559 is a CON of 15994559 05/31/2018 PAT 10143412

15994559 is a CON of 15140448 04/27/2016 PAT 10010282

15140448 has PRO of 62318194 04/04/2016

15140448 has PRO of 62238636 10/07/2015

15140448 has PRO of 62196797 07/24/2015

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

11/07/2023

** SMALL ENTITY **

STATE OR COUNTRY

UNITED STATES

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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L57	272301	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/04/13 04:29 PM
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L81	1071	L80 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 02:20 PM
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L109	121	L108 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:17 PM
L110	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:31 PM
L111	6	L110 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:31 PM
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L120	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:06 PM
L121	1074	L120 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L122	80	L121 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L123	301210	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L124	6556	L123 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L125	3664	L124 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L126	12749	"19" and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L127	117	L125 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L128	1348	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:16 PM
L129	75	L128 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:17 PM
L130	1	("20120291564").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:21 PM
L131	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:25 PM
L132	18	L131 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:25 PM
L133	98	("20020002349" "20020183651" "20030055381" "20030208151" "20040010228" "20040054333"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:44 PM

		"20040147855" "20050004524" "20050240161" "20050245885" "20050281713" "20060287639" "20080108954" "20080145933" "2707953" "3013557" "3098016" "3382865" "3405706" "3494351" "3577980" "3648684" "3848579" "3937211" "4057050" "4133863" "4166450" "4340067" "4370987" "4444203" "4459997" "4509534" "4657160" "4676256" "4865583" "4890627" "4988339" "5009847" "5097842" "5108927" "5122129" "5269317" "5330464" "5360011" "5429610" "5450856" "5507299" "5577513" "5762633" "5865812" "5882318" "5922551" "6016712" "6057105" "6159164" "6210909" "6364890" "6387086" "6403381" "6626884" "6692479" "6746420" "6913580" "7044941" "7087047" "7335188" "7744573" "8197420" "8231546" "8337418").PN. OR ("8535241").URPN.					
L134	307	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:47 PM
L135	23	("4166450").PN. OR ("4412548").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L136	307	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L137	4	("2007/0088279").URP N.	(USPAT)	OR	ON	ON	2018/07/24 02:48 PM
L138	1	(14/990763).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:58 PM
L139	9	(blood and sequest\$5 and junction and first	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 03:07 PM

L140	1	and portion and sampl\$4).clm. (15/287421).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/25 09:39 PM
L141	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/26 11:56 AM
L142	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:24 PM
L143	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:25 PM
L144	34	("20020004647" "20030 105414" "20040054333 " "20040073171" "2004 0147855" "2005000452 4" "20050240161" "200 70088279" "200801459 33" "20100057004" "20 130317391" "20160174 888" "3817240" "38743 67" "3886930" "405705 0" "4106497" "4154229" "4207870" "4412548" "5 5222502" "5520193" "5 749857" "6569117" "81 97420" "8523826" "853 5241" "8540663" "8568 371" "8864684" "90229 51" "9060724" "913857 2" "9204864").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 05:53 PM
L145	272	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian")) OR (("GARRETT") near3 ("Chad"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/11/07 05:57 PM
L146	9	L145 and (blood near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 05:58 PM
L147	34	("20020004647" "20030 105414" "20040054333 " "20040073171" "2004 0147855" "2005000452 4" "20050240161" "200 70088279" "200801459	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 06:26 PM

		33" 20100057004" 20130317391" 20160174888" 3817240" 3874367" 3886930" 4057050" 4106497" 4154229" 4207870" 4412548" 5222502" 5520193" 5749857" 6569117" 8197420" 8523826" 8535241" 8540663" 8568371" 8864684" 9022951" 9060724" 9138572" 9204864").PN.					
L148	5	L147 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 06:29 PM
L149	6	("2010/0057004").URP N.	(USPAT)	OR	ON	ON	2019/11/07 06:40 PM
L150	0	L149 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:20 PM
L151	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:21 PM
L152	4	L151 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L153	1766	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:21 PM
L154	13	L153 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L155	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:22 PM
L156	48	L155 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:22 PM
L157	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L158	17	L157 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:43 PM
L159	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L160	6	L159 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L161	333030	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L162	6981	L161 AND (A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L163	139	L162 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L164	117	L163 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:45 PM
L165	1	L146 and (enclos\$3	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07

L166	1	near4 mechanism) ("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	07:51 PM 2019/11/08 04:57 PM
L167	1	(15/139716).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/11 12:09 PM
L168	1	(15/520430).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 11:02 AM
L169	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:11 PM
L170	1	("20120253321").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:13 PM
L171	1	(15/861959).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:14 PM
L172	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 02:17 PM
L173	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:14 PM
L174	1	("20080167577").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:19 PM
L175	4	("2008/0167577").URP N.	(USPAT)	OR	ON	ON	2019/12/09 03:30 PM
L176	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:31 PM
L177	39	(US-20040073171-\$ or US-20160174888-\$ or US-20050240161-\$ or US-20040147855-\$ or US-20130317391-\$ or US-20050004524-\$ or US-20030105414-\$ or US-20020004647-\$ or US-20100057004-\$ or US-20070088279-\$ or US-20080145933-\$ or US-20040054333-\$ or US-20100010372-\$ or US-20080319346-\$ or US-20080167577-\$).did. or (US-9138572-\$ or US-8568371-\$ or US-8540663-\$ or US- 8523826-\$ or US- 8197420-\$ or US- 4057050-\$ or US- 8864684-\$ or US- 8535241-\$ or US- 5749857-\$ or US- 9060724-\$ or US- 9204864-\$ or US- 3817240-\$ or US- 3874367-\$ or US- 3886930-\$ or US- 4106497-\$ or US- 4154229-\$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:37 PM

L178	8	4207870-\$ or US-4412548-\$ or US-5222502-\$ or US-5520193-\$ or US-9022951-\$ or US-6569117-\$ or US-3741197-\$ or US-8603009-\$).did. ("20040054333" "8197420" "9855001" "9861306" "10045724" "10028687" "8337418" "10028689").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:42 PM
L179	100	("20020002349" "20020183651" "20030055381" "20040010228" "20040054333" "20040147855" "20050004524" "20050240161" "20050245885" "20050281713" "20060287639" "2707953" "3013557" "3098016" "3382865" "3405706" "3494351" "3577980" "3648684" "3848579" "3937211" "4057050" "4133863" "4166450" "4340067" "4370987" "4444203" "4459997" "4509534" "4676256" "4865583" "4890627" "4988339" "5009847" "5097842" "5108927" "5122129" "5269317" "5360011" "5429610" "5450856" "5507299" "5577513" "5762633" "5882318" "5922551" "6016712" "6057105" "6159164" "6210909" "6364890" "6387086" "6403381" "6692479" "6746420" "6913580" "7044941" "7087047").PN. OR ("8197420").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 03:43 PM
L180	70	L179 and (blood near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 03:43 PM
L181	43	L180 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 03:44 PM
L182	270	((("BULLINGTON")	(US-PGPUB; USPAT;	OR	ON	ON	2019/12/09

L183	335813	near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR ("GAW") near3 ("Shan"))).INV. (blood near4 (sequest\$5 or sampl\$4))	USOCR; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	04:13 PM 2019/12/09 04:22 PM
L184	7259	L183 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L185	325	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 04:33 PM
L186	594	L184 and (flash\$6 and seal\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L187	476	L186 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L188	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:14 PM
L189	1123	L188 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L190	1013	L189 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L191	10	L190 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:16 PM
L192	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:23 PM
L193	1143	L192 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L194	1038	L193 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L195	3	L194 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L196	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:24 PM
L197	618	L196 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L198	557	L197 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L199	1	(15/854273).APP.	(US-PGPUB; USPAT;	OR	OFF	OFF	2019/12/09

L200	1351	(604/164.01).CCLS.	USOCR) (US-PGPUB; USPAT)	OR	ON	ON	05:25 PM 2019/12/09 05:31 PM
L201	219	L200 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L202	199	L201 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L203	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:36 PM
L204	44	L203 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:37 PM
L205	1	(15/508871).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/10 11:58 AM
L206	342199	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/03/16 12:53 PM
L207	4239	L206 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:53 PM
L208	146	L207 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:54 PM
L209	101	L208 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:55 PM
L210	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:38 PM
L211	1123	L210 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:38 PM
L212	1013	L211 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L213	22	L212 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L214	108	("20020193748" "20030093009" "20030105414" "20030220614" "20030229315" "20040059302" "20040092872" "20040193120" "20050004524" "20050065482" "20050124944" "20050187493" "20050245868"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 01:46 PM

		"20050245869" "20050245870" "20050245879" "20050245885" "20060036219" "20060224122" "20070106220" "20070106224" "20070167914" "20080086085" "20080177202" "20080319345" "20080319346" "20090204026" "20100262038" "4106497" "4207870" "4305406" "4572210" "4573976" "4641663" "4795443" "4840619" "4894055" "4900307" "4994046" "5015241" "5195985" "5215534" "5222502" "5242417" "5246428" "5256153" "5295970" "5303713" "5312372" "5336199" "5348544" "5356392" "5411492" "5439449" "5466223" "5501675" "5542932" "5599313" "5662617" "5665075" "5672161" "5676658" "5702369" "5704920" "5733265" "5755522" "5957892" "5984899" "6149629" "6224576" "6254575" "6261263" "6298541" "6344032" "6436086" "6440104" "6524277" "6533760" "6592556" "6623456" "6635032" "6648855" "6695819" "6699217" "6712792" "6780169" "6837877" "6869415" "6984223" "7001363" "7128726" "7147624" "7160267" "7163526" "7223258" "7226432" "7396343" "7428773" "7537581" "7766879" "D422700" "D442280" "D604836" "D604837" "D604838" "D604839" "D605287").PN. OR ("8603009").URPN.					
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L215	26	L214 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:47 PM
L216	27	("2008/0319346").URP N.	(USPAT)	OR	ON	ON	2020/03/16 01:47 PM
L217	23	("2003/0105414").URP N.	(USPAT)	OR	ON	ON	2020/03/16 01:48 PM
L218	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:52 PM
L219	1143	L218 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L220	25	L219 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L221	353695	((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:54 PM
L222	3643	L221 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L223	1926	L222 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L224	785	L223 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:56 PM
L225	7046	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 02:32 PM
L226	14	L225 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:35 PM
L227	1352	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:36 PM
L228	135	L227 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L229	19	L228 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L230	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:47 PM
L231	3	L230 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:47 PM
L232	19	("2008/0145933").URP N.	(USPAT)	OR	ON	ON	2020/03/16 02:48 PM
L233	795	(600/576).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16

L234	71	L233 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	02:58 PM 2020/03/16 02:58 PM
L235	57	L234 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:59 PM
L236	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:12 PM
L237	11	L236 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:12 PM
L238	45	("20040054333" "20050240161" "4412548" "5749857" "8197420" "9855001" "9861306" "20020004647" "20100057004" "3741197" "20040073171" "3874367" "4057050" "4106497" "8197420" "8535241" "8540663" "8603009" "8864684" "10045724" "3817240" "10028687" "20030105414" "5222502" "5520193" "6569117" "8568371" "20040147855" "20070088279" "20080145933" "20100010372" "3886930" "8523826" "9060724" "9204864" "8337418" "20050004524" "20080167577" "20080319346" "20130317391" "4154229" "9022951" "10028689" "20160174888" "4207870" "9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:13 PM
L239	6	("2008/0167577").URP N.	(USPAT)	OR	ON	ON	2020/03/16 03:13 PM
L240	118	("3500828" "3670729" "3714945" "3977400" "3994293" "3995619" "4106491" "4200096" "4468224" "4531987" "4549554" "4735215" "4828548" "4874373" "4893635" "4894052" "4907599" "4944308" "4994042" "5129884" "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 03:15 PM
L241	6	("2008/0167577").URP N.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 03:15 PM
L242	274	((("BULLINGTON") near3 ("Gregory")) OR	(US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	ON	ON	2020/03/16 03:25 PM

L243	61	((("PATTON") near3 ("Richard"))) OR ((("MIAZGA") near3 ("Jay"))) OR ((("GAW") near3 ("Shan"))).INV.	DERWENT)				
		L242 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:25 PM
L244	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:47 PM
L245	0	(14/502498).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:11 PM
L246	1	("20110082383").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L247	1	("8150506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L252	1	(15/057214).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/17 11:28 AM
L253	348964	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L254	7453	L253 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L255	155	L254 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:23 PM
L256	77	((("ROGERS") near3 ("Bobby"))).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:35 PM
L257	343953	(blood same (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:40 PM
L258	11	L256 and (blood same (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:41 PM
L259	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:50 PM
L260	121	("3500828" "3670729" "3714945" "3977400" "3994293" "3995619" "4106491" "4200096" "4468224" "4531987" "4549554" "4735215" "4828548" "4874373" "4893635" "4894052" "4907599" "4944308" "4994042" "5129884" "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:19 PM
L261	32	L260 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:20 PM

L262	1	("3648684").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L263	1	("4056101").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L264	329	(600/577).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/06/10 06:39 PM
L265	11	L264 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:39 PM
L266	29	("2008/0319346").URP N.	(USPAT)	OR	ON	ON	2020/06/10 06:40 PM
L267	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:40 PM
L268	72	L267 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:40 PM
L269	1767	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:44 PM
L270	31	L269 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:45 PM
L271	77	("4676249" "4787891" "4850960" "4874382" "4886067" "4886500" "4900307" "4904242" "4917102" "4950252" "4955862" "5046508" "5116353" "5125718" "5129884" "5163911" "5217435" "5290244" "5295974" "5314503" "5318585" "5330432" "5360410" "5366441" "5376075" "5395337" "5531692" "5695475" "5695479" "5702367" "5735813" "5749857" "5788654" "5800395" "5846226" "5871470" "5882342" "5919172" "5935108" "5935113" "5989220" "6050976" "6077244" "6099504" "6126641" "6162195").PN. OR ("6398743").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:46 PM
L272	18	L271 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:46 PM
L273	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:48 PM
L274	7050	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:49 PM

L275	14	L274 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:49 PM
L276	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:51 PM
L277	7	L276 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:51 PM
L278	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:52 PM
L279	135	L278 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:52 PM
L280	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 07:08 PM
L281	3	L280 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 07:08 PM
L282	20	("2008/0145933").URP N.	(USPAT)	OR	ON	ON	2020/06/10 07:08 PM
L286	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 08:56 PM
L287	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:16 PM
L288	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:17 PM
L289	100	((("ROGERS") near3 ("Bobby")) OR ("KANG") near3 ("Gino")) OR ((("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/03/01 09:17 PM
L290	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:36 PM
L291	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:39 PM
L292	180	((("ROGERS") near3 ("Bobby"))).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/03/02 12:19 PM
L293	11	L292 and (blood near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 12:20 PM
L294	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:47 PM
L295	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:49 PM
L296	1	("20020048170").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:36 PM
L297	1	("20040174525").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:49 PM
L298	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02

L299	27321	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.	USOCR) (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	03:09 PM 2021/03/02 03:17 PM
L300	4594	L299 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:27 PM
L301	3762	L300 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:28 PM
L302	257	L301 and (air near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L303	420	L301 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L304	1	("20110167658").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:30 PM
L305	5	("2015/0306288").URP N.	(USPAT)	OR	ON	ON	2021/03/02 04:15 PM
L306	1	(16/208559).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 04:32 PM
L307	2	("2009/0043225").URP N.	(USPAT)	OR	ON	ON	2021/03/02 04:49 PM
L308	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/03/02 05:00 PM
L309	1363	L308 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:00 PM
L310	73	L309 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L311	73	L310 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L312	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:34 PM
L313	711	L312 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L314	58	L313 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L315	58	L314 and	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02

L316	371	@ad<"20150724" (600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	05:34 PM 2021/03/02 05:42 PM
L317	277	L316 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:42 PM
L318	20	L317 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:43 PM
L319	336	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/03/02 05:44 PM
L320	210	L319 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L321	196	L320 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L322	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:48 PM
L323	1208	L322 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L324	73	L323 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L325	73	L324 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:49 PM
L326	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:59 PM
L327	271	L326 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L328	10	L327 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L329	268	L327 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L330	182	("ROGERS") near3 ("Bobby").INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/07/08 02:22 PM
L331	27660	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/07/08 03:27 PM

L332	4684	A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc. L331 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:28 PM
L333	3769	L332 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L334	579	L333 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L335	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:54 PM
L336	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:56 PM
L337	337	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:19 PM
L338	211	L337 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L339	196	L338 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L340	37	L339 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L341	221	("20010021827" "20020004650" "20020055716" "20020072715" "20020103464" "20020103465" "20020107488" "20020151856" "20020193748" "20030028171" "20030036730" "20030050608" "20030055385" "20030078544" "20030093009" "20030105414" "20030114797" "20030120222" "20030176842" "20030181873" "20030191438" "20030199827" "20030216687"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"20030220614" "20030229315" "20030229316" "20040024370" "20040059302" "20040092872" "20040102740" "20040111068" "20040193120" "20040204681" "20040210197" "20050004524" "20050059936" "20050065482" "20050124944" "20050165353" "20050187493" "20050228345" "20050245868" "20050245869" "20050245870" "20050245879" "20050245885" "20050283093" "20060015073" "20060036217" "20060036219" "20060079847" "20060129064" "20060189934" "20060189936" "20060224122" "20060270947" "20060276756" "20070021724" "20070027430" "20070106220" "20070106224" "20070167914" "20070282275" "20080015513" "20080086085" "20080177202" "20080221528" "20080269691" "20080306452" "20080319345" "20080319346" "20090204026" "20090227896" "20100063455" "20100191189" "20100262038" "20110118674" "4106497" "4207870" "4305406" "4572210" "4573976" "4641663" "4795443" "4813426"				
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		"4840619" "4887998" "4894055" "4900307" "4923477" "4994046" "5015241" "5195985" "5215534" "5219333" "5222502" "5242417" "5246428" "5256153").PN. OR ("5295970" "5295975" "5303713" "5312372" "5318547" "5336199" "5344408" "5348544" "5356392" "5389085" "5403286" "5411492" "5439449" "5466223" "5501675" "5542932" "5549558" "5595566" "5599313" "5607402" "5662617" "5665075" "5669889" "5672161" "5676658" "5681295" "5685855" "5687740" "5688241" "5695474" "5702369" "5704920" "5718239" "5733265" "5755522" "5769826" "5795336" "5879337" "5893845" "5910130" "5921964" "5957892" "5984899" "6149629" "6171284" "6183445" "6224576" "6254575" "6261263" "6261265" "6298541" "6344032" "6419658" "6436086" "6440104" "6471677" "6475191" "6485469" "6524277" "6533760" "6554807" "6575939" "6592556" "6623456" "6623461" "6635032" "6641555" "6648855" "6648856" "6659983" "6695819" "6699217" "6712792" "6716199" "6761704" "6773419" "6780169" "6805689" "6811545" "6835190" "6837877" "6846302" "6860872" "6869415" "6905483" "6918891" "6958054" "6974423" "6984223" "6997913" "7001363" "7083600" "7101355" "7128726" "7147624" "7160267" "7163526" "7201740" "7211065" "7223258"				
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L342	115	"7226432" "7361159" "7396343" "7428773" "7524308" "7537581" "7670320" "7727190" "7766879" "7938808" "8066679" "8282605" "8795198" "D422700" "D442280" "D604836" "D604837" "D604838" "D604839" "D605287" "RE35539" "RE43473").PN. OR ("9615783").URPN. ("20020193748" "20030093009" "20030105414" "20030220614" "20030229315" "20040059302" "20040092872" "20040193120" "20050004524" "20050065482" "20050124944" "20050187493" "20050245868" "20050245869" "20050245870" "20050245879" "20050245885" "20060036219" "20060224122" "20070106220" "20070106224" "20070167914" "20080086085" "20080177202" "20080319345" "20080319346" "20090204026" "20100262038" "4106497" "4207870" "4305406" "4572210" "4573976" "4641663" "4795443" "4840619" "4894055" "4900307" "4994046" "5015241" "5195985" "5215534" "5222502" "5242417" "5246428" "5256153" "5295970" "5303713" "5312372" "5336199" "5348544" "5356392" "5411492" "5439449" "5466223" "5501675" "5542932" "5599313"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM
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L343	148	"5662617" "5665075" "5672161" "5676658" "5702369" "5704920" "5733265" "5755522" "5957892" "5984899" "6149629" "6224576" "6254575" "6261263" "6298541" "6344032" "6436086" "6440104" "6524277" "6533760" "6592556" "6623456" "6635032" "6648855" "6695819" "6699217" "6712792" "6780169" "6837877" "6869415" "6984223" "7001363" "7128726" "7147624" "7160267" "7163526" "7223258" "7226432" "7396343" "7428773" "7537581" "7766879" "D422700" "D442280" "D604836" "D604837" "D604838" "D604839" "D605287").PN. OR ("8603009").URPN. ("20020193748" "20030105414" "20030229315" "20040059302" "20040092872" "20050004524" "20050187493" "20050245868" "20050245869" "20050245870" "20050245885" "20060036219" "20070106220" "20070167914" "20080086085" "20080177202" "4106497" "4207870" "4305406" "4573976" "4641663" "4795443" "4840619" "4894055" "4900307" "4994046" "5015241" "5195985" "5215534" "5222502" "5242417" "5256153" "5295970" "5303713" "5312372" "5336199" "5348544" "5356392" "5411492" "5439449" "5466223" "5501675" "5542932" "5672161"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM
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		"5676658" "5702369" "5704920" "5755522" "5984899" "6149629" "6261263" "6298541" "6436086" "6440104" "6524277" "6533760" "6592556" "6623456" "6635032" "6648855" "6699217" "6712792" "6780169" "6837877" "6869415" "6984223" "7001363" "7128726" "7147624" "7160267" "7163526" "7223258" "7226432" "7396343" "7428773" "D422700" "D442280").PN. OR ("7766879").URPN.					
L344	41	("2735430" "2798487" "3187749" "3240209" "3585984" "3817240" "4166450" "4207870" "4295477" "4312362").PN. OR ("4436098").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:22 PM
L345	163	L341 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:22 PM
L346	163	L345 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:23 PM
L347	22	("2005/0283093").URP N.	(USPAT)	OR	ON	ON	2021/07/08 04:23 PM
L348	163	L345 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L349	163	L348 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L350	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/08 04:37 PM
L351	1363	L350 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:37 PM
L352	1346	L351 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L353	136	L352 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L354	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:41 PM
L355	711	L354 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM

L356	699	or flash\$4 or collect\$4)) L355 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L357	123	L356 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L358	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:44 PM
L359	277	L358 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L360	260	L359 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L361	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:46 PM
L362	1208	L361 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:46 PM
L363	1194	L362 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L364	1194	L363 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L366	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:05 PM
L367	319	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MAZGA") near3 ("Jay")) OR ("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/02/02 03:14 PM
L368	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:35 PM
L369	190	((("ROGERS") near3 ("Bobby"))).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 03:36 PM
L370	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:41 PM
L371	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L372	1	("9060725").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L373	1	("9060724").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:43 PM
L374	1	("9022950").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L375	1	("9022951").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L376	1	("10292633").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2022/02/02

L377	1	("10433779").PN.	USOCR) (US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	03:46 PM 2022/02/02 03:47 PM
L378	1	("10436554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:48 PM
L379	1	("10736554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L380	1	("10912506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L381	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L382	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:50 PM
L383	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:51 PM
L384	276	(600/579).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:52 PM
L385	204	L384 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 03:53 PM
L386	37427	(A61B5/150221 or A61B5/15003 or A61B5/150236 or A61B5/150244 or A61B5/150251 or A61B5/150389 or A61B5/150503 or A61B5/150992 or A61B5/153 or A61B5/155 or A61B10/0048 or A61B10/0051 or A61B10/007 or A61B2010/0061 or A61B2010/0077 or A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 04:35 PM
L387	7279	L386 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L388	4442	L387 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L389	874	L388 and (seal\$4 near4 (member or mechanism\$4 or vent\$4 or elastic\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:38 PM
L390	26	("2008/0145933").URP N.	(USPAT)	OR	ON	ON	2022/02/02 04:52 PM
L391	44	("2008/0319346").URP N.	(USPAT)	OR	ON	ON	2022/02/02 04:59 PM
L392	385	L386 and ((blood or fluid) near4 (seal\$4 near4 (member or	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM

L393	171	mechanism\$4 or vent\$4 or elastic\$4))) L392 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L394	355	(604/103).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 05:52 PM
L395	7	L394 and ((blood or fluid) near4 (seal\$4 near4 (member or mechanism\$4 or vent\$4 or elastic\$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:52 PM
L396	1	(16/328127).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/03 12:00 PM
L397	0	"1020130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L398	8	"20130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L399	14	"2013021595"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:18 PM
L400	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/04 07:10 PM
L401	1	(15/746656).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/05 11:48 AM
L402	0	(17/388440).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/07 09:34 AM
L403	1	("20050048465").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2022/02/07 09:34 AM
L404	196	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:08 PM
L405	16	L404 and (blood near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L406	16	L404 and ((blood or chamber) near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L407	16	L406 and (junct\$4 or bypass\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L408	16	L406 and junct\$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L409	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:54 PM

L410	4525	A61B5/150572 or A61B5/154 or A61B5/15074).cpc. L409 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4 or flush\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:55 PM
L411	3810	L410 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:56 PM
L412	820	L411 and ((vent\$4 or open\$4 or apertur\$4) near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:57 PM
L413	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 05:51 PM
L414	4603	L413 and ((blood or fluid\$4 or chamber) same (sequest\$5 or sampl\$4 or flash\$4 or collect\$4 or flush\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:51 PM
L415	511	L414 and ((junct\$4 or bypass\$4 or divert\$4) near4 (blood or fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:52 PM
L416	355	L415 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:53 PM
L417	1	(16/819033).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:10 PM
L418	1	(17/094692).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L419	1	(17/538990).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L420	1	("11311219").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:27 PM
L421	1	("11185266").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:30 PM
L422	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:31 PM
L423	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:32 PM
L424	331	((("BULLINGTON") near3 ("Gregory")) OR ((("PATTON") near3 ("Richard")) OR ((("MAZGA") near3 ("Jay")) OR ((("GAW") near3 ("Shan")))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/06/06 03:44 PM

L425	8944	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:17 PM
L426	58747	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/06/06 05:17 PM
L427	7420	426 AND ((blood OR fluid\$4) near4 (sequest\$5 OR sampl\$4 OR flash\$4 OR collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:18 PM
L428	4441	427 AND @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:18 PM
L429	846	428 AND (seal\$4 near4 (member OR mechanism\$4 OR vent\$4 OR elastic\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:20 PM
L430	2	"17525682"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:46 PM
L431	547	426 AND (((blood OR fluid\$4) near4 (sequest\$5 OR bypass\$4 OR flash\$4)) AND seal\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:50 PM
L432	231	431 AND @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:50 PM
L433	1	18/113710	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/22 02:58 PM
L434	209	((("ROGERS") near3	(US-PGPUB; USPAT;	OR	OFF	OFF	2023/08/22

L435	21	("Bobby")).INV. 434 AND (((blood OR fluid\$4) near4 (sequest\$5 OR bypass\$4 OR flash\$4)) AND seal\$4)	USOCR; FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT)	OR	OFF	OFF	03:09 PM 2023/08/22 03:09 PM
L436	9	"20100057004"	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/22 03:11 PM
L437	49165	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068 OR A61B5/150251).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/08/22 03:49 PM
L438	33727	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/154 OR A61B5/153 OR A61M39/0693 OR A61M39/04 OR A61B5/150221 OR A61M2039/0633 OR A61M2039/0202 OR A61M2039/068 OR A61B5/150251).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/08/22 03:51 PM
L439	36143	438 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2023/08/22 03:52 PM

L440	3944	439 AND ((blood OR fluid\$4) near4 (sequest\$5 OR bypass\$4 OR flash\$4 OR collect\$4 OR sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 03:52 PM
L441	1473	440 AND (seal\$4 near4 (member OR mechanism\$4 OR vent\$4 OR elastic\$4 OR filter\$4 OR material\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 03:53 PM
L442	8	"20080167577"	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/22 04:42 PM
L443	115	440 AND (seal\$4 near4(expos\$4 OR contact\$4) near5 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 04:58 PM
L444	116	440 AND (seal\$4 near4(expos\$4 OR contact\$4 OR absorb\$4) near5 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 04:59 PM
L445	1	18/317558	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 02:44 PM
L446	303	((("ROGERS") near3 ("Bobby")) OR ((("KANG") near3 ("Gino")) OR ((("STROUP") near3 ("David")) OR ((("COCHRAN") near3 ("Jonas")) OR ((("DEPTALA") near3 ("Arthur")) OR ((("DETLOFF") near3 ("John")) OR ((("POGUE") near3 ("Lonnie")) OR ((("MACOWSKI") near3 ("Brian")))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/05/06 02:45 PM
L447	127	446 AND ((blood OR fluid\$4) near4 (sequest\$5 OR bypass\$4 OR flash\$4 OR collect\$4 OR sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 02:54 PM
L448	122	447 AND (((vent\$4 OR open\$5 OR hole OR aperture) near5 air) sam (clos\$4 OR plug\$4 OR cap\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 02:56 PM
L449	3	17/094692	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 03:07 PM

L450	46753	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/05/06 03:08 PM
L451	37283	450 AND @ad<"20170210"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/05/06 03:09 PM
L452	4944	451 AND ((blood OR fluid\$4) near5 (sequest\$5 OR sampl\$4 OR flash\$4 OR collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 03:14 PM
L453	511	452 AND (((vent\$4 OR open\$5 OR hole OR aperture) near5 air) SAME (clos\$4 OR plug\$4 OR cap\$4 OR seal\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 03:15 PM
L454	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 03:25 PM
L455	233	("3500828" "3670729" "3714945" "3977400" "3994293" "3995619" "4106491" "4200096" "4468224" "4531987" "4549554" "4735215" "4828548" "4874373" "4893635" "4894052" "4907599" "4944308" "4994042" "5129884" "5400798").pn. OR	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/05/06 03:37 PM

L456	228	("5749857").urpn. AND (PGPB USPT USOC).dbnm. 455 AND @ad<"20170210"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/05/06 03:37 PM
L457	14	456 AND (((vent\$4 OR open\$5 OR hole OR aperture) near5 air) SAME (clos\$4 OR plug\$4 OR cap\$4 OR seal\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 03:37 PM
L458	8	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 03:57 PM
L459	387	452 AND (((vent\$4 OR open\$5 OR hole OR aperture) near5 air) near5 (chamber OR hous\$4 OR contain\$4 OR tub\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 04:01 PM
L460	601	452 AND (air near5 (displac\$4 OR mov\$4 OR substit\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 04:22 PM
L461	346	452 AND (air near5 (displac\$4 OR substit\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 04:22 PM
L462	1	17/250875	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 04:58 PM
L463	1	("5376100").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:06 PM
L464	19	"20140276233"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:07 PM
L465	13	"20120101508"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:08 PM
L466	2	"20070179473"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:09 PM
L467	6	"20060073538"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:56 PM
L468	1	18/079528	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/07 01:22 PM

L469	9	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 02:35 PM
L470	122	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/09/30 02:39 PM
L471	34	470 AND ((blood OR fluid\$4) near4 (sequest\$5 OR bypass\$4 OR flash\$4 OR collect\$4 OR sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 02:40 PM
L472	53	("20020004647" "20030 105414" "20040054333 " "20040073171" "2004 0147855" "2005000452 4" "20050240161" "200 60009713" "200700831 62" "20070088279" "20 080086085" "20080145 933" "20080167577" "2 0080319346" "2010001 0372" "20100057004" " 20120016266" "201303 17391" "20150314105" " "20150359473" "20160 008579" "20160073937 " "20160174888" "3741 197" "3817240" "38743 67" "3886930" "405705 0" "4106497" "4154229" "4207870" "4412548" " 4436098" "4444203" "5 222502" "5520193" "57 49857" "6398743" "656 9117" "8197420" "8523 826" "8535241" "85406 63" "8568371" "860300 9" "8864684" "9022950" "9022951" "9060724" "9 9138572" "9155495" "9 204864" "9877675").PN .	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 02:50 PM
L473	50987	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO,	OR	ON	ON	2024/09/30 02:57 PM

L474	203	A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc. 455 AND @ad<"20150724"	RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/09/30 02:58 PM
L475	36038	473 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/09/30 02:59 PM
L476	22627	475 AND ((collect\$4 OR sampl\$4 OR draw\$4 OR withdraw\$4) near5 (blood OR fluid))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/09/30 03:02 PM
L477	499	476 AND ((blood OR fluid\$4) NEAR (sequest\$5 OR	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 03:02 PM

L478	0	bypass\$4 OR flash\$4 OR subsequent\$4)) 18/783088	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 03:24 PM
L479	3918	475 AND ((blood OR fluid\$4) near5 (sequest\$5 OR bypass\$4 OR flash\$4 OR collect\$4 OR sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 03:27 PM
L480	648	479 AND ((pump\$4 OR vacuum) near5 (draw\$4 OR withdraw\$4 OR forc\$4) near5 blood)	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 03:30 PM
L481	7	("2014/0309557").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2024/09/30 03:56 PM
L482	0	476 AND (blood near5 (impereamble OR impenetrat\$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/09/30 04:07 PM
L483	122	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/10/16 02:28 PM
L484	34	483 AND ((blood OR fluid\$4) near5 (sequest\$5 OR bypass\$4 OR flash\$4 OR collect\$4 OR sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/10/16 02:28 PM
L485	53	("20020004647" "20030105414" "20040054333" "20040073171" "20040147855" "20050004524" "20050240161" "20060009713" "20070083162" "20070088279" "20080086085" "20080145933" "20080167577" "20080319346" "2010001	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/16 02:33 PM

		0372" "20100057004" "20120016266" "20130317391" "20150314105" "20150359473" "20160008579" "20160073937" "20160174888" "3741197" "3817240" "3874367" "3886930" "4057050" "4106497" "4154229" "4207870" "4412548" "4436098" "4444203" "5222502" "5520193" "5749857" "6398743" "6569117" "8197420" "8523826" "8535241" "8540663" "8568371" "8603009" "8864684" "9022950" "9022951" "9060724" "9138572" "9155495" "9204864" "9877675").PN					
L486	27	("2016/0073937").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/16 02:42 PM
L487	0	18/783088	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/16 03:06 PM
L488	52227	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068 OR A61B5/150251).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/16 03:08 PM
L489	36429	488 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO;	OR	OFF	OFF	2024/10/16 03:08 PM

L490	3974	489 AND ((blood OR fluid\$4) near5 (sequest\$5 OR bypass\$4 OR flash\$4 OR collect\$4 OR sampl\$4))	JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT)	OR	OFF	OFF	2024/10/16 03:08 PM
L491	0	490 AND (blood near5 (impereamble OR impenetrat\$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/16 03:09 PM
L492	0	489 AND (blood near5 (impereamble OR impenetrat\$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/16 03:10 PM
L493	22949	489 AND ((collect\$4 OR sampl\$4 OR draw\$4 OR withdraw\$4) near5 (blood OR fluid))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/16 03:10 PM

L494	0	493 AND (blood near5 (impeream\$5 OR impenetrat\$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/10/16 03:11 PM
L495	944	493 AND ((vent\$4 OR open\$4 OR apertur\$4) near5 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/10/16 03:12 PM
L496	1406	493 AND (blood near5 (member\$4 OR mechanism\$4 OR vent\$4 OR elastic\$4 OR flexibl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/10/16 03:28 PM
L497	671	493 AND ((pump\$4 OR vacuum) near5 (draw\$4 OR withdraw\$4 OR forc\$4) near5 blood)	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/10/16 06:17 PM
L498	9	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/10/16 07:03 PM
L499	38	("2008/0145933").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/10/16 07:04 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N94	1	(port and sequest\$5 and junction and chamber and sampl\$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:15 PM
N112	3	(port and sequest\$5 and chamber and sampl\$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:39 PM
N248	4	(blood and fluid\$4 and inlet and outlet and port and reservoir and allow and initial\$4 and sequest\$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N249	4	(blood and fluid\$4 and inlet and outlet and port	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM

N250	495	and reservoir and allow\$4 and initial\$4 and sequest\$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N251	107	(blood and fluid\$4 and allow\$4 and initial\$4 and subsequent\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N283	9	((blood or fluid\$4) and sequestrat\$4 and chamber and sampl\$4 and vent\$4 and air\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N284	530	((blood or fluid\$4) and chamber and sampl\$4 and vent\$4 and air\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N285	84	((blood or fluid\$4) and chamber and cap and sampl\$4 and vent\$4 and air\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:32 PM
N365	6	(port and sequest\$5 and junction and chamber and sampl\$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:49 PM
N366	0	(blood AND seal\$4 AND sampl\$4 AND state AND transfer\$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 03:50 PM
N367	41	(blood AND seal\$4 AND bypass\$4 AND transfer\$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 03:51 PM
N368	396	(blood AND seal\$4 AND sampl\$4 AND transfer\$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:13 PM
N369	172	(blood AND seal\$4 AND sampl\$4 AND transfer\$4 AND volume).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:13 PM
N370	5	(blood AND seal\$4 AND sampl\$4 AND transfer\$4 AND volume AND bypass\$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:14 PM
N371	8944	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:16 PM

N372	22	A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc. (chamber AND inlet AND outlet AND channel AND forc\$4 AND draw\$4 AND blood).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 04:09 PM
N373	8	(chamber AND inlet AND outlet AND channel AND forc\$4 AND draw\$4 AND blood AND hous\$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 04:10 PM

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)

Approved for use through 05/31/2024. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		18494622
	Filing Date		2023-10-25
	First Named Inventor	Bobby ROGERS	
	Art Unit	OPAP	
	Examiner Name	CENTRAL, DOCKET	
	Attorney Docket Number	069366-0577657_KUR2C05US	

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4312362		1982-01-26	KAUFMAN JOSEPH	

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140163419		2014-06-12	BULLINGTON GREGORY J	
	2	20140309558		2014-10-16	FLETCHER GARY D	
	3	20140073990		2014-03-13	HOLMES ELIZABETH A	
	4	20140323911		2014-10-30	SLOAN DEBORAH	
	5	20040112808		2004-06-17	TAKAGI YOSHIKI	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number		18494622
Filing Date		2023-10-25
First Named Inventor	Bobby ROGERS	
Art Unit	OPAP	
Examiner Name	CENTRAL, DOCKET	
Attorney Docket Number	069366-0577657_KUR2C05US	

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	Office Action (Non-Final Rejection) dated 9/24/2024 for U.S. Application No. 18/783,173 ; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	2	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 17/893,079 ; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-50).	☐
	3	Office Action (Non-Final Rejection) dated 9/23/2024 for U.S. Application No. 17/730,118 ; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-73).	☐
	4	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 18/783,088 ; Attorney Docket No. 069366-0580418_KUR2C06US (pages 1-60).	☐
	5	Office Action (Notice of Deficiencies) dated 10/14//2023 for IL App No. 309380 (pages 1-7).	☐

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	11/26/2024
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**INFORMATION DISCLOSURE
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(Not for submission under 37 CFR 1.99)

Application Number	18494622
Filing Date	2023-10-25
First Named Inventor	Bobby ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0577657_KUR2C05US

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Attorney Docket Number	069366-0577657_KUR2C05US

CERTIFICATION STATEMENT

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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-10-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	18494622
	Filing Date	2023-10-25
	First Named Inventor	Bobby ROGERS
	Art Unit	3791
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0577657_KUR2C05US

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First Named Inventor	Bobby ROGERS
Art Unit	3791
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0577657_KUR2C05US

1	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
2	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
3	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
4	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
5	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
6	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	10/16/2024
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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Doc code: IDS

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PTO/SB/08a (01-22)

Approved for use through 05/31/2024. OMB 0651-0031

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	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0577657_KUR2C05US

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1	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
2	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
3	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	10/16/2024
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Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Receipt date: 04/23/2024

18/494,622 - GAU: 3791

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)

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	3	5972294		1999-10-26	SMITH JOHN L		
	4	6187347		2001-02-13	PATTERSON JAMES A		
	5	6599474		2003-07-29	EVTODIENKO VLADIMIR		
	6	8197420		2012-06-12	PATTON RICHARD G		
	7	8535241		2013-09-17	BULLINGTON GREGORY		
	8	9060724		2015-06-23	BULLINGTON GREGORY J		

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	9	9155495		2015-10-13	BULLINGTON GREGORY J	
	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
	13	9022951		2015-05-05	BULLINGTON GREGORY	
	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
	16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
	18	9877675		2018-01-30	BAID RISHI	
	19	4444203		1984-04-24	ENGELMAN ALLAN	

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	20	6398743		2002-06-04	HALSETH THOR R	
	21	9022950		2015-05-05	BULLINGTON GREGORY	
	22	4436098		1984-03-13	KAUFMAN JOSEPH	
	23	9138572		2015-09-22	ZEYTOONIAN PAUL	
	24	8568371		2013-10-29	SIOPEs WILLIAM	
	25	8540663		2013-09-24	DAVEY CHRISTOPHER T	
	26	8523826		2013-09-03	LAYTON JR RUSSELL K	
	27	4057050		1977-11-08	SARSTEDT WALTER	
	28	8864684		2014-10-21	BULLINGTON GREGORY J	
	29	5749857		1998-05-12	CUPPY MICHAEL J	
	30	9204864		2015-12-08	BULLINGTON GREGORY J	

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	31	3874367		1975-04-01	AYRES WALDEMAR A	
	32	3886930		1975-06-03	RYAN GEORGE R	
	33	4106497		1978-08-15	PERCARPIO EDWARD P	
	34	4154229		1979-05-15	NUGENT EDWARD L	
	35	4980297		1990-12-25	HAYNES JOHN L	
	36	9820682		2017-11-21	ROGERS BOBBY E	
	37	10010282		2018-07-03	ROGERS BOBBY E	
	38	10143412		2018-12-04	ROGERS BOBBY E	
	39	11185266		2021-11-30	ROGERS BOBBY E	
	40	10827964		2020-11-10	ROGERS BOBBY E	
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	42	3817240		1974-06-18	AYRES W	
	43	3648684		1972-03-14	BARNWELL CLEORA W	
	44	4056101		1977-11-01	GEISSLER ULRICH C	
	45	4416290		1983-11-22	LUTKOWSKI LAWRENCE	
	46	8070725		2011-12-06	CHRISTENSEN KELLY D	
	47	4349035		1982-09-14	THOMAS JOSEPH J	
	48	4813433		1989-03-21	DOWNEY JOHN M	
	49	5401262		1995-03-28	KARWOSKI THEODORE	
	50	3859998		1975-01-14	THOMAS JOSEPH JOHN	
	51	4373535		1983-02-15	MARTELL MICHAEL D	
	52	4690154		1987-09-01	WOODFORD TIMOTHY	

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	53	5097842		1992-03-24	BONN GINA B	
	54	5865803		1999-02-02	MAJOR MIKLOS	
	55	5873841		1999-02-23	BRANNON JAMES K	
	56	6013037		2000-01-11	BRANNON JAMES K	
	57	6913580		2005-07-05	STONE BENJAMIN CURTIS	
	58	11213232		2022-01-04	IVOSEVIC MILAN	
	59	6626884		2003-09-30	DILLON JAGMOHANBIR SINGH	
	60	4904240		1990-02-27	HOOVER ROCKLIN L	
	61	4673386		1987-06-16	GORDON MARK G	
	62	7461671		2008-12-09	EHWALD RUDOLF	
	63	6506182		2003-01-14	ESTABROOK BRIAN K	

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	64	3382865		1968-05-14	WORRALL JR ASHTON L	
	65	3848579		1974-11-19	VILLA REAL A	
	66	6106509		2000-08-22	LOUBSER PAUL G	
	67	3494352		1970-02-10	RUSO RONALD D	
	68	6224561		2001-05-01	SWENDSON DAVID L	
	69	7055401		2006-06-06	PRYBELLA JOHN R	
	70	5135489		1992-08-04	JEPSON STEVEN C	
	71	5811658		1998-09-22	VAN DRIEL MICHAEL R	
	72	3604410		1971-09-14	WHITACRE GARY L	
	73	5772608		1998-06-30	DHAS V VARAPRABHU	
	74	4150089		1979-04-17	LINET MICHAEL S	

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	75	4257416		1981-03-24	PRAGER DAVID	
	76	4193400		1980-03-18	LOVELESS JAMES C	
	77	6843775		2005-01-18	HYUN DONGCHUL D	
	78	7666166		2010-02-23	EMMERT MICHAEL	
	79	7479131		2009-01-20	MATHIAS JEAN-MARIE	
	80	8377040		2013-02-19	BURKHOLZ JONATHAN KARL	
	81	5417673		1995-05-23	GORDON MARK G	
	82	6638252		2003-10-28	MOULTON WILLIAM G	
	83	3945380		1976-03-23	DABNEY WILLIAM C	
	84	5100394		1992-03-31	DUDAR THOMAS E	
	85	8827958		2014-09-09	BIERMAN STEVEN F	

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	87	6860871		2005-03-01	KURACINA THOMAS C	
	88	6945948		2005-09-20	BAINBRIDGE MARLENE	
	89	7306736		2007-12-11	COLLINS GREGORY R	
	90	5691486		1997-11-25	BEHRINGER BRUCE E	
	91	5980830		1999-11-09	SAVAGE DOUGLAS ROBERT	
	92	5045185		1991-09-03	OHNAKA YUKIHIRO	
	93	5632906		1997-05-27	ISHIDA NOBORU	
	94	6695004		2004-02-24	RAYBUCK JOHN L	
	95	6733433		2004-05-11	FELL CLAUDE	
	96	7241281		2007-07-10	COELHO PHILIP H	

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	97	8349254		2013-01-08	HOSHINO YOSHITERU	
	98	5439450		1995-08-08	HAEDT LORI E	
	99	6905483		2005-06-14	NEWBY C MARK	
	100	5431811		1995-07-11	TUSINI ANDREA	
	101	6736783		2004-05-18	BLAKE KEVIN R	
	102	7052603		2006-05-30	SCHICK KARL G	
	103	3835835		1974-09-17	THOMPSON R	
	104	4416291		1983-11-22	KAUFMAN JOSEPH	
	105	10299713		2019-05-28	PATTON RICHARD G	
	106	10265007		2019-04-23	BULLINGTON GREGORY	
	107	11395612		2022-07-26	BULLINGTON GREGORY J	

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	108	10881343		2021-01-05	BULLINGTON GREGORY J	
	109	10596315		2020-03-24	BULLINGTON GREGORY J	
	110	11660030		2023-05-30	BULLINGTON GREGORY J	
	111	11259727		2022-03-01	BULLINGTON GREGORY J	
	112	11737693		2023-08-29	BULLINGTON GREGORY J	
	113	11439332		2022-09-13	BULLINGTON GREGORY J	
	114	11589843		2023-02-28	BULLINGTON GREGORY J	
	115	11612340		2023-03-28	BULLINGTON GREGORY J	
	116	11234626		2022-02-01	BULLINGTON GREGORY J	
	117	10624977		2020-04-21	BULLINGTON GREGORY J	
	118	11653863		2023-05-23	BULLINGTON GREGORY J	

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	120	11786155		2023-10-17	BULLINGTON GREGORY J	
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	7	20150246352		2015-09-03	BULLINGTON GREGORY J	
	8	20150342510		2015-12-03	BULLINGTON GREGORY J	
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	12	20140112841		2014-04-24	SCHOEN CHRISTIAN	
	13	20180271425		2018-09-27	ROGERS BOBBY E	
	14	20080319346		2008-12-25	CRAWFORD JAMIESON	
	15	20100057004		2010-03-04	CHRISTENSEN KELLY D	
	16	20070088279		2007-04-19	SHUE MING-JENG	

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	18	20040054333		2004-03-18	THEEUWES FELIX	
	19	20100010372		2010-01-14	BROWN LEROY R	
	20	20080167577		2008-07-10	WEILBACHER EUGENE E	
	21	20080086085		2008-04-10	BROWN LEROY R	
	22	20070083162		2007-04-12	OREAGAN JAMES	
	23	20160008579		2016-01-14	BURKHOLZ JONATHAN KARL	
	24	20120016266		2012-01-19	BURKHOLZ JONATHAN KARL	
	25	20130317391		2013-11-28	BULLINGTON GREGORY J	
	26	20160174888		2016-06-23	BERTHIER ERWIN	
	27	20050240161		2005-10-27	CRAWFORD JAMIESON W M	

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29	20040073171		2004-04-15	ROGERS BOBBY E	
30	20050004524		2005-01-06	NEWBY C MARK	
31	20030105414		2003-06-05	LEONG ALVIN TAN CHEE	
32	20020004647		2002-01-10	LEONG ALVIN TAN CHEE	
33	20140155781		2014-06-05	BULLINGTON GREGORY J	
34	20030208151		2003-11-06	KRAUS MENACHEM	
35	20090227953		2009-09-10	TAN CHEE LEONG	
36	20170020428		2017-01-26	ROGERS BOBBY E	
37	20170020427		2017-01-26	ROGERS BOBBY E	
38	20050005635		2005-01-13	LE METAIS MARC	

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	40	20140039348		2014-02-06	BULLINGTON GREGORY J	
	41	20140107564		2014-04-17	BULLINGTON GREGORY J	
	42	20140155782		2014-06-05	BULLINGTON GREGORY J	
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	44	20160017488		2016-01-21	KOBAYASHI MASAYUKI	
	45	20180177445		2018-06-28	ROGERS BOBBY E	
	46	20180353117		2018-12-13	BULLINGTON GREGORY J	
	47	20190159711		2019-05-30	ROGERS BOBBY E	
	48	20050245885		2005-11-03	BROWN LEROY	
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	51	20050273019		2005-12-08	CONWAY HUGH	
	52	20150351678		2015-12-10	BULLINGTON GREGORY	
	53	20220160271		2022-05-26	IVOSEVIC MILAN	
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	56	20220304600		2022-09-29	HAMMER JEREMY	
	57	20220151525		2022-05-19	BULLINGTON GREGORY J	
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	59	20200289039		2020-09-17	BULLINGTON GREGORY J	
	60	20210275068		2021-09-09	MIAZGA JAY M	

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10	2011162772A1	WO		2011-12-29	CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC		☐
11	2993646	CA		2017-02-02	KURIN INC		☐
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	20	2012016496A	JP		2012-01-26	TERUMO CORP		☒
	21	2016504075	JP		2016-02-12	マグノリア メディカル テクノロジーズ, イン コーポレイテッド		☒
	22	2019534792A	JP		2019-12-05	ブライメタルズ・テクノ ロジーズ・オーストリ ア・ゲーエムベーハー		☒
	23	H09504726A	JP		1997-05-13	BAXTER INT		☒
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	31	5643474	JP		2014-12-17	ヴェロシス , インク .		☒
	32	5825146B2	JP		2015-12-02	JVC KENWOOD CORP,		☒
	33	2020000340A	JP		2020-01-09	TOSHO INC		☒
	34	2013240628	JP		2013-12-05	COVIDIEN LP		☒
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	38	10243129	DE		2004-04-01	RITTER GMBH		☒
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	Filing Date	2023-10-25
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	Examiner Name	
	Attorney Docket Number	069366-0577657_KUR2C05US

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Name/Print	Benjamin F. Hudson	Registration Number	71,474

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41	Notice of Allowance mailed 03-01-2023; Attorney Docket No. 069366-0572419_KUR2D01AU. 3 pages.	☐
42	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
43	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
44	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
45	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐
46	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	18494622
Filing Date	2023-10-25
First Named Inventor	Bobby ROGERS
Art Unit	3791
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0577657_KUR2C05US

47	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
48	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
49	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
50	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐

If you wish to add additional non-patent literature document citation information please click the Add button **EXAMINER SIGNATURE**

Examiner Signature	/MAY A ABOUELELA/	Date Considered	10/16/2024
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	18494622
Filing Date	2023-10-25
First Named Inventor	Bobby ROGERS
Art Unit	3791
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0577657_KUR2C05US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

TO: Docket_IP@pillsburylaw.com
FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 27500

Mon Dec 02 05:00:06 EST 2024

Dear Patent Center Customer:

Correspondence Address:

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean,VIRGINIA,22102
UNITED STATES

This is a courtesy notification regarding the following USPTO patent application(s) associated with your Customer Number, 27500, that have new outgoing correspondence. This correspondence is now available for viewing in Patent Center.

The official date of notification of the outgoing correspondence will be indicated on the form (e.g., PTOL-90) accompanying the correspondence.

Disclaimer:

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Application	Document	Mailroom Date	Attorney Docket No.
18494622	CTNF	12/02/2024	069366-0577657_KUR2C05US
18494622	892	12/02/2024	069366-0577657_KUR2C05US
18494622	1449	12/02/2024	069366-0577657_KUR2C05US
18494622	1449	12/02/2024	069366-0577657_KUR2C05US
18494622	1449	12/02/2024	069366-0577657_KUR2C05US
18494622	1449	12/02/2024	069366-0577657_KUR2C05US
18494622	1449	12/02/2024	069366-0577657_KUR2C05US

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Sincerely,

The Patent Center Team



P.O. Box 1450
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

APPLICATION #	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET #
18494622	10/25/2023	Bobby ROGERS	069366-0577657_KUR2C05US

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE



Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action



This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent interest
KURIN, INC	100%
Total	100%

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

Application #	Filing Date
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as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

Patent #

11832944

12138052

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.



Terminal disclaimer fee under 37 CFR 1.20(d) included with Electronic Terminal Disclaimer request.

Applicant claims the following entity status:

Small

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I certify, in accordance with 37 CFR 1.4(d)(4) that I am: An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Signature

Name

Registration #

/Ben Hudson/

Benjamin Hudson

71474

* Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP 324.



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PATENT AND TRADEMARK OFFICE

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APPROVAL LETTER

APPLICATION #
18/494,622

FILING DATE
10/25/2023

APPLICANT/PATENT UNDER REEXAMINATION
Bobby ROGERS

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Electronic terminal disclaimer filed on 05/30/2025



Approved

This patent is subject to a Terminal Disclaimer

Approved / Disapproved by: Electronic Terminal Disclaimer automatically approved



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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/494,622	05/30/2025 06:07:25 PM Z ET	069366-0577657_KUR2C05US

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9839	FILED BY	Benjamin Hudson
PATENT CENTER #	70656203	FILING DATE	10/25/2023
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. ROGERS
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
petition-request.pdf	3	Terminal Disclaimer-Filed (Electronic)	44 KB
grantLetter.pdf	1	Terminal Disclaimer-Electronic- Approved	18 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
petition-request.pdf	E9C75E88EF1AB2FA1F9DD89B8C778C1C483647365B937B687 67A66B1ED8E14BFC97EAF973A9A8F6BBA334F12BC2A59748 F433AAE63C0671299348A392B57A313
grantLetter.pdf	0E03DB3DB2F2DE8D72F16418F0351358201FDCC7EC0BD2BF

20D6AD44D561734BDDFDC9BC5033CFB7583B2BCBF9C4EA7
33203BD9F4D439D386EEA2AEE934FB922

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/494,622	05/30/2025 06:07:25 PM Z ET	069366-0577657_KUR2C05US

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9839	FILED BY	Benjamin Hudson
PATENT CENTER #	70656203	AUTHORIZED BY	Benjamin Hudson
CUSTOMER #	27500	FILING DATE	10/25/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Bobby E. ROGERS

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 033975	E20255T107519051	Benjamin Hudson

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
2814	STATUTORY DISCLAIMER, INCLUDING TERMINAL DISCLAIMER	183.00	1	183.00
TOTAL AMOUNT:				\$183.00

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Application No. 18/494,622

Attorney's Docket No.: 069366-0577657_KUR2C05US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bobby E. Rogers, et al.

Confirmation No: 9839

Application No.: 18/494,622

Art Unit: 3791

Filed: October 25, 2023

Examiner: May A. Abuelela

For: BLOOD SAMPLE OPTIMIZATION DEVICE

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NON-FINAL OFFICE ACTION

Dear Examiner Abouelela:

This reply is responsive to the Non-Final Office Action mailed December 2, 2024, in the above-referenced matter (hereinafter “the Office Action”). Reconsideration and allowance of the application is requested in view of the following:

Listing of Claims beginning on page 2.

Remarks beginning on page 8.

LISTING OF CLAIMS

This listing of claims replaces all prior versions of claims in the application:

1. (Cancelled)
2. (Currently Amended) A device comprising:
 - an inlet port configured for receiving a blood sample;
 - an outlet port;
 - a chamber connected to the inlet port and being configured to collect a first portion of the blood sample, the chamber having a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood sample;
 - a housing, separate from the blood impermeable membrane; and
 - a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port.
3. (Currently Amended) The device in accordance with claim 2, wherein the blood impermeable membrane ~~causes~~ is configured to cause the first portion of the blood sample to back up into the chamber following application of ~~[[the]]~~ a drawing force applied from the outlet port.
4. (Previously Presented) The device in accordance with claim 2, wherein the device is configured such that, when a drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

5. (Previously Presented) The device in accordance with claim 2, further comprising a valve configured to initially close off the sampling channel.
6. (Previously Presented) The device in accordance with claim 2, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.
7. (Currently Amended) The device in accordance with claim 2, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, ~~follow-on amounts~~ the subsequent portion of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port.
8. (Previously Presented) The device in accordance with claim 5, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.
9. (Previously Presented) The device in accordance with claim 2, wherein the housing defines the inlet port, the sampling channel, and the outlet port.
10. (Previously Presented) The device in accordance with claim 2, further comprising a patient needle and a sample collection device.
11. (Currently Amended) The device in accordance with claim 2, the chamber having a volume configured to be sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered.

12. (Previously Presented) The device in accordance with claim 2, wherein the chamber has a volume of less than 1.5 cubic centimeters.

13. (Currently Amended) A device comprising:
an inlet port configured for receiving blood;
an outlet port;
a chamber connected to the inlet port and being configured to collect a first portion of the blood, the chamber comprising a flexible blood impermeable membrane that allows the chamber to collect the first portion of the blood; and
a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port.

14. (Currently Amended) The device in accordance with claim 13, wherein the flexible blood impermeable membrane ~~causes~~ is configured to cause the first portion of the blood to back up into the chamber following application of ~~[[the]]~~ a drawing force applied from the outlet port.

15. (Previously Presented) The device in accordance with claim 13, wherein the device is configured such that, when a drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a material that is blood impermeable.

16. (Previously Presented) The device in accordance with claim 13, further comprising a valve configured to initially close off the sampling channel.

17. (Previously Presented) The device in accordance with claim 13, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.

18. (Currently Amended) The device in accordance with claim 13, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the chamber and is further configured such that, upon release, ~~follow-on amounts~~ the subsequent portion of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.

19. (Previously Presented) The device in accordance with claim 16, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.

20. (Previously Presented) The device in accordance with claim 13, further comprising a patient needle and a sample collection device.

21. (Currently Amended) The device in accordance with claim 13, the chamber having a volume configured to be sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.

22. (Currently Amended) A device comprising:
an inlet port configured for receiving [[a]] blood;
an outlet port;

a chamber connected to the inlet port, the chamber having a blood impermeable membrane and being configured to collect a first portion of the blood; and

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port.

23. (Currently Amended) The device in accordance with claim 22, wherein the blood impermeable membrane ~~causes~~ is configured to cause the first portion of the blood to back up into the chamber following application of ~~[[the]]~~ a drawing force applied from the outlet port.

24. (Previously Presented) The device in accordance with claim 22, wherein the device is configured such that, when a drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a material that is blood impermeable.

25. (Previously Presented) The device in accordance with claim 22, further comprising a valve configured to initially close off the sampling channel.

26. (Previously Presented) The device in accordance with claim 22, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.

27. (Currently Amended) The device in accordance with claim 22, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the chamber and is further configured such that, upon release, ~~follow-on amounts~~ the subsequent portion of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.

28. (Previously Presented) The device in accordance with claim 25, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.

29. (Previously Presented) The device in accordance with claim 22, further comprising a patient needle and a sample collection device.

30. (Currently Amended) The device in accordance with claim 22, the chamber having a volume configured to be sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.

31. (Previously Presented) The device in accordance with claim 22, wherein the chamber has a volume of less than 1.5 cubic centimeters.

REMARKS

Claim Summary: Prior to this response, Claims 2-31 were pending. Claims 2, 3, 7, 11, 13, 14, 18, 21, 22, 23, 27, and 30 are amended. After entry of this response, Claims 2-31 will be pending. No new matter is added with this amendment. Reconsideration and allowance of the current application are requested in light of the following remarks.

Summary of Rejections: The Office objects to Claims 2, 3, 7, 11, 13, 14, 18, 21-23, 26 and 30; rejects Claims 2-31 on the grounds of non-statutory double patenting over Claims 1-15 of U.S. Patent No. 11,832,944 and Claims 1-9, 11-22, and 24-26 of application 18/783,088 (now U.S. 12,138,052); rejects Claims 3, 4, 14, 15, 23 and 24 under 35 U.S.C. §112(b) as allegedly being indefinite; and rejects Claims 2-8 and 10-31 as allegedly being unpatentable under 35 U.S.C. §103 over Patton, et al. (U.S. 2008/0145933), hereinafter "Patton," in view of Flaherty, et al. (U.S. 2006/0009713), hereinafter "Flaherty."

No Change in Scope of Claims: The Office is respectfully reminded that the scope of at least one claim has remained unchanged in this Response. If new grounds of rejection for an unchanged claim are presented in a subsequent action, per MPEP§706.07(a), that subsequent action cannot properly be made final.

While the independent claims have been amended to include the preferred language of the examiner, these amendments are believed sufficiently minor such that the scope of the amended independent claims has not substantively changed. Accordingly, any new ground of rejection of these independent claims will not be necessitated by the instant amendments. As such, the next action cannot properly be made final.

Request for Interview: The present response is believed to be sufficient to overcome the pending rejections. However, if this paper is not deemed sufficient to result in a notice of

allowance, or if any remaining issues can be more efficiently handled by telephone, the Examiner is respectfully requested to contact the undersigned by either phone or e-mail to schedule an interview at a mutually convenient time.

Claim objections

The instant amendments incorporate nearly all of the Office's suggested amendments to the objected claims, except as noted below.

The suggested amendments to Claims 13-30 that suggest reciting "blood **sample**" were not adapted because Independent Claims 13 and 22 introduce the term "blood" in line 2 and not "blood **sample**." Thus, this aspect of the dependent claims are consistent with their respective independent claims.

The Office's objection to Claim 26 in fact appears to refer instead to text from Claim 27. Claim 27 has been amended accordingly.

Rejections for Non-Statutory Double Patenting

The Office Action rejects Claims 2-31 over Claims 1-15 of U.S. Patent No. 11,832,944 and Claims 1-9, 11-22, and 24-26 of application 18/783,088 (now U.S. 12,138,052). In order to further prosecution of the present application and obtain allowance of the pending claims, Applicant submits herewith a terminal disclaimer to overcome the rejections. In so doing, Applicant does not indicate agreement with the propriety of the rejections.

Rejections under 35 U.S.C. §112(b) (indefiniteness)

The Office Action rejects Claims 4, 15, and 24 as allegedly failing to particularly point out and distinctly claim the subject matter regarded as the invention. Applicant believes that these rejections stem merely from an incomplete reading of the full text of these claims. The

Office Action states “Claims 4, 15 and 24 recite the limitation “a material blood impermeable” this limitation is not defined by the claims, which renders the claims indefinite.” However, the full text of Claim 4 includes the words “that is” and therefore the claim is written correctly:

“4. The device in accordance with claim 2, wherein ... contact a material **that is** blood impermeable.”

Accordingly, it is respectfully requested that the rejection of Claim 4 under 35 U.S.C. § 112(b) be withdrawn. The statements above also apply to the corresponding rejections of Claims 15 and 24.

The Office Action rejects Claims 3, 14, and 23 as allegedly failing to particularly point out and distinctly claim the subject matter regarded as the invention. These claims have been amended to provide proper antecedent basis for the disputed term. Accordingly, it is respectfully requested that the rejection of Claims 3, 4, and 23 under 35 U.S.C. § 112(b) be withdrawn.

Rejections under 35 U.S.C. §103

The Office Action rejects Claim 2 as allegedly obvious in view of Patton in view of Flaherty. However, the combination of Patton and Flaherty fail to disclose or suggest at least the following elements of Claim 2:

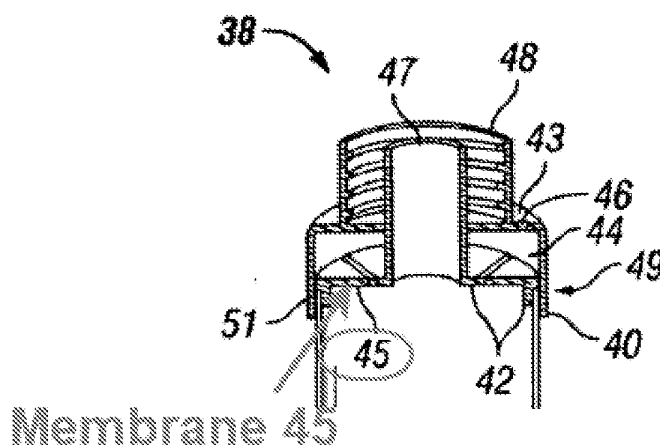
“a chamber connected to the inlet port and being configured to collect a first portion of the blood sample, **the chamber having a blood impermeable membrane** configured to facilitate the chamber collecting the first portion of the blood sample.

Adding Flaherty's membrane detracts from or adds no benefit to Patton's design

The Office concedes that Patton does not disclose a chamber having a *blood impermeable* membrane, as claimed. The Office relies on Flaherty's disclosure of a membrane as allegedly curing this deficit of Patton. However, the membrane of Flaherty fails to teach a blood

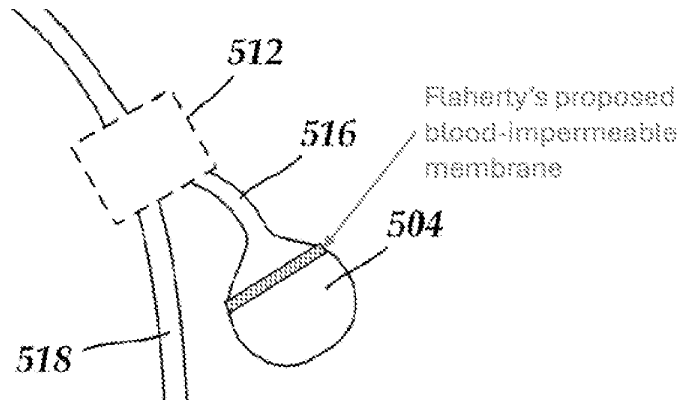
impermeable membrane. Flaherty's membrane 45 (shown below) is disclosed as *having a hole through it* for blood flow tube 47. See, e.g., Flaherty's Paragraph [0039] and Figure 8:

“A blood flow tube 47 extends centrally through the male luer connector 48 and extends downwardly through the center of the upper housing plate 43, the membrane 45 and the membrane support 42.”



As such, Flaherty fails to teach “a *blood impermeable* membrane” as claimed, because Flaherty’s membrane is configured to allow blood to flow through it.

Even if Flaherty’s membrane was modified to remove the hole, there would be no benefit or motivation to combine such a membrane with Patton and, in fact, it would likely render Patton’s device inoperative. The Office Action has not provided any details about how such a membrane might be added to Patton, but a modification could look like the below (based on Patton’s Figure 5):



A person of skill in the art would not make such a modification because the membrane would block free flow of blood into 504 as intended by Patton and reduce the amount of blood that can be collected.

Accordingly, it would not be obvious to modify Patton with Flaherty in the manner proposed in the Office Action, and thus a *prima facie* case of obviousness against Claim 2 has not been made and the rejection over Patton in view of Flaherty should be withdrawn.

Patton and Flaherty have opposed teachings that discourage their combination

Flaherty disparages Patton's use of vacuum-based blood draws and therefore a person of skill in the art would not combine the teachings of the two references.

Patton teaches the use of a vacuum. See, e.g., Paragraph [0040]:

“The vacuum in each of the one or more sample vessels 506 causes blood to pass from the vein 520 [ultimately to sample vessel 506 as shown in Fig. 5, below].”

Flaherty disparages the use of vacuum-based blood draws because the vacuum can lead to vein collapse. See, e.g., Flaherty's Paragraph [0004]:

“Conventional methods of drawing blood from a patient typically utilize partial vacuum pressure to draw the blood from one of the patient's veins into a collecting device. Such utilization of partial vacuum pressure to draw blood from the vein tends to prematurely collapse the vein, thus necessitating re-

insertion of the collecting device in another vein or in the same vein at a separate location to draw additional blood.”

Per MPEP § 2145(I)(X)(D)(2) “It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).” The references (Patton and Flaherty) teach away from the combination due to Flaherty’s disparagement of using vacuum-based blood draws (as in Patton). Accordingly, a person of skill would not look to Flaherty’s vacuum-avoiding teachings for potential modifications to Patton’s vacuum-based designs.

For at least the reasons given above, the art of record fails to disclose or suggest each of the elements of Claim 2 and thus withdrawal of the pending rejection under §103 is respectfully requested.

Independent Claims 13 and 22 are directed to subject matter differing in scope from Claim 2 but each of these independent claims (as amended) includes features related to the discussion above. As such, independent Claims 13 and 22 are believed to be allowable for at least the reasons described above.

Each of the remaining pending claims depends from one of independent Claims 2, 13, or 22 and thus each is likewise patentable for at least the reasons discussed above.

CONCLUSION

On the basis of the foregoing remarks and/or amendments, allowance of the pending claims is respectfully requested. It is believed that all the pending rejections have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does

not signify agreement with or concession of that rejection, issue or comment. In addition, because any arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper.

Applicant is also submitting a petition and fee for a three-month extension of time. No additional fees are believed to be due, however the Commissioner is authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account 033975, Reference No. 069366-0577657_KUR2C05US. If there are any questions regarding this submission, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,
PILLSBURY WINTHROP SHAW PITTMAN LLP

Date: May 30, 2025

By: /Ben Hudson/
Benjamin F. Hudson, Ph.D.
Reg. No. 71,474

PO BOX 10500
McLean, Virginia 22102
Telephone: (858) 509-4000
Customer No. 27500



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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/494,622	05/30/2025 06:09:29 PM Z ET	069366-0577657_KUR2C05US

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9839	FILED BY	Benjamin Hudson
PATENT CENTER #	70654595	AUTHORIZED BY	Benjamin Hudson
CUSTOMER #	27500	FILING DATE	10/25/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Bobby E. ROGERS

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 033975	E20255T110209070	Benjamin Hudson

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
2253	EXTENSION FOR RESPONSE WITHIN THIRD MONTH, EXCEPT PROVISIONAL APPLICATIONS	636.00	1	636.00
TOTAL AMOUNT:				\$636.00

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C.

371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/494,622	05/30/2025 06:09:29 PM Z ET	069366-0577657_KUR2C05US

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BLOOD SAMPLE OPTIMIZATION DEVICE

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CONFIRMATION #	9839	FILED BY	Benjamin Hudson
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CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. ROGERS
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
069366-0577657_Response 02DEC2024-APP.TEXT.docx	14	Application body structured text document	101 KB

Warning: Bookmarks were found and have been removed.

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
069366-0577657_Response 02DEC2024-APP.TEXT.docx	750B06B972BCC56FE8FC8663673DC63A2124328C5665EF318 876A80616797FE693C91B7F555D11E4407462CD8A058E9DE5 9C9D4AEB94094FC0B126366A5695DF

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 18/494,622		Filing Date 10/25/2023		☐ To be Mailed			
ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO											
APPLICATION AS FILED - PART I											
		(Column 1)		(Column 2)							
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A		N/A		N/A					
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A		N/A		N/A					
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A		N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(j))		minus 20 =		*		x \$40 =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 =		*		x \$ 192 =					
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))											
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL					
APPLICATION AS AMENDED - PART II											
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	05/30/2025	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0	x \$ 80 =		0			
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	x \$ 240 =		0			
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
								TOTAL ADD'L FEE		0	
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$ 0 =					
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$ 0 =					
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
								TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.								LIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".								/TAMARA D HARRELL/			
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".											
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.											

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 06/18/2025
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER

ABOUELELA, MAY A

ART UNIT PAPER NUMBER

3791

DATE MAILED: 06/18/2025

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/494,622	10/25/2023	Bobby E. ROGERS	069366-0577657_KUR2C05US	9839

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION DEVICE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$516	\$0.00	\$0.00	\$516	09/18/2025

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 06/18/2025

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/494,622	10/25/2023	Bobby E. ROGERS	069366-0577657_KUR2C05US	9839

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION DEVICE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$516	\$0.00	\$0.00	\$516	09/18/2025

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-577000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via the USPTO patent electronic filing system ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/494,622	10/25/2023	Bobby E. ROGERS	069366-0577657_KUR2C05US	9839
27500	7590	06/18/2025	EXAMINER	
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)			ABOUELELA, MAY A	
ATTENTION: DOCKETING DEPARTMENT			ART UNIT	
P.O BOX 10500			PAPER NUMBER	
McLean, VA 22102			3791	

DATE MAILED: 06/18/2025

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).

<https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf>

Routine uses of the information in this record may include disclosure to:

- 1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
- 2) a federal, state, local, or international agency, in response to its request;
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- 6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
- 7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
- 8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
- 9) the Office of Personnel Management (OPM) for personnel research purposes; and
- 10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 18/494,622	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 05/30/2025.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 2-31. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:
a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892) 2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____. 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material ____. 4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.	5. ☐ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
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/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	
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Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Terminal Disclaimer

2. The terminal disclaimer filed on 05/30/2025 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S Patents No.11832944 and 12138052 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

3. Applicant's arguments with respect to claim objections, 112 rejections, 103 rejection and double patenting rejection have been fully considered and are persuasive. The claim objections, 112 rejections, 103 rejection and double patenting rejection have been withdrawn.

Allowable Subject Matter

4. Claims 2-31 are allowed.
5. The following is an examiner's statement of reasons for allowance: the combination of the most pertinent prior art (see Non-Final Rejection mailed on 12/02/2024) teaches a device comprising: an inlet port configured for receiving a blood sample; an outlet port; a chamber connected to the inlet port and being configured to collect a first portion of the blood sample; and a sampling channel connected with the

inlet port and configured to convey a subsequent portion of the blood sample to the outlet port.

The prior art does not teach, disclose and/or fairly suggest the chamber having a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood sample; and a housing, separate from the blood impermeable membrane.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached at 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

<i>Index of Claims</i> 	Application/Control No. 18/494,622	Applicant(s)/Patent Under Reexamination ROGERS et al.
	Examiner MAY A ABOUELELA	Art Unit 3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant					☐ CPA		☒ T.D.		☐ R.1.47	
CLAIM		DATE								
Final	Original	10/16/2024	06/03/2025							
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1	2	✓	=							
2	3	✓	=							
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28	29	✓	=							
29	30	✓	=							
30	31	✓	=							

<i>Search Notes</i> 	Application/Control No. 18/494,622	Applicant(s)/Patent Under Reexamination ROGERS et al.
	Examiner MAY A ABOUELELA	Art Unit 3791

CPC - Searched*		
Symbol	Date	Examiner
A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068 OR A61B5/150251	10/16/2024	MA
updated as above	06/03/2025	MA

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
class/subclass search, inventor name search, text search	10/16/2024	MA
updated as above	06/03/2025	MA

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
as above		06/03/2025	MA

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	
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Issue Classification 	Application/Control No. 18/494,622	Applicant(s)/Patent Under Reexamination ROGERS et al.
	Examiner MAY A ABOUELELA	Art Unit 3791

CPC						
Symbol					Type	Version
A61B	/	5	/	150992	F	2013-01-01
A61M	/	39	/	04	I	2013-01-01
A61B	/	5	/	150221	I	2013-01-01
A61B	/	5	/	15003	I	2013-01-01
A61B	/	5	/	150213	I	2013-01-01
A61B	/	5	/	150389	I	2013-01-01
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A61M	/	39	/	0693	I	2013-01-01
A61M	/	2039	/	0202	A	2013-01-01
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A61M	/	2039	/	0633	A	2013-01-01

CPC Combination Sets					
Symbol				Type	Set

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	30	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	05 June 2025	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	2	15B

Issue Classification 	Application/Control No. 18/494,622	Applicant(s)/Patent Under Reexamination ROGERS et al.
	Examiner MAY A ABOUELELA	Art Unit 3791

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61B	/	5	/ 00
NON-CLAIMED			
/		/	

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE (Assistant Examiner)		Total Claims Allowed: 30	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791 (Primary Examiner)		05 June 2025 (Date)	O.G. Print Claim(s) 2
			O.G. Print Figure 15B

Issue Classification 	Application/Control No. 18/494,622	Applicant(s)/Patent Under Reexamination ROGERS et al.
	Examiner MAY A ABOUELELA	Art Unit 3791

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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8	9	17	18	26	27										

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 30	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791 (Primary Examiner) _____ (Date) _____		05 June 2025 O.G. Print Claim(s) 2	O.G. Print Figure 15B

Bibliographic Data

Application No: 18/494,622

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☒ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/

M.A.A

Examiner's Signature

Initials

Title:

BLOOD SAMPLE OPTIMIZATION DEVICE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
10/25/2023	600	3791	069366-0577657_KUR2C05US
RULE			

APPLICANTS

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INVENTORS

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Gino KANG, Irvine, CA, UNITED STATES

John DETLOFF, San Diego, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 18113710 02/24/2023 PAT 11832944

18113710 is a CON of 17538990 11/30/2021 PAT 11963769

17538990 is a CON of 16208559 12/04/2018 PAT 11185266

16208559 is a CON of 15994559 05/31/2018 PAT 10143412

15994559 is a CON of 15140448 04/27/2016 PAT 10010282

15140448 has PRO of 62318194 04/04/2016

15140448 has PRO of 62238636 10/07/2015

15140448 has PRO of 62196797 07/24/2015

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

11/07/2023

** SMALL ENTITY **

STATE OR COUNTRY

UNITED STATES

ADDRESS

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)

ATTENTION: DOCKETING DEPARTMENT

P.O BOX 10500
McLean, VA 22102
UNITED STATES

FILING FEE RECEIVED

\$1,320

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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L51	1	("20100057004").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:16 PM
L52	1	("20070088279").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 02:29 PM
L53	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/04/13 03:29 PM
L54	13	L53 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/13 03:52 PM
L55	1255	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/13 04:23 PM
L56	4	L55 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/13 04:23 PM
L57	272301	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/04/13 04:29 PM
L58	5898	L57 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/04/13 04:29 PM
L59	114	L58 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/13 04:29 PM
L60	2	("2007/0088279").URP N.	(USPAT)	OR	OFF	OFF	2017/04/13 05:58 PM
L61	1	("6358217").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/21 02:02 PM
L62	6	("2002/0004647").URP N.	(USPAT)	OR	OFF	OFF	2017/09/27 12:48 PM
L63	2	("14493796").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:21 PM
L64	2	("14494208").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:23 PM
L65	1	("15140443").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/27 01:28 PM
L66	1	("20080145933").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:51 PM
L67	9	("2008/0145933").URP N.	(USPAT)	OR	OFF	OFF	2017/09/27 01:55 PM

L68	1	("20040054333").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:59 PM
L69	1	("20120109034").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 02:37 PM
L70	1	("20100228206").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 02:39 PM
L71	3	("2010/0228206").URP N.	(USPAT)	OR	OFF	OFF	2017/09/27 02:47 PM
L72	66	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:41 PM
L73	4	L72 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:42 PM
L74	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 01:58 PM
L75	845	L74 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:58 PM
L76	9	L75 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:59 PM
L77	86	("2007/0083162").URP N.	(USPAT)	OR	OFF	OFF	2017/09/28 01:59 PM
L78	1	("15140443").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 01:59 PM
L79	9	("2008/0145933").URP N.	(USPAT)	OR	OFF	OFF	2017/09/28 02:04 PM
L80	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 02:20 PM
L81	1071	L80 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 02:20 PM
L82	78	L81 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 02:21 PM
L83	282596	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/09/28 04:01 PM
L84	6183	L83 AND (A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/09/28 04:01 PM
L85	387	L84 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:01 PM
L86	362	L85 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:02 PM
L87	12	("2005/0010189").URP N.	(USPAT)	OR	OFF	OFF	2017/09/28 04:03 PM
L88	1363	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:04 PM
L89	74	L88 and (blood near4 (sequest\$5 or	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:05 PM

L90	21	sampl\$4)) ("3965910" "3996923" "4131127" "4301811" "4450854" "4506691" "4819684" "5147333" "5393035" "5636975").PN. OR ("6569117").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2017/09/28 04:09 PM
L91	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:12 PM
L92	18	L91 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:12 PM
L93	9	("2008/0145933").URP N.	(USPAT)	OR	OFF	OFF	2017/09/28 04:13 PM
L95	67	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:23 PM
L96	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:25 PM
L97	4	L96 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:25 PM
L98	3	L97 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:26 PM
L99	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:50 PM
L100	13	L99 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:50 PM
L101	255	("1779451" "2004050" "2700385" "2836942" "2854976" "2953243" "3021942" "3073307" "3074542" "3255873" "3294231" "3323523" "3329146" "3333682" "3367488" "3382865" "3485239" "3537452" "3585984" "3610240" "3658061" "3664879" "3817240" "3828775" "3859998" "3874367" "3886930" "3890971" "3904033" "3934722" "3968876" "4106497" "4108175" "4113090" "4139009" "4154229" "4166450" "4175008" "4193400" "4207870" "4269186" "4300678" "4312362" "4317445" "4340068" "4375849" "4398544" "4409990" "4412548" "4416290" "4416291" "4418703"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/01/09 04:51 PM

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L102	215	L101 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:51 PM
L103	1347	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:11 PM
L104	17	L103 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L105	19	("2009/0312711").URP N.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L106	11	("2007/0106220").URP N.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L107	288967	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L108	6321	L107 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L109	121	L108 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:17 PM
L110	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:31 PM
L111	6	L110 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:31 PM
L113	71	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:31 PM
L114	0	("15140443").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2018/07/24

L115	2	(15/140443).APP.	USOCR) (US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	01:38 PM 2018/07/24 01:38 PM
L116	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:40 PM
L117	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 01:56 PM
L118	854	L117 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:56 PM
L119	91	L118 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:57 PM
L120	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:06 PM
L121	1074	L120 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L122	80	L121 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L123	301210	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L124	6556	L123 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L125	3664	L124 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L126	12749	"19" and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L127	117	L125 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L128	1348	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:16 PM
L129	75	L128 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:17 PM
L130	1	("20120291564").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:21 PM
L131	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:25 PM
L132	18	L131 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:25 PM
L133	98	("20020002349" "20020183651" "20030055381" "20030208151" "20040010228" "20040054333"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:44 PM

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L134	307	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:47 PM
L135	23	("4166450").PN. OR ("4412548").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L136	307	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L137	4	("2007/0088279").URP N.	(USPAT)	OR	ON	ON	2018/07/24 02:48 PM
L138	1	(14/990763).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:58 PM
L139	9	(blood and sequest\$5 and junction and first	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 03:07 PM

L140	1	and portion and sampl\$4).clm. (15/287421).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/25 09:39 PM
L141	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/26 11:56 AM
L142	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:24 PM
L143	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:25 PM
L144	34	("20020004647" "20030 105414" "20040054333 " "20040073171" "2004 0147855" "2005000452 4" "20050240161" "200 70088279" "200801459 33" "20100057004" "20 130317391" "20160174 888" "3817240" "38743 67" "3886930" "405705 0" "4106497" "4154229" "4207870" "4412548" "5 5222502" "5520193" "5 749857" "6569117" "81 97420" "8523826" "853 5241" "8540663" "8568 371" "8864684" "90229 51" "9060724" "913857 2" "9204864").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 05:53 PM
L145	272	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian")) OR (("GARRETT") near3 ("Chad"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/11/07 05:57 PM
L146	9	L145 and (blood near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 05:58 PM
L147	34	("20020004647" "20030 105414" "20040054333 " "20040073171" "2004 0147855" "2005000452 4" "20050240161" "200 70088279" "200801459	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 06:26 PM

		33" 20100057004" 20130317391" 20160174888" 3817240" 3874367" 3886930" 4057050" 4106497" 4154229" 4207870" 4412548" 5222502" 5520193" 5749857" 6569117" 8197420" 8523826" 8535241" 8540663" 8568371" 8864684" 9022951" 9060724" 9138572" 9204864").PN.					
L148	5	L147 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 06:29 PM
L149	6	("2010/0057004").URP N.	(USPAT)	OR	ON	ON	2019/11/07 06:40 PM
L150	0	L149 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:20 PM
L151	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:21 PM
L152	4	L151 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L153	1766	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:21 PM
L154	13	L153 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L155	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:22 PM
L156	48	L155 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:22 PM
L157	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L158	17	L157 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:43 PM
L159	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L160	6	L159 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L161	333030	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L162	6981	L161 AND (A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L163	139	L162 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L164	117	L163 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:45 PM
L165	1	L146 and (enclos\$3	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07

L166	1	near4 mechanism) ("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	07:51 PM 2019/11/08 04:57 PM
L167	1	(15/139716).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/11 12:09 PM
L168	1	(15/520430).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 11:02 AM
L169	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:11 PM
L170	1	("20120253321").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:13 PM
L171	1	(15/861959).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:14 PM
L172	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 02:17 PM
L173	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:14 PM
L174	1	("20080167577").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:19 PM
L175	4	("2008/0167577").URP N.	(USPAT)	OR	ON	ON	2019/12/09 03:30 PM
L176	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:31 PM
L177	39	(US-20040073171-\$ or US-20160174888-\$ or US-20050240161-\$ or US-20040147855-\$ or US-20130317391-\$ or US-20050004524-\$ or US-20030105414-\$ or US-20020004647-\$ or US-20100057004-\$ or US-20070088279-\$ or US-20080145933-\$ or US-20040054333-\$ or US-20100010372-\$ or US-20080319346-\$ or US-20080167577-\$).did. or (US-9138572-\$ or US-8568371-\$ or US-8540663-\$ or US- 8523826-\$ or US- 8197420-\$ or US- 4057050-\$ or US- 8864684-\$ or US- 8535241-\$ or US- 5749857-\$ or US- 9060724-\$ or US- 9204864-\$ or US- 3817240-\$ or US- 3874367-\$ or US- 3886930-\$ or US- 4106497-\$ or US- 4154229-\$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:37 PM

L178	8	4207870-\$ or US-4412548-\$ or US-5222502-\$ or US-5520193-\$ or US-9022951-\$ or US-6569117-\$ or US-3741197-\$ or US-8603009-\$).did. ("20040054333" "8197420" "9855001" "9861306" "10045724" "10028687" "8337418" "10028689").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:42 PM
L179	100	("20020002349" "20020183651" "20030055381" "20040010228" "20040054333" "20040147855" "20050004524" "20050240161" "20050245885" "20050281713" "20060287639" "2707953" "3013557" "3098016" "3382865" "3405706" "3494351" "3577980" "3648684" "3848579" "3937211" "4057050" "4133863" "4166450" "4340067" "4370987" "4444203" "4459997" "4509534" "4676256" "4865583" "4890627" "4988339" "5009847" "5097842" "5108927" "5122129" "5269317" "5360011" "5429610" "5450856" "5507299" "5577513" "5762633" "5882318" "5922551" "6016712" "6057105" "6159164" "6210909" "6364890" "6387086" "6403381" "6692479" "6746420" "6913580" "7044941" "7087047").PN. OR ("8197420").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 03:43 PM
L180	70	L179 and (blood near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 03:43 PM
L181	43	L180 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 03:44 PM
L182	270	((("BULLINGTON")	(US-PGPUB; USPAT;	OR	ON	ON	2019/12/09

L183	335813	near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR ("GAW") near3 ("Shan"))).INV. (blood near4 (sequest\$5 or sampl\$4))	USOCR; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	04:13 PM 2019/12/09 04:22 PM
L184	7259	L183 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L185	325	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 04:33 PM
L186	594	L184 and (flash\$6 and seal\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L187	476	L186 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L188	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:14 PM
L189	1123	L188 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L190	1013	L189 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L191	10	L190 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:16 PM
L192	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:23 PM
L193	1143	L192 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L194	1038	L193 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L195	3	L194 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L196	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:24 PM
L197	618	L196 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L198	557	L197 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L199	1	(15/854273).APP.	(US-PGPUB; USPAT;	OR	OFF	OFF	2019/12/09

L200	1351	(604/164.01).CCLS.	USOCR) (US-PGPUB; USPAT)	OR	ON	ON	05:25 PM 2019/12/09 05:31 PM
L201	219	L200 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L202	199	L201 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L203	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:36 PM
L204	44	L203 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:37 PM
L205	1	(15/508871).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/10 11:58 AM
L206	342199	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/03/16 12:53 PM
L207	4239	L206 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:53 PM
L208	146	L207 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:54 PM
L209	101	L208 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:55 PM
L210	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:38 PM
L211	1123	L210 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:38 PM
L212	1013	L211 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L213	22	L212 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L214	108	("20020193748" "20030093009" "20030105414" "20030220614" "20030229315" "20040059302" "20040092872" "20040193120" "20050004524" "20050065482" "20050124944" "20050187493" "20050245868"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 01:46 PM

		"20050245869" "20050245870" "20050245879" "20050245885" "20060036219" "20060224122" "20070106220" "20070106224" "20070167914" "20080086085" "20080177202" "20080319345" "20080319346" "20090204026" "20100262038" "4106497" "4207870" "4305406" "4572210" "4573976" "4641663" "4795443" "4840619" "4894055" "4900307" "4994046" "5015241" "5195985" "5215534" "5222502" "5242417" "5246428" "5256153" "5295970" "5303713" "5312372" "5336199" "5348544" "5356392" "5411492" "5439449" "5466223" "5501675" "5542932" "5599313" "5662617" "5665075" "5672161" "5676658" "5702369" "5704920" "5733265" "5755522" "5957892" "5984899" "6149629" "6224576" "6254575" "6261263" "6298541" "6344032" "6436086" "6440104" "6524277" "6533760" "6592556" "6623456" "6635032" "6648855" "6695819" "6699217" "6712792" "6780169" "6837877" "6869415" "6984223" "7001363" "7128726" "7147624" "7160267" "7163526" "7223258" "7226432" "7396343" "7428773" "7537581" "7766879" "D422700" "D442280" "D604836" "D604837" "D604838" "D604839" "D605287").PN. OR ("8603009").URPN.				
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L215	26	L214 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:47 PM
L216	27	("2008/0319346").URP N.	(USPAT)	OR	ON	ON	2020/03/16 01:47 PM
L217	23	("2003/0105414").URP N.	(USPAT)	OR	ON	ON	2020/03/16 01:48 PM
L218	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:52 PM
L219	1143	L218 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L220	25	L219 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L221	353695	((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:54 PM
L222	3643	L221 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L223	1926	L222 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L224	785	L223 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:56 PM
L225	7046	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 02:32 PM
L226	14	L225 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:35 PM
L227	1352	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:36 PM
L228	135	L227 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L229	19	L228 and (((vent\$4 or open\$5 or hole or aperture) near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L230	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:47 PM
L231	3	L230 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:47 PM
L232	19	("2008/0145933").URP N.	(USPAT)	OR	ON	ON	2020/03/16 02:48 PM
L233	795	(600/576).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16

L234	71	L233 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	02:58 PM 2020/03/16 02:58 PM
L235	57	L234 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:59 PM
L236	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:12 PM
L237	11	L236 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:12 PM
L238	45	("20040054333" "20050240161" "4412548" "5749857" "8197420" "9855001" "9861306" "20020004647" "20100057004" "3741197" "20040073171" "3874367" "4057050" "4106497" "8197420" "8535241" "8540663" "8603009" "8864684" "10045724" "3817240" "10028687" "20030105414" "5222502" "5520193" "6569117" "8568371" "20040147855" "20070088279" "20080145933" "20100010372" "3886930" "8523826" "9060724" "9204864" "8337418" "20050004524" "20080167577" "20080319346" "20130317391" "4154229" "9022951" "10028689" "20160174888" "4207870" "9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:13 PM
L239	6	("2008/0167577").URP N.	(USPAT)	OR	ON	ON	2020/03/16 03:13 PM
L240	118	("3500828" "3670729" "3714945" "3977400" "3994293" "3995619" "4106491" "4200096" "4468224" "4531987" "4549554" "4735215" "4828548" "4874373" "4893635" "4894052" "4907599" "4944308" "4994042" "5129884" "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 03:15 PM
L241	6	("2008/0167577").URP N.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 03:15 PM
L242	274	((("BULLINGTON") near3 ("Gregory")) OR	(US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	ON	ON	2020/03/16 03:25 PM

L243	61	((("PATTON") near3 ("Richard"))) OR ((("MIAZGA") near3 ("Jay"))) OR ((("GAW") near3 ("Shan"))).INV.	DERWENT)				
		L242 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:25 PM
L244	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:47 PM
L245	0	(14/502498).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:11 PM
L246	1	("20110082383").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L247	1	("8150506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L252	1	(15/057214).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/17 11:28 AM
L253	348964	(blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L254	7453	L253 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L255	155	L254 and ((vent\$4 near4 air) and flash\$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:23 PM
L256	77	((("ROGERS") near3 ("Bobby"))).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:35 PM
L257	343953	(blood same (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:40 PM
L258	11	L256 and (blood same (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:41 PM
L259	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:50 PM
L260	121	("3500828" "3670729" "3714945" "3977400" "3994293" "3995619" "4106491" "4200096" "4468224" "4531987" "4549554" "4735215" "4828548" "4874373" "4893635" "4894052" "4907599" "4944308" "4994042" "5129884" "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:19 PM
L261	32	L260 and (blood near4 (sequest\$5 or sampl\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:20 PM

L262	1	("3648684").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L263	1	("4056101").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L264	329	(600/577).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/06/10 06:39 PM
L265	11	L264 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:39 PM
L266	29	("2008/0319346").URP N.	(USPAT)	OR	ON	ON	2020/06/10 06:40 PM
L267	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:40 PM
L268	72	L267 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:40 PM
L269	1767	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:44 PM
L270	31	L269 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:45 PM
L271	77	("4676249" "4787891" "4850960" "4874382" "4886067" "4886500" "4900307" "4904242" "4917102" "4950252" "4955862" "5046508" "5116353" "5125718" "5129884" "5163911" "5217435" "5290244" "5295974" "5314503" "5318585" "5330432" "5360410" "5366441" "5376075" "5395337" "5531692" "5695475" "5695479" "5702367" "5735813" "5749857" "5788654" "5800395" "5846226" "5871470" "5882342" "5919172" "5935108" "5935113" "5989220" "6050976" "6077244" "6099504" "6126641" "6162195").PN. OR ("6398743").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:46 PM
L272	18	L271 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:46 PM
L273	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:48 PM
L274	7050	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:49 PM

L275	14	L274 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:49 PM
L276	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:51 PM
L277	7	L276 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:51 PM
L278	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:52 PM
L279	135	L278 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:52 PM
L280	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 07:08 PM
L281	3	L280 and ((blood or fluid\$4) near4 (sequest\$5 or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 07:08 PM
L282	20	("2008/0145933").URP N.	(USPAT)	OR	ON	ON	2020/06/10 07:08 PM
L286	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 08:56 PM
L287	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:16 PM
L288	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:17 PM
L289	100	((("ROGERS") near3 ("Bobby")) OR ("KANG") near3 ("Gino")) OR ((("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/03/01 09:17 PM
L290	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:36 PM
L291	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:39 PM
L292	180	((("ROGERS") near3 ("Bobby"))).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/03/02 12:19 PM
L293	11	L292 and (blood near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 12:20 PM
L294	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:47 PM
L295	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:49 PM
L296	1	("20020048170").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:36 PM
L297	1	("20040174525").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:49 PM
L298	1	("10045704").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2021/03/02

L299	27321	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.	USOCR) (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	03:09 PM 2021/03/02 03:17 PM
L300	4594	L299 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:27 PM
L301	3762	L300 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:28 PM
L302	257	L301 and (air near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L303	420	L301 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L304	1	("20110167658").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:30 PM
L305	5	("2015/0306288").URP N.	(USPAT)	OR	ON	ON	2021/03/02 04:15 PM
L306	1	(16/208559).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 04:32 PM
L307	2	("2009/0043225").URP N.	(USPAT)	OR	ON	ON	2021/03/02 04:49 PM
L308	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/03/02 05:00 PM
L309	1363	L308 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:00 PM
L310	73	L309 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L311	73	L310 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L312	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:34 PM
L313	711	L312 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L314	58	L313 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L315	58	L314 and	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02

L316	371	@ad<"20150724" (600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	05:34 PM 2021/03/02 05:42 PM
L317	277	L316 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:42 PM
L318	20	L317 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:43 PM
L319	336	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/03/02 05:44 PM
L320	210	L319 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L321	196	L320 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L322	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:48 PM
L323	1208	L322 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L324	73	L323 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L325	73	L324 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:49 PM
L326	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:59 PM
L327	271	L326 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L328	10	L327 and ((air or gas\$4) near4 permeab\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L329	268	L327 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L330	182	("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/07/08 02:22 PM
L331	27660	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/07/08 03:27 PM

L332	4684	A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc. L331 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:28 PM
L333	3769	L332 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L334	579	L333 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L335	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:54 PM
L336	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:56 PM
L337	337	("2913000" "3817240" "3859998" "3864979" "4016879" "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:19 PM
L338	211	L337 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L339	196	L338 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L340	37	L339 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L341	221	("20010021827" "20020004650" "20020055716" "20020072715" "20020103464" "20020103465" "20020107488" "20020151856" "20020193748" "20030028171" "20030036730" "20030050608" "20030055385" "20030078544" "20030093009" "20030105414" "20030114797" "20030120222" "20030176842" "20030181873" "20030191438" "20030199827" "20030216687"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"20030220614" "20030229315" "20030229316" "20040024370" "20040059302" "20040092872" "20040102740" "20040111068" "20040193120" "20040204681" "20040210197" "20050004524" "20050059936" "20050065482" "20050124944" "20050165353" "20050187493" "20050228345" "20050245868" "20050245869" "20050245870" "20050245879" "20050245885" "20050283093" "20060015073" "20060036217" "20060036219" "20060079847" "20060129064" "20060189934" "20060189936" "20060224122" "20060270947" "20060276756" "20070021724" "20070027430" "20070106220" "20070106224" "20070167914" "20070282275" "20080015513" "20080086085" "20080177202" "20080221528" "20080269691" "20080306452" "20080319345" "20080319346" "20090204026" "20090227896" "20100063455" "20100191189" "20100262038" "20110118674" "4106497" "4207870" "4305406" "4572210" "4573976" "4641663" "4795443" "4813426"				
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		"4840619" "4887998" "4894055" "4900307" "4923477" "4994046" "5015241" "5195985" "5215534" "5219333" "5222502" "5242417" "5246428" "5256153").PN. OR ("5295970" "5295975" "5303713" "5312372" "5318547" "5336199" "5344408" "5348544" "5356392" "5389085" "5403286" "5411492" "5439449" "5466223" "5501675" "5542932" "5549558" "5595566" "5599313" "5607402" "5662617" "5665075" "5669889" "5672161" "5676658" "5681295" "5685855" "5687740" "5688241" "5695474" "5702369" "5704920" "5718239" "5733265" "5755522" "5769826" "5795336" "5879337" "5893845" "5910130" "5921964" "5957892" "5984899" "6149629" "6171284" "6183445" "6224576" "6254575" "6261263" "6261265" "6298541" "6344032" "6419658" "6436086" "6440104" "6471677" "6475191" "6485469" "6524277" "6533760" "6554807" "6575939" "6592556" "6623456" "6623461" "6635032" "6641555" "6648855" "6648856" "6659983" "6695819" "6699217" "6712792" "6716199" "6761704" "6773419" "6780169" "6805689" "6811545" "6835190" "6837877" "6846302" "6860872" "6869415" "6905483" "6918891" "6958054" "6974423" "6984223" "6997913" "7001363" "7083600" "7101355" "7128726" "7147624" "7160267" "7163526" "7201740" "7211065" "7223258"				
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L342	115	"7226432" "7361159" "7396343" "7428773" "7524308" "7537581" "7670320" "7727190" "7766879" "7938808" "8066679" "8282605" "8795198" "D422700" "D442280" "D604836" "D604837" "D604838" "D604839" "D605287" "RE35539" "RE43473").PN. OR ("9615783").URPN. ("20020193748" "20030093009" "20030105414" "20030220614" "20030229315" "20040059302" "20040092872" "20040193120" "20050004524" "20050065482" "20050124944" "20050187493" "20050245868" "20050245869" "20050245870" "20050245879" "20050245885" "20060036219" "20060224122" "20070106220" "20070106224" "20070167914" "20080086085" "20080177202" "20080319345" "20080319346" "20090204026" "20100262038" "4106497" "4207870" "4305406" "4572210" "4573976" "4641663" "4795443" "4840619" "4894055" "4900307" "4994046" "5015241" "5195985" "5215534" "5222502" "5242417" "5246428" "5256153" "5295970" "5303713" "5312372" "5336199" "5348544" "5356392" "5411492" "5439449" "5466223" "5501675" "5542932" "5599313"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM
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L343	148	"5662617" "5665075" "5672161" "5676658" "5702369" "5704920" "5733265" "5755522" "5957892" "5984899" "6149629" "6224576" "6254575" "6261263" "6298541" "6344032" "6436086" "6440104" "6524277" "6533760" "6592556" "6623456" "6635032" "6648855" "6695819" "6699217" "6712792" "6780169" "6837877" "6869415" "6984223" "7001363" "7128726" "7147624" "7160267" "7163526" "7223258" "7226432" "7396343" "7428773" "7537581" "7766879" "D422700" "D442280" "D604836" "D604837" "D604838" "D604839" "D605287").PN. OR ("8603009").URPN. ("20020193748" "20030105414" "20030229315" "20040059302" "20040092872" "20050004524" "20050187493" "20050245868" "20050245869" "20050245870" "20050245885" "20060036219" "20070106220" "20070167914" "20080086085" "20080177202" "4106497" "4207870" "4305406" "4573976" "4641663" "4795443" "4840619" "4894055" "4900307" "4994046" "5015241" "5195985" "5215534" "5222502" "5242417" "5256153" "5295970" "5303713" "5312372" "5336199" "5348544" "5356392" "5411492" "5439449" "5466223" "5501675" "5542932" "5672161"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM
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L344	41	("2735430" "2798487" "3187749" "3240209" "3585984" "3817240" "4166450" "4207870" "4295477" "4312362").PN. OR ("4436098").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:22 PM
L345	163	L341 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:22 PM
L346	163	L345 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:23 PM
L347	22	("2005/0283093").URP N.	(USPAT)	OR	ON	ON	2021/07/08 04:23 PM
L348	163	L345 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L349	163	L348 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L350	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/08 04:37 PM
L351	1363	L350 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:37 PM
L352	1346	L351 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L353	136	L352 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L354	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:41 PM
L355	711	L354 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM

L356	699	or flash\$4 or collect\$4)) L355 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L357	123	L356 and (vent\$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L358	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:44 PM
L359	277	L358 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L360	260	L359 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L361	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:46 PM
L362	1208	L361 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:46 PM
L363	1194	L362 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L364	1194	L363 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L366	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:05 PM
L367	319	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MAZGA") near3 ("Jay")) OR ("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/02/02 03:14 PM
L368	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:35 PM
L369	190	((("ROGERS") near3 ("Bobby"))).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 03:36 PM
L370	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:41 PM
L371	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L372	1	("9060725").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L373	1	("9060724").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:43 PM
L374	1	("9022950").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L375	1	("9022951").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L376	1	("10292633").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2022/02/02

L377	1	("10433779").PN.	USOCR) (US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	03:46 PM 2022/02/02 03:47 PM
L378	1	("10436554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:48 PM
L379	1	("10736554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L380	1	("10912506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L381	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L382	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:50 PM
L383	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:51 PM
L384	276	(600/579).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:52 PM
L385	204	L384 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 03:53 PM
L386	37427	(A61B5/150221 or A61B5/15003 or A61B5/150236 or A61B5/150244 or A61B5/150251 or A61B5/150389 or A61B5/150503 or A61B5/150992 or A61B5/153 or A61B5/155 or A61B10/0048 or A61B10/0051 or A61B10/007 or A61B2010/0061 or A61B2010/0077 or A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 04:35 PM
L387	7279	L386 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L388	4442	L387 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L389	874	L388 and (seal\$4 near4 (member or mechanism\$4 or vent\$4 or elastic\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:38 PM
L390	26	("2008/0145933").URP N.	(USPAT)	OR	ON	ON	2022/02/02 04:52 PM
L391	44	("2008/0319346").URP N.	(USPAT)	OR	ON	ON	2022/02/02 04:59 PM
L392	385	L386 and ((blood or fluid) near4 (seal\$4 near4 (member or	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM

L393	171	mechanism\$4 or vent\$4 or elastic\$4))) L392 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L394	355	(604/103).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 05:52 PM
L395	7	L394 and ((blood or fluid) near4 (seal\$4 near4 (member or mechanism\$4 or vent\$4 or elastic\$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:52 PM
L396	1	(16/328127).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/03 12:00 PM
L397	0	"1020130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L398	8	"20130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L399	14	"2013021595"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:18 PM
L400	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/04 07:10 PM
L401	1	(15/746656).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/05 11:48 AM
L402	0	(17/388440).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/07 09:34 AM
L403	1	("20050048465").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2022/02/07 09:34 AM
L404	196	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:08 PM
L405	16	L404 and (blood near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L406	16	L404 and ((blood or chamber) near4 sequest\$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L407	16	L406 and (junct\$4 or bypass\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L408	16	L406 and junct\$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L409	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:54 PM

L410	4525	A61B5/150572 or A61B5/154 or A61B5/15074).cpc. L409 and ((blood or fluid\$4) near4 (sequest\$5 or sampl\$4 or flash\$4 or collect\$4 or flush\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:55 PM
L411	3810	L410 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:56 PM
L412	820	L411 and ((vent\$4 or open\$4 or apertur\$4) near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:57 PM
L413	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 05:51 PM
L414	4603	L413 and ((blood or fluid\$4 or chamber) same (sequest\$5 or sampl\$4 or flash\$4 or collect\$4 or flush\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:51 PM
L415	511	L414 and ((junct\$4 or bypass\$4 or divert\$4) near4 (blood or fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:52 PM
L416	355	L415 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:53 PM
L417	1	(16/819033).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:10 PM
L418	1	(17/094692).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L419	1	(17/538990).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L420	1	("11311219").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:27 PM
L421	1	("11185266").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:30 PM
L422	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:31 PM
L423	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:32 PM
L424	252	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	OFF	OFF	2022/10/13 01:41 PM

			IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L425	38	424 AND (closur\$4 OR enclos\$4)	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:42 PM
L426	42781	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/13 01:47 PM
L427	5205	426 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:50 PM
L428	4803	427 AND ((blood OR fluid\$4) near4 (sequest\$5 OR sampl\$4 OR flash\$4 OR collect\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:51 PM
L429	519	428 AND ((closur\$4 OR enclos\$4 OR pug\$4) near5 (vent OR open\$4 OR air))	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:54 PM
L430	169	"5749857"	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:14 PM
L431	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:14 PM
L432	346	427 AND ((junct\$4 OR bypass\$4 OR divert\$4) near4 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 02:18 PM
L433	186	("3500828" "3670729" "3714945" "3977400" "3994293" "3995619" "4106491" "4200096" "4468224" "4531987" "4549554" "4735215" "4828548" "4874373" "4893635" "4894052" "4907599" "4944308" "4994042" "5129884"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/10/13 02:32 PM

L434	124	"5400798").pn. OR ("5749857").urpn. AND (PGPB USPT USOC).dbnm. 433 AND ((blood OR fluid\$4) near4 (sequest\$5 OR sampl\$4 OR flash\$4 OR collect\$4 OR optimiz\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 02:34 PM
L435	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:34 PM
L436	1	17/138056	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/19 11:35 AM
L437	253	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/11/16 03:25 PM
L438	39	437 AND (closur\$4 OR enclos\$4)	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 03:25 PM
L439	35391	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/154 OR A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/11/16 03:46 PM
L440	4100	439 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:48 PM
L441	3875	440 AND ((blood OR fluid\$4 OR urine) SAME (sequest\$5 OR sampl\$4 OR flash\$4 OR collect\$4 OR	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:49 PM

L442	368	optimiz\$5)) 441 AND ((junct\$4 OR bypass\$4 OR divert\$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:50 PM
L443	7	"10827964"	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 04:13 PM
L444	1	16/819033	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 04:48 PM
L445	359	"4207870"	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 05:07 PM
L446	1	("4207870").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 05:07 PM
L447	3814	440 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR sampl\$4 OR flash\$4 OR collect\$4 OR optimiz\$5))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:17 PM
L448	366	447 AND ((junct\$4 OR bypass\$4 OR divert\$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:17 PM
L449	89	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 01:13 PM
L450	24	449 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR sampl\$4 OR flush\$4 OR collect\$4 OR optimiz\$5or flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:14 PM
L451	24	449 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR sampl\$4 OR flush\$4 OR collect\$4 OR optimiz\$5 OR flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:14 PM
L452	6634	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 01:32 PM
L453	5326	452 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:32 PM
L454	4928	453 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR sampl\$4 OR flush\$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:32 PM

L455	371	OR collect\$4 OR optimiz\$5 OR flash\$4)) 454 AND ((junct\$4 OR bypass\$4 OR divert\$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:33 PM
L456	11	("2016/0361006").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:03 PM
L457	1	17/094692	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:11 PM
L458	49	("20020004647" "20030 105414" "20040054333 " "20040073171" "2004 0147855" "2005000452 4" "20050240161" "200 70083162" "200700882 79" "20080086085" "20 080145933" "20080167 577" "20080319346" "2 0100010372" "2010005 7004" "20120016266" " 20130317391" "201600 08579" "20160174888" " "3741197" "3817240" "3 874367" "3886930" "40 57050" "4106497" "415 4229" "4207870" "4412 548" "4436098" "44442 03" "5222502" "552019 3" "5749857" "6398743" "6569117" "8197420" " 8523826" "8535241" "8 540663" "8568371" "86 03009" "8864684" "902 2950" "9022951" "9060 724" "9138572" "91554 95" "9204864" "987767 5").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:18 PM
L459	13	458 AND ((junct\$4 OR bypass\$4 OR divert\$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:18 PM
L460	155	("2707953" "2992974" "3013557" "3098016" "3382865" "3405706" "3494351" "3577980" "3635798" "3648684" "3848579" "3890203" "3937211" "4057050" "4133863" "4166450" "4340067" "4370987" "4425235" "4444203" "4459997" "4509534" "4657160" "4676256" "4865583" "4890627"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:21 PM

		"4988339" "5009847" "5097842" "5108927" "5122129" "5269317" "5330464" "5360011" "5429610" "5450856" "5454786" "5485854" "5507299" "5577513" "5762633" "5865812" "5882318" "5922551" "6016712" "6057105" "6159164" "6210909" "6328726" "6364890" "6387086" "6403381" "6520948" "6626884" "6692479" "6716187" "6746420" "6913580" "7044941" "7087047" "7335188" "7384416" "7744573" "8197420" "8231546" "8337418" "8535241" "8647286" "8864684" "8876734" "20020002349" "20020183651" "20030055381" "20030208151" "20040010228" "20040054283" "20040054333" "20040147855" "20050004524" "20050240161" "20050245885" "20050281713" "20060287639" "20080108954" "20080145933" "20100152681" "20120095367" "20120215131" "20130079604" "20130116599" "20130317391" "20140081172").pn. OR ("9060724").urpn. AND (PGPB USPT USOC).dbnm. ("2008/0145933").urpn. AND (PGPB USPT USOC).dbnm. ("5749857").pn. 459 AND ((junct\$4 OR bypass\$4 OR divert\$4) near5 (blood OR fluid OR urine))					
L461	31		(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:30 PM
L462	1		(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:46 PM
L463	13		(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:47 PM

L464	4994	453 AND ((blood OR fluid\$4 OR urine OR semen) SAME (sequest\$5 OR sampl\$4 OR flush\$4 OR collect\$4 OR optimiz\$5 OR flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:58 PM
L465	968	464 AND ((junct\$4 OR bypass\$4 OR diver\$5) SAME (blood OR fluid OR urine OR semen))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:59 PM
L466	707	465 AND housing	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:50 PM
L467	2911	464 AND ((blood OR fluid\$4 OR urine OR semen) near5 (first OR second OR subsequent\$4 OR bypass))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L468	2954	464 AND ((blood OR fluid\$4 OR urine OR semen) near5 (first OR second OR subsequent\$4 OR convey\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L469	2891	464 AND ((blood OR fluid\$4 OR urine OR semen) near5 (first OR second OR subsequent\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L470	790	469 AND ((junct\$4 OR bypass\$4 OR diver\$5) SAME (blood OR fluid OR urine OR semen))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:53 PM
L471	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 12:35 PM
L472	164	((("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2023/05/08 02:18 PM
L473	1	("4207870").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:23 PM
L474	1	("10827964").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08

L475	1	("11311219").pn.	(US-PGPUB; USPAT)	OR	ON	ON	03:31 PM 2023/05/08 03:32 PM
L476	1	"17094692"	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:34 PM
L477	2	"17730118"	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:34 PM
L478	1	("10012828").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:36 PM
L479	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:36 PM
L480	48138	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/05/08 03:59 PM
L481	5081	480 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 04:15 PM
L482	3947	481 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR sampl\$4 OR flush\$4 OR collect\$4 OR optimiz\$5 OR flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 04:17 PM
L483	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 04:17 PM
L484	1069	482 AND (air near5 (filter\$4 OR material\$4 OR membrane OR permeab\$4 OR vent\$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 04:32 PM
L485	203	("3500828" "3670729" "3714945" "3977400" "3994293" "3995619" "4106491" "4200096" "4468224" "4531987" "4549554" "4735215" "4828548" "4874373" "4893635" "4894052" "4907599" "4944308" "4994042" "5129884" "5400798").pn. OR ("5749857").urpn. AND	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/05/08 04:51 PM

L486	606	(PGPB USPT USOC).dbnm. 484 AND ((pressure OR vacuum) near5 (draw OR forc\$4 OR withdraw OR flow\$4)) SAME (blood OR fluid)	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 05:32 PM
L487	24	("2010/0057004").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/05/08 05:35 PM
L488	3	487 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 05:55 PM
L489	49	((US-20080319346-A1 OR US-20100057004-A1 OR US-20070088279-A1 OR US-20080145933-A1 OR US-20040054333-A1 OR US-20100010372-A1 OR US-20080167577-A1 OR US-20080086085-A1 OR US-20070083162-A1 OR US-20160008579-A1 OR US-20120016266-A1 OR US-20130317391-A1 OR US-20160174888-A1 OR US-20050240161-A1 OR US-20040147855-A1 OR US-20040073171-A1 OR US-20050004524-A1 OR US-20030105414-A1 OR US-20020004647-A1).did. AND PGPB.dbnm.) OR ((US-4412548-A OR US-5222502-A OR US-5520193-A OR US-9022951-B2 OR US-6569117-B1 OR US-3741197-A OR US-8603009-B2 OR US-4207870-A OR US-9877675-B2 OR US-4444203-A OR US-6398743-B1 OR US-9022950-B2 OR US-9155495-B2 OR US-4436098-A OR US-9138572-B2 OR US-8568371-B2 OR US-8540663-B2 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/05/08 06:07 PM

		8523826-B2 OR US-8197420-B2 OR US-4057050-A OR US-8864684-B2 OR US-8535241-B2 OR US-5749857-A OR US-9060724-B2 OR US-9204864-B2 OR US-3817240-A OR US-3874367-A OR US-3886930-A OR US-4106497-A OR US-4154229-A).did. AND USPT.dbnm.)					
L490	25	489 AND (air near5 (filter\$4 OR material\$4 OR membrane OR permeab\$4 OR vent\$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:07 PM
L491	204	482 AND (hous\$4 SAME (inlet AND outlet AND channel))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:29 PM
L492	118	491 AND (hous\$4 near5 ((top OR upper) AND (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:33 PM
L493	1	489 AND (hous\$4 near5 ((top OR upper) AND (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L494	0	489 AND (hous\$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L495	27	492 AND (hous\$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L496	172	484 AND (hous\$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:41 PM
L497	113	((("ROGERS") near3 ("Bobby")) OR ((("KANG") near3 ("Gino")) OR ((("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2023/07/05 01:58 PM
L498	26	497 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR sampl\$4 OR flush\$4 OR collect\$4 OR optimiz\$5 OR flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 01:58 PM

L499	4	15/855439	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 03:12 PM
L500	48306	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/05 03:36 PM
L501	5081	500 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 03:36 PM
L502	3947	501 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR sampl\$4 OR flush\$4 OR collect\$4 OR optimiz\$5 OR flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 03:37 PM
L503	1069	502 AND (air near5 (filter\$4 OR material\$4 OR membrane OR permeab\$4 OR vent\$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 03:37 PM
L504	3871	501 AND ((blood OR fluid\$4 OR urine) near5(divert\$4 OR direct\$4 OR flow\$4 OR bypass\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:18 PM
L505	3030	501 AND ((blood OR fluid\$4 OR urine) near5(divert\$4 OR direct\$4 OR flow\$4 OR bypass\$4 OR allow\$4)) SAME (channel\$4 OR chamber OR junct\$4 OR inlet OR outlet OR path\$4 OR contain\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:20 PM
L506	921	503 AND ((blood OR fluid\$4 OR urine) near5(divert\$4 OR direct\$4 OR flow\$4 OR bypass\$4 OR allow\$4)) SAME (channel\$4 OR chamber OR junct\$4 OR inlet OR outlet OR path\$4 OR contain\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:20 PM
L507	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05

L508	1	16/961875	(US-PGPUB; USPAT)	OR	ON	ON	06:04 PM 2023/07/05 08:21 PM
L509	7	"20070148624"	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 01:02 PM
L510	43469	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO)	OR	ON	ON	2023/08/31 01:28 PM
L511	5081	510 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L512	3947	511 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR sampl\$4 OR flush\$4 OR collect\$4 OR optimiz\$5 OR flash\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L513	2653	512 AND ((blood OR fluid\$4 OR urine) near5(divert\$4 OR direct\$4 OR flow\$4 OR bypass\$4 OR allow\$4)) SAME (channel\$4 OR chamber OR junct\$4 OR inlet OR outlet OR path\$4 OR contain\$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L514	921	513 AND (air near5 (filter\$4 OR material\$4 OR membrane OR permeab\$4 OR vent\$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 01:33 PM
L515	1	18/113710	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:05 PM
L516	372	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR ("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2023/11/20 02:30 PM
L517	172	516 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:41 PM

L518	165	sample\$4 OR flush\$4 OR collect\$4 OR optimize\$5 OR flush\$4 OR divert\$4 OR bypass\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:42 PM
L519	165	516 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR flush\$4 OR optimize\$5 OR flush\$4 OR divert\$4 OR bypass\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:42 PM
L520	1	("11395612").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:43 PM
L521	1	("11395611").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:45 PM
L522	1	("10292633").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:46 PM
L523	1	("9022950").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:52 PM
L524	11	"10736554"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L525	1	("10736554").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L526	1	("10912506").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L527	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:56 PM
L528	1	("9820682").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:58 PM
L529	67080	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/11/20 03:05 PM
L530	1791	529 AND ((blood OR fluid\$4 OR urine)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 03:05 PM

L531	322	near5(sequest\$5 OR flush\$4 OR optimiz\$5 OR flash\$4 OR diver\$5 OR bypass\$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:07 PM
L532	420	530 AND (flow\$4 OR control\$4 OR divert\$4 OR mechanism) near5 rotat\$4	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:07 PM
L533	0	("2021/0128037").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/20 03:39 PM
L534	1267	530 AND (flow\$4 OR control\$4 OR divert\$4 OR mechanism OR valve) near5 (chamber OR reservoir OR hous\$4 OR container)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:56 PM
L535	1142	530 AND (flow\$4 OR control\$4 OR divert\$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:56 PM
L536	1	17/863605	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 04:48 PM
L537	1	("10292633").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 05:19 PM
L538	505	530 AND (flow\$4 OR control\$4 OR divert\$4 OR mechanism OR valve) near5 (multiple OR pluarlit\$4 OR first OR second) near5 (lumen OR channel OR path\$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 05:25 PM
L539	8	"20080077183"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 01:29 PM
L540	1	15/933356	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 01:47 PM
L541	7	("20060074354" "20080077183" "20100131454" "20140228714" "20150196247" "20200129380" "9974476").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:08 PM
L542	6	541 AND (suck\$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:09 PM
L543	146297	(A61B5/4542 OR A61B5/7242 OR A61B5/7246 OR	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY,	OR	ON	ON	2023/11/21 02:17 PM

		A61B5/7257 OR A61B5/7267 OR A61B5/7282 OR A61B2503/045 OR A61B2562/0247 OR A61B5/038 OR A61B5/002).cpc.	CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L544	16368	543 AND @ad<"20170322"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:17 PM
L545	15	544 AND (determin\$4 OR measur\$4 OR detect\$4 OR process\$4) near5(suck\$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:18 PM
L546	120	544 AND (determin\$4 OR measur\$4 OR detect\$4 OR process\$4 OR estimat\$4) near5((suck\$4 OR feed\$4) near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:20 PM
L547	15	544 AND (determin\$4 OR measur\$4 OR detect\$4 OR process\$4 OR estimat\$4) near5((suck\$4) near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:20 PM
L548	1868	(determin\$4 OR measur\$4 OR detect\$4 OR process\$4 OR estimat\$4) near5(suck\$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:27 PM
L549	1387	548 AND @ad<"20170322"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:27 PM
L550	48	(determin\$4 OR measur\$4 OR detect\$4 OR process\$4 OR estimat\$4) near5(suck\$4 near5 pressure) AND (nutrit\$4 SAME feed\$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:34 PM
L551	39	550 AND (baseline OR threshold OR predetermin\$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:35 PM
L552	16	"20150011874"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:55 PM
L553	5	"20140288398"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21

L554	6	"20140120531"	(US-PGPUB; USPAT)	OR	ON	ON	02:55 PM 2023/11/21 03:01 PM
L555	1	("9060724").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:45 PM
L556	1	("10433779").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:49 PM
L557	12	"10736554"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:50 PM
L558	1	("10912506").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:54 PM
L559	0	18/381369	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 05:01 PM
L560	21	(Artificial Intelligence) More like doc: US-10912506-B2 Text: (US-20200359951-A1 OR US-11395611-B2 OR US-20220071533- A1 OR US- 20180116577-A1 OR US-11395612-B2 OR US-20220079482-A1 OR US-10736554-B2 OR US-10433779-B2 OR US-20150351679- A1 OR US- 20140155781-A1 OR US-9060724-B2 OR US-20150011910-A1 OR US-9022951-B2 OR US-20210361206-A1 OR US-20150011911- A1 OR US-9022950-B2 OR US-20150257691- A1 OR US- 20200060595-A1 OR US-10292633-B2 OR US-20230172502- A1).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/11/21 07:16 PM
L561	0	("10912506").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/21 07:16 PM
L562	273	("2707953" "2992974" "3013557" "3098016" "3382865" "3405706" "3467095" "3494351" "3494352" "3577980" "3604410" "3635798" "3648684" "3730168" "3741197" "3777773" "3803810" "3817240" "3834372" "3835835" "3848579" "3848581"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/21 07:16 PM

		"3874367" "3886930"					
		"3890203" "3890968"					
		"3937211" "3945380"					
		"3978846" "4056101"					
		"4057050" "4063460"					
		"4077395" "4106497"					
		"4133863" "4150089"					
		"4154229" "4166450"					
		"4190426" "4193400"					
		"4207870" "4212308"					
		"4238207" "4257416"					
		"4275730" "4298358"					
		"4340067" "4340068"					
		"4349035" "4370987"					
		"4398544" "4412548"					
		"4416290" "4425235"					
		"4444203" "4459997"					
		"4509534" "4608996"					
		"4654027" "4657027"					
		"4657160" "4673386"					
		"4676256" "4679571"					
		"4705497" "4714461"					
		"4772273" "4865583"					
		"4879098" "4886072"					
		"4890627" "4904240"					
		"4980297" "4988339"					
		"5009847" "5027827"					
		"5032116" "5045185"					
		"5066284" "5084034"					
		"5097842" "5100394"					
		"5108927" "5116323"					
		"5122129" "5135489"					
		"5222502" "5269317"					
		"5330464" "5417673"					
		"5431811" "5439450"					
		"5450856" "5466228"					
		"5472605" "5485854"					
		"5507299" "5520193"					
		"5575777" "5603700"					
		"5632906" "5649912"					
		"5691486" "5749857"					
		"5772608" "5811658"					
		"5824001" "5865812"					
		"5871699" "5911705"					
		"5961472" "5971956"					
		"5980830" "6001307"					
		"6010633" "6106509"					
		"6210909" "6224561"					
		"6325975" "6328726"					
		"6364890" "6387086"					
		"6403381" "6506182"					
		"6520948" "6569117"					
		"6626884" "6638252"					
		"6648835" "6692479"					
		"6695004" "6716187"					
		"6733433" "6736783"					
		"6746420" "6843775"					
		"6860871" "6905483"					

		"6913580" "6945948" "7044941" "7052603" "7055401" "7087047" "7141097" "7241281" "7306736" "7314452" "7316662" "7335188" "7384416" "7461671" "7479131" "7614857" "7615033" "7618407" "7648491" "7666166" "7744573" "7766879" "8070725" "8197420" "8231546" "8337418" "8349254" "8377040" "8382712" "8383044" "8412300" "8523826" "8535241" "8540663" "8568371" "8574203" "8603009" "8647286" "8795198" "8827958" "8864684" "8876734" "9022950" "9022951" "D731643" "9060724" "9060725" "9138572" "9149576" "9155495" "9204864" "9314201" "9855001" "9855002" "9855386" "9861306" "9872645" "9877675" "9895092" "9950084" "9999383" "10028687" "10028689" "10045724" "10251590" "10736554" "20010039058" "20020002349" "20020004647" "20020183651" "20020193751" "20030013991" "20030055381" "20030069543" "20030105414" "20030208151" "20040009542" "20040010228" "20040054283" "20040054333" "20040127816" "20040147855" "20050004524" "20050148993" "20050161112" "20050199077" "20050240161" "20050245885"				
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L563	303	"20050273019" "20050281713" "20060251622" "20060287639" "20070088279" "20070100250" "20070119508" "20070287948" "20080086085" "20080108954" "20080167577" "20080185056" "20080319346" "20090050213" "20090306601" "20100010372" "20100042048" "20100057004" "20100094171" "20100152681" "20100268118" "20110306899" "20120035540" "20120265099" "20120265128" "20140066880" "20150018715" "20150342510" "20150351679" "20160174888" "20160213294" "20170071519" "20180160958" "20180353117" "20190076074" "20190175087" "20200060595" "20200060596").pn. OR ("10912506").urpn. AND (PGPB USPT USOC).dbnm. (("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/01/08 02:52 PM
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L564	26	563 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR flush\$4 OR optimiz\$5 OR flash\$4 OR diver\$5 OR bypass\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 02:55 PM
L565	33645	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/01/08 03:06 PM
L566	5091	565 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:09 PM
L567	1014	566 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR flush\$4 OR optimiz\$5 OR flash\$4 OR diver\$5 OR bypass\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:09 PM
L568	828	567 AND (flow\$4 OR control\$4 OR divert\$4 OR mechanism OR valve OR junct\$4) near5 (chamber OR reservoir OR container OR hous\$4 OR inlet OR outlet OR channel OR port)	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 03:15 PM
L569	51	("20020004647" "20030105414" "20040054333" "20040073171" "20040147855" "20050004524" "20050240161" "20070083162" "20070088279" "20080086085" "20080145933" "20080167577" "20080319346" "20100010372" "20100057004" "20120016266" "20130317391" "20150314105" "20150359473" "20160008579" "20160174888" "3741197" "3817240" "3874367" "3886930" "4057050" "4106497" "4154229" "4207870" "4412548" "443609	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 03:40 PM

L570	35	8" "4444203" "5222502" "5520193" "5749857" "6398743" "6569117" "8197420" "8523826" "8535241" "8540663" "8568371" "8603009" "8864684" "9022950" "9022951" "9060724" "9138572" "9155495" "9204864" "9877675").PN. 569 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR flush\$4 OR optimiz\$5 OR flash\$4 OR diver\$5 OR bypass\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:40 PM
L571	353	567 AND (air near5 (filter\$4 OR material\$4 OR membrane OR permeab\$4 OR vent\$4))	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:09 PM
L572	3	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:12 PM
L573	1	17/110651	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:28 PM
L574	16	"20150011874"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:23 PM
L575	5	"20140288398"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:26 PM
L576	7	"20140120531"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:27 PM
L577	2	"20140135604"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:26 PM
L578	1	("10624616").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L579	7	"20090118628"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L580	1	("10687811").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L581	2	"20060287603"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:41 PM
L582	1	18/494622	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:48 PM
L583	1	("11832944").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:49 PM
L584	21	"20100057004"	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:51 PM
L585	24	"20080167577"	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:00 PM
L586	1	("11963769").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:26 PM
L587	1	("11185266").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16

L588	1	("10143412").pn.	(US-PGPUB; USPAT)	OR	ON	ON	06:26 PM 2024/09/16 06:27 PM
L589	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	06:28 PM 2024/09/16 06:52 PM
L590	122	((("ROGERS") near3 ("Bobby")) OR ((("KANG") near3 ("Gino")) OR ((("DETLOFF") near3 ("John")))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/09/16 06:54 PM
L591	25	590 AND (flow\$4 OR control\$4 OR divert\$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container) AND (blood near5 impermeable)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:03 PM
L592	50925	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/09/16 07:03 PM
L593	5094	592 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/16 07:04 PM
L594	1015	593 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR flush\$4 OR optimiz\$5 OR flash\$4 OR diver\$5 OR bypass\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/16 07:06 PM
L595	6	594 AND (blood near5 (filter OR impermeabl\$4 OR membrane)) WITH (facilitat\$4 OR caus\$4) near5 (withdraw\$4 OR draw\$4 OR sampl\$4 OR collect\$4)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:07 PM
L596	0	594 AND (blood near5 (filter OR impermeabl\$4 OR membrane)) WITH (facilitat\$4 near5 (withdraw\$4 OR draw\$4 OR sampl\$4 OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:07 PM

L597	2	collect\$4)) 594 AND (blood near5 (filter OR impermeabl\$4 OR membrane)) SAME (facilitat\$4 near5 (withdraw\$4 OR draw\$4 OR sampl\$4 OR collect\$4))	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:08 PM
L598	66	593 AND (flow\$4 OR control\$4 OR divert\$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container) AND (blood near5 impermeable)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:20 PM
L599	0	18/783088	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:35 PM
L600	1	18/494622	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 08:32 PM
L601	1	("11832944").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 08:32 PM
L602	1	18/549438	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/17 01:14 PM
L603	326	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/12/23 03:36 PM
L604	32	603 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR flush\$4 OR optimiz\$5 OR flash\$4 OR diver\$5 OR bypass\$4 OR subsequent\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/12/23 03:37 PM
L605	1635	593 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR flush\$4 OR optimiz\$5 OR flash\$4 OR diver\$5 OR bypass\$4 OR subsequent\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/12/23 03:40 PM
L606	33	605 AND (blood near5	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/23

L607	1189	(filter OR impermeabl\$4 OR membrane)) WITH (facilitat\$4 OR caus\$4) near5 (withdraw\$4 OR draw\$4 OR sampl\$4 OR collect\$4)	(US-PGPUB; USPAT)	OR	ON	ON	03:41 PM 2024/12/23 03:59 PM
L608	700	605 AND (flow\$4 OR control\$4 OR collect\$4 OR sampl\$4) near5 (force OR pressure OR pump\$4 OR vacuum\$4)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/23 04:00 PM
L609	11	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/23 04:12 PM
L610	1	16/331180	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 01:18 PM
L611	12	2017/0065824	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 04:38 PM
L612	6	"20170065824"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 04:38 PM
L613	3	"20010047198"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 04:38 PM
L614	20	"20050154321"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 04:53 PM
L615	1	"20050049689"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 04:58 PM
L616	12	"20170290686"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 05:03 PM
L617	30	"20160199204"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/25 05:08 PM
L618	1	18/066515	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/26 12:43 PM
L619	22	"20160082222"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/26 02:02 PM
L620	50	("20020004647" "20030105414" "20040054333" "20040073171" "20040147855" "20050004524" "20050240161" "20070083162" "20070088279" "20080086085" "20080145933" "20080167577" "20080319346" "20100010372" "20100057004" "20120016266" "20130317391" "201600	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 11:38 AM

		08579" "20160174888" "20160325085" "3741197" "3817240" "3874367" "3886930" "4057050" "4106497" "4154229" "4207870" "4412548" "4436098" "4444203" "5222502" "5520193" "5749857" "6398743" "6569117" "8197420" "8523826" "8535241" "8540663" "8568371" "8603009" "8864684" "9022950" "9022951" "9060724" "9138572" "9155495" "9204864" "9877675").PN.					
L621	128	((("ROGERS") near3 ("Bobby")) OR ((("KANG") near3 ("Gino")) OR ((("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2025/06/03 01:19 PM
L622	35	621 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR flush\$4 OR optimiz\$5 OR flash\$4 OR diver\$5 OR bypass\$4 OR subsequent\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 01:19 PM
L623	1	("12138052").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 01:24 PM
L624	1	("11963769").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 01:25 PM
L625	1	("11185266").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 01:25 PM
L626	1	("10143412").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 01:26 PM
L627	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 01:26 PM
L628	55585	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068 OR A61B5/150251).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2025/06/03 01:27 PM

L629	38203	628 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2025/06/03 01:28 PM
L630	4451	629 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR flush\$4 OR optimiz\$5 OR flash\$4 OR diver\$5 OR bypass\$4 OR collect\$4 OR sampl\$4 OR draw\$4 OR withdraw\$4 OR receiv\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 01:29 PM
L631	2304	630 AND ((blood OR fluid\$4 OR urine) near5(filter\$4 OR material\$4 OR membrane OR permeab\$4 OR impermeab\$4 OR vent\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 01:30 PM
L632	735	630 AND ((blood OR fluid\$4 OR urine) near5(filter\$4 OR permeab\$4 OR impermeab\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 01:30 PM
L633	1047	629 AND ((blood OR fluid\$4 OR urine) near5(sequest\$5 OR flush\$4 OR optimiz\$5 OR flash\$4 OR diver\$5 OR bypass\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 02:15 PM
L634	345	633 AND ((blood OR fluid\$4 OR urine) near5(filter\$4 OR permeab\$4 OR impermeab\$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2025/06/03 02:16 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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N94	1	(port and sequest\$5 and junction and chamber and sampl\$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:15 PM
N112	3	(port and sequest\$5 and chamber and sampl\$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:39 PM
N248	4	(blood and fluid\$4 and inlet and outlet and port and reservoir and allow and initial\$4 and sequest\$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N249	4	(blood and fluid\$4 and inlet and outlet and port and reservoir and allow\$4 and initial\$4 and sequest\$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N250	495	(blood and fluid\$4 and allow\$4 and initial\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N251	107	(blood and fluid\$4 and allow\$4 and initial\$4 and subsequent\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N283	9	((blood or fluid\$4) and sequestrat\$4 and chamber and sampl\$4 and vent\$4 and air\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N284	530	((blood or fluid\$4) and chamber and sampl\$4 and vent\$4 and air\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N285	84	((blood or fluid\$4) and chamber and cap and sampl\$4 and vent\$4 and air\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:32 PM
N365	6	(port and sequest\$5 and junction and chamber and sampl\$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:49 PM
N366	9	(blood AND fluid\$4 AND inlet AND outlet AND junct\$4 AND inhibit\$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:31 PM
N367	84	((blood OR fluid\$4) AND chamber AND sampl\$4 AND junction AND (inhibit\$4 OR prevent\$4)).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:36 PM
N368	25	(blood AND chamber AND sampl\$4 AND	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:48 PM

N369	4	junction AND inlet AND outlet AND port AND first).clm. (blood AND chamber AND sampl\$4 AND junction AND inlet AND outlet AND port AND first AND hous\$4 AND subsequent).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:49 PM
N370	64902	"465" AND housing	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:50 PM
N371	6	(inlet AND outlet AND junct\$4 AND channel AND sampl\$4 AND fluid\$4 AND vent AND air AND permeab\$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:51 PM
N372	167	(inlet AND outlet AND junct\$4 AND channel AND sampl\$4 AND fluid\$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:52 PM
N373	23	(inlet AND outlet AND junct\$4 AND channel AND sampl\$4 AND fluid\$4 AND bypass\$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:53 PM
N374	33	(inlet AND outlet AND chamber AND blood AND sampl\$4 AND bypass).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:35 PM
N375	18	(inlet AND outlet AND chamber AND blood AND sampl\$4 AND bypass AND air AND permeable).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:36 PM
N376	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl\$4 AND bypass AND air AND permeable AND junct\$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:24 PM
N377	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl\$4 AND bypass AND air AND permeable AND junct\$4 AND channel).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:25 PM
N378	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl\$4 AND bypass AND air AND	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:25 PM

N379	156	permeable AND junct\$4 AND channel AND vent).clm. (inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND memb\$5 AND impermeable AND channel).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 02:28 PM
N380	18	(inlet AND outlet AND chamber AND blood AND memb\$5 AND impermeable AND channel).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2025/06/03 02:28 PM

TO: Docket_IP@pillsburylaw.com
FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 27500

Wed Jun 18 10:33:30 EDT 2025

Dear Patent Center Customer:

Correspondence Address:

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
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McLean,VIRGINIA,22102
UNITED STATES

This is a courtesy notification regarding the following USPTO patent application(s) associated with your Customer Number, 27500, that have new outgoing correspondence. This correspondence is now available for viewing in Patent Center.

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Application	Document	Mailroom Date	Attorney Docket No.
18494622	NOA	06/18/2025	069366-0577657_KUR2C05US

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Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/494,622	06/18/2025 08:14:22 PM Z ET	069366-0577657_KUR2C05US

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9839	FILED BY	TRENT TERCENIO
PATENT CENTER #	70968638	FILING DATE	10/25/2023
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. ROGERS
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
069366- 0577657_KUR2C05US Comments on Reasons for Allowance-TRAN.LET.docx	2	Transmittal Letter	32 KB
Warning: Text decorations have been removed.			
069366- 0577657_KUR2C05US Issue Fee Transmittal.pdf	1	Issue Fee Payment (PTO-85B)	335 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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069366-0577657_KUR2C05US	3BCF05908C51736F40625720931A68146D827F1452798DD5CD
Comments on Reasons for	21CCED1008A1F124D2B6ECEEBD4141635975566B638A92F5F
Allowance-TRAN.LET.docx	6AFBD62B6DF60C0F81AB39B9A8D7C
069366-0577657_KUR2C05US	97442560AD5D9F6223260962C84FED8C579333197162164B3F
Issue Fee Transmittal.pdf	1F9FAAD4329B0C8CECE76783CFE5F6DD49C3608449DCB37
	D8B6539848D9B6D515B43BF677F81DA

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bobby E. Rogers, et al.

Confirmation No: 9839

Application No.: 18/494,622

Art Unit: 3791

Filed: October 25, 2023

Examiner: May A. Abouelela

For: Blood Sample Optimization Device

Mail Stop Issue Fee

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

COMMENTS ON EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

Applicant thanks Examiner Abouelela for the Notice of Allowance and the Examiner's efforts in examining the above-referenced application.

Applicant received the Examiner's "Statement Of Reasons For Allowance" (hereafter the "Statement") along with the Notice and wishes to note that entry of this Statement should not be construed as Applicant necessarily agreeing with or acquiescing to the reasons stated therein.

Applicant recognizes that, in accordance with MPEP § 1302.14, the Statement need not set forth all of the details as to why claims are allowed and, respectfully, Applicant does not concede that the Statement contains the only reasons for which the pending claims are allowable. Each of the claims stands on its own merits and is patentable because of the combination it recites and not because of the presence or absence of any one particular element.

CONCLUSION

It is believed that no fees are due in connection with the filing of this paper. In the event that it is determined that fees are due, however, the Commissioner is hereby authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account 033975, Reference No. 069366-0577657_KUR2C05US.

Respectfully submitted,
PILLSBURY WINTHROP SHAW PITTMAN LLP

Date: June 18, 2025

By: /Ben Hudson/
Benjamin F. Hudson, Ph.D.
Reg. No. 71,474

PO Box 10500
McLean, Virginia 22102
Telephone: (858) 509-4000
Customer No. 27500



UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/494,622	06/18/2025 08:14:22 PM Z ET	069366-0577657_KUR2C05US

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9839	FILED BY	TRENT TERCENIO
PATENT CENTER #	70968638	AUTHORIZED BY	Benjamin Hudson
CUSTOMER #	27500	FILING DATE	10/25/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Bobby E. ROGERS

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 033975	E20256HK14385967	TRENT TERCENIO

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
2501	UTILITY ISSUE FEE	516.00	1	516.00
TOTAL AMOUNT:				\$516.00

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 06/18/2025

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/494,622	10/25/2023	Bobby E. ROGERS	069366-0577657_KUR2C05US	9839

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION DEVICE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$516	\$0.00	\$0.00	\$516	09/18/2025

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-577000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Pillsbury Winthrop Shaw Pittman LLP

2

3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

Kurin, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

San Diego, CA

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☒ Electronic Payment via the USPTO patent electronic filing system ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 033975

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Ben Hudson/

Date June 18, 2025

Typed or printed name Benjamin F. Hudson

Registration No. 71,474



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/494,622	07/15/2025	12357209	069366-0577657_KUR2C0SUS	9839

27500

7590

07/02/2025

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
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ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at <https://patentcenter.uspto.gov/>. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at <https://certifiedcopycenter.uspto.gov/index.html>. The Certified Copy Center may be reached at (800)972-6382.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Center (<https://patentcenter.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PATENT CENTER site <https://patentcenter.uspto.gov> for additional inventors):

Bobby E. ROGERS, Park City, UT;
Gino KANG, Irvine, CA;
John DETLOFF, San Diego, CA;

APPLICANT(s) (Please see PATENT CENTER site <https://patentcenter.uspto.gov> for additional applicants):

Kurin, Inc., San Diego, CA;

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TO: Docket_IP@pillsburylaw.com
FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 27500

Thu Jul 03 05:00:46 EDT 2025

Dear Patent Center Customer:

Correspondence Address:

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McLean,VIRGINIA,22102
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The official date of notification of the outgoing correspondence will be indicated on the form (e.g., PTOL-90) accompanying the correspondence.

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Application	Document	Mailroom Date	Attorney Docket No.
18494622	ISSUE.NTF	07/02/2025	069366-0577657_KUR2C05US

To view your correspondence online, please sign in to [Patent Center](#) and then select Workbench/View correspondence. To update your email address(es), select Manage/Manage customer numbers.

If you have any questions, please contact the [Patent Electronic Business Center](#) (EBC) at ebc@uspto.gov or 866-217-9197 Monday – Friday, 6 a.m. to midnight ET.

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The Patent Center Team



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/494,622	10/25/2023	Bobby E. ROGERS	069366-0577657_KUR2C05US	9839
27500	7590	07/15/2025		
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)			EXAMINER	
ATTENTION: DOCKETING DEPARTMENT			ABOUELELA, MAY A	
P.O BOX 10500				
McLean, VA 22102			ART UNIT	PAPER NUMBER
			3791	
			NOTIFICATION DATE	DELIVERY MODE
			07/15/2025	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com



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APPLICATION NO.	ISSUE DATE	PATENT NO.
18/494,622	15-Jul-2025	12357209

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
McLean, VA 22102

EGRANT NOTIFICATION

Your electronic patent grant (eGrant) is now available, which can be accessed via Patent Center at <https://patentcenter.uspto.gov>

The electronic patent grant is the official patent grant under 35 U.S.C. 153. For more information, please visit <https://www.uspto.gov/electronicgrants>

TO: Docket_IP@pillsburylaw.com
FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - eGrant Notification for Customer Number 27500

Wed Jul 16 07:55:52 EDT 2025

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Correspondence Address:

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Application	Patent	Document	Mailroom Date	Attorney Docket No.
18494622	12357209	EGRANT.NTF	07/15/2025	069366-0577657_KUR2C05US

To examine your eGrant and eCofC online, please access [Patent Center](#) then search using the listed application or patent number. To download your eGrant, click on the eGrant and eCofC link on the left-hand menu or select the "Download eGrant" link on the Application data page. To download your eCofC, click on the eGrant and eCofC link on the left-hand menu.

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