

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

Civil Action No.: 25-cv-1409-RMR-SBP

HAEMONETICS CORPORATION,
a Massachusetts Corporation,
Plaintiff,

v.

TERUMO BCT, INC.,
a Colorado Corporation,
Defendant.

JOINT DISPUTED CLAIM TERMS CHART

Pursuant to the District of Colorado Local Patent Rule 14, D.C.COLO.LPtR 14, and Section 8(h) of the Scheduling Order (Dkt. 54), the Parties, Plaintiff Haemonetics Corp. (“Haemonetics” or “Plaintiff”) and Defendant Terumo BCT, Inc. (“Terumo” or “Defendant”) and (together, “the Parties”), hereby provide the following Joint Claim Terms Chart listing the disputed claim terms recited in the Asserted Claims¹ of U.S. Patent Nos. 10,758,652; 10,792,416; 10,980,926; 10,980,934; 11,738,124; 12,171,916; 12,186,474; 12,324,873; and 12,377,204 (“the Asserted Patents”), along with each Party’s proposed construction with citations to supporting intrinsic and extrinsic evidence.

¹ Claims 1–19 of U.S. Patent No. 10,758,652, claims 1–4, 6, 9–21, and 24–30 of U.S. Patent No. 10,792,416, claims 1–30 of U.S. Patent No. 10,980,926, claims 1–4, 6, 8–11, 13, 15–19, and 21–29 of U.S. Patent No. 10,980,934, claims 1–20 of U.S. Patent No. 11,738,124, claims 1–7 and 10–22 of U.S. Patent No. 12,171,916, claims 1–6 and 9–26 of U.S. Patent No. 12,186,474, claims 1–30 of U.S. Patent No. 12,324,873, and claims 1, 3–9, 11–15, 17–25, and 27–30 of U.S. Patent No. 12,377,204.

The terms and constructions set forth below are based on information currently available to the Parties. The Parties' investigation and analysis of prior art is ongoing, expert disclosures and expert discovery have not yet occurred, and fact discovery has not yet been completed. Accordingly, the Parties reserve the right to revise, amend, withdraw, and/or supplement the proposed constructions, including through claim construction briefing and/or to the extent further information becomes available through discovery, in light of Court rulings, and/or in view of clarified positions advanced by the Parties. To the extent that any Party has previously identified any claim limitations as indefinite or as having a construction but has not expressly identified them below, the Parties reserve the right to assert such arguments or constructions at an appropriate later stage of this proceeding.

To the extent that a Party has previously identified any of the below claim limitations as lacking written description, any citation to intrinsic evidence is provided solely for the limited purpose of demonstrating what the claim language would mean if the Court determines that written description exists. These citations do not waive, concede, or detract from the Party's written-description arguments, and the Parties reserve the right to assert such arguments at an appropriate later stage in the proceeding.

The Parties' identification of intrinsic and extrinsic evidence is preliminary. The Parties reserve their respective rights to supplement and/or amend their portions of the chart and to rebut any evidence cited by the other.

I. Disputed Claim Terms and Intrinsic and Extrinsic Evidence

The Parties identify the following disputed claim terms and intrinsic and extrinsic evidence for each respective term below:

Claim Term	Defendant's Proposed Construction and Identification of Intrinsic and Extrinsic Evidence	Plaintiff's Proposed Construction and Identification of Intrinsic and Extrinsic Evidence	Appears in at least:
"donor plasma volume"	<p>"total volume of pure plasma within the donor"</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p>'416 Patent: Abstract; 3:64-4:3; 4:32-35; 5:19-27; 5:48-51; 6:63-66; 13:1258; 15:6-14; 16:40-65; FIG. 5.</p> <p>'934 Patent: Abstract; 4:3-14; 4:38-41; 5:25-32; 5:52-57; 7:2-6; 13:17-63; 15:11-20; 16:46-17:4; FIG. 5; Amendment in Response to Non-Final Office Action, Jan. 8, 2021, HAEM-TER_0002680-2686.</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>All intrinsic evidence cited above for this term is hereby incorporated as extrinsic evidence if the above cited intrinsic evidence would not qualify as intrinsic evidence for the relevant patent.</p>	<p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><i>E.g.</i>, '416 Patent: Abstract, Fig. 5, 1:37-56, 3:62-4:35, 5:18-51, 6:54-67, 12:61-14:3, 14:63-15:14, 16:40-65, cls. 1, 7, 8, 17, 22, 23</p> <p><i>E.g.</i>, '934 Patent: Abstract, Fig. 5, 1:43-62, 4:1-41, 5:24-6:8, 6:60-7:6, 12:66-14:8, 15:1-30, 16:46-17:4, cls. 1, 5, 7, 8, 12, 14, 15, 20, 23, 30</p> <p><i>See also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.</p>	<p>'416 Patent: Claims 1 and 17</p> <p>'934 Patent: Claims 1, 8, 15, and 23</p>

	<p>TERUMO_PA_0000291-328, US 4,898,675 (“Lavender”): 2:7-11; 2:13-19; 22:39-46; Cl. 1.</p> <p>TERUMO_PA_0002241-2245, Calculations in Apheresis” by Marleen M. Neyrinck et al. (“Neyrinck”): p. 39-41.</p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff’s arguments.</p>		
<p>“target plasma collection volume”</p>	<p>“the target pure plasma collection volume”</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p>’416 Patent: Abstract; FIGS. 4 and 5; 2:12-18; 2:49-50; 2:55-57; 3:13-19; 4:13-20; 5:30-37; 6:54-56; 9:67-10:2; 10:50-55; 11:29-51; 12:47-50; 12:56-60; 14:39-15:14.</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or</p>	<p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><i>E.g.</i>, ’416 Patent: Abstract, Fig. 4, Fig. 5, 1:37-56, 1:60-2:18, 2:49-57, 3:6-19, 3:62-2:35, 5:18-51, 6:54-67, 8:34-56, 9:59-10:6, 10:50-11:9, 11:29-59, 12:35-60, 13:41-14:3, 14:25-15:24, 15:62-16:10, 16:66-17:19, cls. 1, 2, 17, 18</p> <p><i>See also</i> Asserted Patents</p>	<p>’416 Patent: Claims 1, 2, 17, and 18</p>

	<p>another qualified expert in support of its claim construction positions. Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff's arguments.</p>	<p><u>Exemplary Extrinsic Evidence:</u> Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.</p>	
<p>"target percentage of plasma"</p>	<p>"target percentage of the donor's pure plasma"</p> <p><u>Exemplary Intrinsic Evidence:</u> '416 Patent: Abstract; 3:66-4:5; 5:24-27; 5:46-51; 6:63-66; 13:12-58; 15:6-14; 16:40-65. '934 Patent: Abstract; 4:5-11; 5:30-33; 5:55-57; 6:60-62; 7:2-6; 13:17-63; 15:11-20; 16:46-17:4; Amendment in Response to Non-Final Office Action, Jan. 8, 2021, HAEM-TER_0002680-2686.</p> <p><u>Exemplary Extrinsic Evidence:</u> All intrinsic evidence cited above for this term is hereby incorporated as extrinsic evidence if the above cited intrinsic evidence would not qualify as intrinsic evidence for the relevant patent. Terumo may rely on a declaration or testimony from Dr. Jason Acker or</p>	<p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u> <i>E.g.</i>, '416 Patent: Abstract, Fig. 4, Fig. 5, 1:37-56, 3:62-4:8, 5:18-51, 6:54-67, 13:41-58, 14:63-15:14, 16:40-65, cls. 1, 8, 17, 23 <i>E.g.</i>, '934 Patent: Abstract, Fig. 4, Fig. 5, 1:43-62, 5:24-57, 6:60-7:6, 13:46-63, 15:1-20, 16:46-17:4, cls. 1, 7, 8, 14, 15, 23 <i>See also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u> Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.</p>	<p>'416 Patent: Claims 1 and 17 '934 Patent: Claims 1, 8, 15, and 23</p>

	<p>another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff's arguments.</p>			
"the contents"	<p>Indefinite</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p>'416 Patent: FIGS. 4 and 5; 3:36-39; 4:21-28; 5:37-41; 6:4-8; 11:47-51; 15:15-24; 15:51-59; Cls. 1, 7.</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff's arguments.</p>	<p>Not indefinite</p> <p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><i>E.g.</i>, '416 Patent: Fig. 4, Fig. 5, 2:58-3:5, 3:34-42, 4:9-35, 5:1-16, 5:34-45, 6:3-27, 9:20-35, 9:48-10:6, 14:4-24, 15:46-61, cls. 1, 2, 3, 17, 19, 27</p> <p><i>See also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.</p>	<p>'416 Patent: Claims 2, 3, 19, and 27</p> <p>In view of its construction, Terumo submits that at least asserted claims 2-4, 6, 19-21, and 27 of the '416 patent are indefinite.</p>	
	<p>All identified claim terms indefinite</p> <p>To the extent these terms are not indefinite, they should be construed as:</p>	<p>Not indefinite</p> <p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p>	<p>'926 Patent: Claims 1, 8, 10, 11, 12, 15, 17, 18, 19, 20, 23, 27, 28, 29</p>	

<p><u>'926 and '934 Patents:</u>²</p> <p>“volume of anticoagulant to be collected with [a/the] plasma component”</p> <p><u>'926 Patent</u></p> <p>“calculated volume of anticoagulant to be collected [in/within] the plasma [collection] container”</p> <p>“volume of anticoagulant to be collected within the plasma [collection] container”</p> <p>“volume of anticoagulant to be collected in the collected plasma component”</p> <p><u>'934 Patent</u></p> <p>“calculated volume of anticoagulant to be collected”</p>	<p><u>'926 and '934 Patents:</u></p> <p>“volume of anticoagulant to be collected with pure plasma”</p> <p><u>'926 Patent</u></p> <p>“calculated volume of anticoagulant to be collected with pure plasma in the plasma [collection] container”</p> <p>“calculated volume of anticoagulant to be collected with pure plasma in the plasma [collection] container</p> <p>“calculated volume of anticoagulant to be collected within the collected plasma component”</p> <p><u>'934 Patent</u></p> <p>“calculated volume of anticoagulant to be collected with pure plasma”</p>	<p><i>E.g., '926 Patent: Fig. 4, 2:14-32, 2:46-54, 3:3-60, 7:63-9:5, 9:30-60, cls. 1, 3, 4, 5, 6, 8, 10, 11, 12, 13, 15, 17, 18, 19, 20, 23, 27, 28, 29</i></p> <p><i>E.g., '934 Patent: Fig. 4, Fig. 5, 2:25-63, 3:12-67, 4:42-60, 5:58-6:33, 10:42-54, 11:14-51, 12:9-39, 14:44-15:20, 16:17-45, cls. 1, 2, 3, 4, 8, 9, 10, 11, 15, 16, 17, 19, 28, 29</i></p> <p><i>See also Asserted Patents</i></p> <p><u>Exemplary Extrinsic Evidence:</u> Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.</p>	<p><u>'934 Patent: Claims</u> 2, 3, 4, 9, 10, 11, 16, 17, 19, and 28</p> <p>In view of its construction, Terumo submits that at least asserted claims 1–30 of the '926 patent and claims 2-4, 9-11, 16-19, and 28-29 of the '934 patent are indefinite.</p>
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² To the extent similar claim terms are disputed for similar reasons or are subject to the same, or substantially similar, constructions, Terumo has consolidated these terms, using brackets and/or bullets to denote differences, for efficiency and clarity. To the extent Terumo has not expressly identified a substantially similar term by claim number, or otherwise, Terumo reserves all rights to similarly add and construe those terms.

	<p><u>Exemplary Intrinsic Evidence:</u></p> <p><u>'926 Patent</u>: FIGS. 3 and 4; 2:4-15; 4:15-27; 7:51-62; 8:9-31; 9:49-60; Cl. 8, 12, 15, 19, 23, 29.</p> <p><u>'934 Patent</u>: FIGS. 3-5; 2:14-24; 6:60-7:6; 10:30-41; 10:55-11:10; 12:28-39.</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>All intrinsic evidence cited above for this term is hereby incorporated as extrinsic evidence if the above cited intrinsic evidence would not qualify as intrinsic evidence for the relevant patent.</p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff's arguments.</p>		
<p>"the calculated volume of pure plasma"</p>	<p>Indefinite</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><u>'926 Patent</u>: Cl. 1, 2-3, 8-10, 15-17, 23, and 27; 2:32-45; 3:42-60</p>	<p>Not indefinite</p> <p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p>	<p><u>'926 Patent</u>: Claims 1, 2-3, 8-10, 15-17, 23, and 27</p>

	<p><u>Exemplary Extrinsic Evidence:</u></p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff's arguments.</p>	<p><i>E.g.</i>, '926 Patent: Abstract, Fig. 4, 1:57-2:15, 2:32-54, 3:3-17, 4:17-27, 7:18-32, 8:8-35, 8:55-9:18, 9:30-10:20, cls. 1, 2, 3, 7, 8, 9, 10, 14, 15, 16, 17, 23, 27</p> <p><i>See also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.</p>	<p>In view of its construction, Terumo submits that at least asserted claims 1-30 of the '926 patent are indefinite.</p>
<p>“[blood processing] end point”</p>	<p>Indefinite</p> <p>To the extent it is not found to be indefinite, it should be construed as a “[blood processing] stopping point equaling the target pure plasma volume”</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p>'926 Patent: Abstract; FIG. 4; 2:1-15; 3:3-17; 4:15-19; 7:26-29; 8:9-9:5; 10:6-20.</p> <p>'934 Patent: Abstract; FIGS. 4 and 5; 2:10-24; 3:12-25; 6:60-63; 10:5-7; 10:55-11:51; 16:45-17:24.</p>	<p>Not indefinite</p> <p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><i>E.g.</i>, '926 Patent: Fig. 4, 1:19-53, 1:57-2:15, 2:46-3:2, 7:18-32, 8:9-35, 8:55-9:29, 9:61-10:20, cls. 1, 8, 15, 24, 26, 30</p> <p><i>E.g.</i>, '934 Patent: Fig. 4, Fig. 5, 1:24-42, 1:66-2:24, 2:55-3:11, 4:15-41, 9:64-10:11, 10:55-11:14, 11:34-12:8, 12:40-65, 14:30-67, 15:1-30, cls. 1, 8, 11, 15, 23, 24, 26, 27</p> <p><i>See also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>Plaintiff reserves the right to rely</p>	<p>'926 Patent: Claims 15, 21, 26, and 30</p> <p>'934 Patent: Claims 15, 21, 26, and 27</p> <p>In view of its construction, Terumo submits that at least asserted claims 15-22, 26, and 30 of the '926 patent and 15-19, 21 and 26-27 of the '934 patent are indefinite.</p>

	<p><u>Exemplary Extrinsic Evidence:</u> All intrinsic evidence cited above for this term is hereby incorporated as extrinsic evidence if the above cited intrinsic evidence would not qualify as intrinsic evidence for the relevant patent.</p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff's arguments.</p>	<p>on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.</p>	
<p>“the controller is further configured to program the blood processing device”</p>	<p>Indefinite</p> <p><u>Exemplary Intrinsic Evidence:</u> '926 Patent: Cl. 15; 3:3-25; 3:52-60; 5:9-17; 5:34-41; 6:18-26; 7:7-17; 8:18-23; 9:10-18; FIG. 3.</p> <p><u>Exemplary Extrinsic Evidence:</u> Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or</p>	<p>Not indefinite</p> <p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u> <i>E.g.</i>, '926 Patent: Abstract Fig. 3, Fig. 4, 3:4-31, 3:52-56, 4:19-24, 5:9-40, 6:16-26, 7:7-17, 8:18-23, 8:55-9:17, cls. 8, 13, 14, 15, 22, 23, 25, 26</p> <p><i>See also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u> Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other</p>	<p>'926 Patent: Claim 26</p>

any evidence needed in response to Plaintiff's arguments.	extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.	
<p><u>'916 Patent</u></p> <p>“controller coupled to the user interface and programmed to receive at least a donor's weight and hematocrit”</p> <p><u>'916 and/or '474 Patents</u></p> <p>“controller coupled to the touchscreen and programmed to receive at least a donor's [weight and hematocrit] [weight, height and hematocrit] [weight, height, sex and hematocrit] from the touchscreen”</p> <p>“the controller coupled to the touchscreen and programmed to receive donor parameters electronically”</p>	<p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><i>E.g.</i>, '916 Patent: Abstract, Fig. 3, Fig. 4, 1:63-2:51, 3:9-23, 3:48-67, 5:24-47, 5:66-6:33, 7:14-24, 10:1-26, cls. 1, 7, 10, 11, 14, 16, 19, 20, 21</p> <p><i>E.g.</i>, '474 Patent: Abstract, Fig. 3, Fig. 4, Fig. 5, 2:8-33, 2:50-63, 3:19-48, 3:58-4:24, 5: 4-49, 5:62-6:45, 8:8-31, 8:50-9:5, 9:64-10:7, 10:66-11:26, 12:51-13:56, cls. 1, 6, 9, 11, 12, 15, 17, 19, 21, 23, 25</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.</p>	<p><u>'916 Patent: Claims 1, 7 and 10</u></p> <p><u>'474 Patent: Claims 1, 6, 9, 15</u></p>
<p><u>'916 Patent</u></p> <p>“controller coupled to the user interface and programmed to receive at least a donor's weight and hematocrit”</p> <p><u>'916 and/or '474 Patents</u></p> <p>“controller coupled to the touchscreen and programmed to receive at least a donor's [weight and hematocrit] [weight, height and hematocrit] [weight, height, sex and hematocrit] from the touchscreen”</p> <p>“the controller coupled to the touchscreen and programmed to receive donor parameters electronically”</p>	<p><u>Exemplary Intrinsic Evidence:</u></p> <p><u>'916 Patent: FIGS. 1 and 2; 5:15-23; 5:45-47.</u></p>	

	<p>'474 Patent: FIGS. 1 and 2; 7:66-8:7; 8:29-31; 14:1-4.</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>All intrinsic evidence cited above for this term is hereby incorporated as extrinsic evidence if the above cited intrinsic evidence would not qualify as intrinsic evidence for the relevant patent.</p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff's arguments.</p>		
<p>“[plurality of] draw and return cycle[s]”</p>	<p>“[plurality of] sequence[s] comprising a draw phase and a return phase”</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p>'916 Patent: This term lacks written description support, but to the extent the Court disagrees, FIG. 4 and 9:4-12 support the proposed construction.</p>	<p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><i>E.g.</i>, '916 Patent: Fig. 4, 1:27-45, 2:15-21, 2:52-3:8, 7:33-36, 8:17-23, 9:4-36, cls. 1, 2, 3, 6, 7, 10, 13, 14</p> <p><i>E.g.</i>, '474 Patent: Fig. 4, Fig. 5, 1:33-51, 2:27-33, 2:64-3:20, 4:31-51, 10:16-18, 10:66-11:4; 11:54-</p>	<p>'916 Patent: Claims 1, 2, and 10</p> <p>'474 Patent: Claims 1, 2, and 9</p>

	<p>'474 Patent: This term lacks written description support, but to the extent the Court disagrees, FIGS. 4 and 5, 11:54-62, and 15:22-30 support the proposed construction.</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>All intrinsic evidence cited above for this term is hereby incorporated as extrinsic evidence if the above cited intrinsic evidence would not qualify as intrinsic evidence for the relevant patent.</p> <p><u>U.S. Patent No. 11,285,251</u> ("Fenwal '251"): 1:35-47; 3:19-27; 3:55-61; 4:16-22; 7:45-8:8; 11:30-32; 11:64-12:2; 12:19-13:10; Cl. 6.</p> <p><u>U.S. Patent No. 11,369,724</u> ("Fenwal '724"): 1:37-49; 3:22-30; 3:58-64; 4:19-25; 7:48-8:10; 11:24-26; 11:58-63; 12:13-13:15; Cls. 9, 10, 19.</p> <p><u>U.S. Patent No. 11,730,873</u> ("Fenwal '873"): 1:44-56; 3:29-37; 3:65-4:4; 4:26-32; 7:54-8:16; 11:35-37; 12:2-7; 12:24-13:26; Cls. 6, and 12.</p> <p><u>U.S. Patent No. 12,144,624</u> ("Fenwal '624"): 1:34-46; 3:52-60; 4:30-38; 4:66-5:5; 5:26-32; 8:58-</p>	<p>12:19, cls. 1, 2, 3, 4, 5, 6, 9, 14, 15</p> <p><i>See also</i> '652 Patent, cl. 10; <i>see also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u> Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.</p>	
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	<p>9:20; 14:61-63; 15:28-31; 15:50-16:52; Cl. 1.</p> <p>Merriam-Webster definition, 10th & 11th Eds. definition, “cycle.”</p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff’s arguments.</p>		
“draw and return phases”	<p>Indefinite</p> <p>To the extent it is not found to be indefinite, it should be construed as a “a draw phase and a return phase”</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p>’916 Patent: FIG. 4; 1:38-40; 1:63-2:3; 2:52-60; 4:63-66; 9:4-25.</p> <p>’474 Patent: FIGS. 4 and 5; 1:33-40; 2:11-15; 3:3-5; 5:17-22; 11:54-62.</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>All intrinsic evidence cited above for this term is hereby incorporated as extrinsic evidence if the above cited intrinsic evidence would not</p>	<p>Not indefinite</p> <p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><i>E.g.</i>, ’916 Patent: Fig. 4, 1:27-45, 2:15-21, 2:52-3:8, 7:33-36, 8:17-23, 9:4-36, cls. 1, 2, 3, 6, 7, 10, 13, 14</p> <p><i>E.g.</i>, ’474 Patent: Fig. 4, Fig. 5, 1:33-51, 2:27-33, 2:64-3:20, 4:31-51, 5:17-20, 5:50-53, 10:16-18, 10:66-11:4; 11:54-12:19, 15:22-30, cls. 1, 2, 3, 4, 5, 6, 9, 14, 15</p> <p><i>See also</i> ’652 Patent, cl. 10; <i>see also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>Plaintiff reserves the right to rely</p>	<p>’916 Patent: Claims 3, 4, 7, and 14</p> <p>’474 Patent: Claims 3, 4, 6, and 15</p>

	<p>qualify as intrinsic evidence for the relevant patent.</p> <p><u>U.S. Patent No. 11,285,251</u> (“Fenwal ’251”): 3:19-35; 3:55-61; 4:16-28; 4:63-5:33; 5:50-54; 7:3-32; 7:40-8:8; 11:30-12:2; 12:35-13:22; 15:26-30; 16:32-17:20; Cls. 1, 6, 7.</p> <p><u>U.S. Patent No. 11,369,724</u> (“Fenwal ’724”): 3:22-38; 3:58-64; 4:19-33; 4:66-5:36; 5:53-56; 7:5-35; 7:43-8:10; 11:24-11:63; 12:29-13:15; 15:19-23; 16:25-17:13; Cls. 1, 6, 7.</p> <p><u>U.S. Patent No. 11,730,873</u> (“Fenwal ’873”): 3:29-45; 3:65-4:7; 4:26-40; 5:6-5:43; 5:60-64; 7:12-41; 7:49-8:16; 11:35-12:7; 12:40-13:26; 15:30-35; 16:36-17:24; Cls. 1, 6 17, 21.</p> <p><u>U.S. Patent No. 12,144,624</u> (“Fenwal ’624”): 3:52-4:2; 4:30-46; 4:66-5:5; 5:26-28; 6:6-44; 6:57-60; 8:15-45; 8:53-9:20; 14:61-63; 15:12-33; 15:66-16:53; 18:3-7; 18:26-29; 18:55-59; 19:17-21; 19:61-20:49.</p> <p>Merriam Webster 10th & 11th Eds. definition, “phase.”</p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or</p>	<p>on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant’s arguments in the Opening Brief.</p>	
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	<p>another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff's arguments.</p>		
<p>“current value of the hematocrit of the donor”</p>	<p>“measured instantaneous value of the hematocrit of the donor”</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><u>'916 Patent</u>: 6:14-22; 7:14-24.</p> <p><u>'474 Patent</u>: 8:65-9:5; 9:64-10:7.</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>All intrinsic evidence cited above for this term is hereby incorporated as extrinsic evidence if the above cited intrinsic evidence would not qualify as intrinsic evidence for the relevant patent.</p> <p><u>U.S. Patent No. 11,285,251</u> (“Fenwal '251”): FIGS. 11a and 11b; 3:55-64; 4:23-44; 6:5-11; 11:3-12:2; 12:65-13:45; 14:8-22.</p> <p><u>U.S. Patent No. 11,369,724</u> (“Fenwal '724”): FIGS. 11a and 11b; 2:66-3:48; 3:58-67; 4:21-47;</p>	<p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><i>E.g.</i>, '916 Patent: Fig. 4, 2:38-51, 3:9-23, 3:48-67, 11:23-33, 5:66-6:22, 7:14-24, 8:3-16, 10:1-26, cls. 1, 3, 7, 10, 11, 14, 16, 20, 21</p> <p><i>E.g.</i>, '474 Patent: Fig. 4, Fig. 5, 2:8-33, 2:50-63, 3:58-4:9, 5:4-16, 6:20-45, 8:50-9:5, 9:64-10:7, 10:53-65, 12:51-13:56, 14:20-40, cls. 1, 3, 5, 9, 12, 14, 17, 21, 25</p> <p><i>See also</i> '652 Patent, cls. 1, 11; <i>see also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.</p>	<p><u>'916 Patent</u>: Claim 1</p> <p><u>'474 Patent</u>: Claim 1</p>

	<p>6:8-13; 10:64-11:63; 12:59-13:38; 13:61-14:15.</p> <p><u>U.S. Patent No. 11,730,873</u> (“Fenwal ’873”): FIGS. 11a and b; 3:39-4:7; 4:26-5:4; 6:15-20; 8:17-35; 11:8-12:7; 13:3-13:49; 14:5-14:26.</p> <p><u>U.S. Patent No. 12,144,624</u> (“Fenwal ’624”): FIGS. 11a and 11b; 4:8-4:46; 4:66-5:7; 5:33-5:4; 7:15-20; 9:21-38; 14:9-14:24; 14:61-15:49; 16:29-17:7; 17:31-51; 19:61-20:49.</p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff’s arguments.</p>		
<p>“wherein the controller is programmed to perform the draw and return cycles at least three times”</p>	<p>Indefinite</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any</p>	<p>Not indefinite</p> <p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><i>E.g.</i>, ’916 Patent: Fig. 4, 1:27-45, 2:15-21, 2:52-3:8, 7:8-13, 7:25-39, 8:17-23, 9:4-36, cls. 1, 2, 3, 6, 7, 10, 13, 14</p>	<p><u>’916 Patent: Claim</u> 13</p> <p><u>’474 Patent: Claim</u> 14</p>

	evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff's arguments.	<p><i>E.g.</i>, '474 Patent: Fig. 4, Fig. 5, 1:33-51, 2:27-33, 2:64-3:20, 4:31-51, 10:16-18, 10:66-11:4; 11:45-12:19, 15:22-30, cls. 1, 2, 3, 4, 5, 6, 9, 14, 15</p> <p><i>See also</i> '652 Patent, cl. 10; <i>see also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u> Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant's arguments in the Opening Brief.</p>	
"optimized safe amount"	<p>Indefinite</p> <p><u>Exemplary Extrinsic Evidence:</u> Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff's arguments.</p>	<p>Not indefinite</p> <p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u> <i>E.g.</i>, '204 Patent: Fig. 4, Fig. 5, 1:64-2:16, 8:63-9:18, 11:58-12:8, 12:41-13:40, 14:3-20, 17:4-49, cls. 1, 3, 5, 8, 9, 12, 14, 15, 20, 21, 22, 23, 25, 28, 29</p> <p><i>See also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u> Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in</p>	'204 Patent: Claims 3, 12, 20, 29

“control system”	<p>The term “control system” by itself is indefinite</p> <p>In addition, certain claim limitations including this term are governed by means-plus-function interpretation under 35 U.S.C. § 112(f) ³ and are also indefinite under that interpretation:</p>	<p>response to Defendant’s arguments in the Opening Brief.</p> <p>Not indefinite</p> <p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u> <i>E.g.</i>, ’926 Patent: Fig. 3, Fig. 4, 3:3-56, 5:9-41, 6:19-26, 7:7-17, 8:17-36, 8:55-9:18, cls. 8, 13, 14, 15, 22, 23, 24, 26 <i>E.g.</i>, ’934 Patent: Fig. 3, Fig. 4, Fig. 5, 3:12-63, 5:24-38, 5:58-6:39, 7:55-63, 8:13-20, 9:55-63, 10:60-11:15, 12:28-39, 14:55-62, 15:1-5, cls. 8, 9, 11, 12, 15, 16, 20, 22, 23, 25, 26, 30 <i>E.g.</i>, ’916 Patent: Fig. 3, Fig. 4, 3:9-35, 3:59-63, 5:15-23, 5:40-56, 8:17-44, 9:47-67, cls. 1, 2, 3, 4, 5,</p>	<p>’926 Patent: Claims 15 and 22</p> <p>’934 Patent: Claims 15, 16, and 22</p> <p>’926 Patent: Claim 15</p> <p>’916 Patent: Claims 14, 16–17, 19–20</p> <p>’474 Patent: Claim 18</p> <p>In view of these constructions, Terumo submits that at least asserted claims 15-19 and 21-22 of the ’934 Patent, at least asserted claims 15-22 for the ’926 patent, at least asserted claims 14-22 of the ’916 patent, and at least</p>
<p>“control system”</p> <p><u>’934 Patent:</u></p> <ul style="list-style-type: none"> “calculating a donor plasma volume, the control system calculating the donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor” “calculating a target plasma volume to collect” 	<p>’934 Patent:</p> <p>Function:</p> <ul style="list-style-type: none"> calculating a donor plasma volume, the control system calculating the donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor calculating a target plasma volume to collect 		

³ Terumo asserts that, to the extent any other limitation such as those in the asserted dependent claims further defines the function of the control system, regardless of whether or not the control system is explicitly mentioned, the proposed constructions and arguments raised here similarly apply to those dependent claims.

<ul style="list-style-type: none"> “calculating a volume of anticoagulant to be collected with a plasma component in a plasma collection container” <p><u>’926 Patent:</u></p> <ul style="list-style-type: none"> “calculating the volume of anticoagulant to be collected with the plasma component based, at least in part on the hematocrit of the donor” “calculating the target volume of pure plasma based, at least in part, on the weight of the donor” <p><u>’916 and ’474 Patents:</u></p> <ul style="list-style-type: none"> “programmed to calculate the target volume for plasma product and/or raw plasma” 	<ul style="list-style-type: none"> calculating a volume of anticoagulant to be collected with a plasma component in a plasma collection container <p><u>’926 Patent:</u></p> <p>Function:</p> <ul style="list-style-type: none"> calculating the volume of anticoagulant to be collected with the plasma component based, at least in part on the hematocrit of the donor calculating the target volume of pure plasma based, at least in part, on the weight of the donor <p><u>’916 and ’474 Patents:</u></p> <p>Function:</p> <ul style="list-style-type: none"> calculate the target volume for plasma product and/or raw plasma <p>Structure: Insufficient disclosure of corresponding structure that performs the claimed functions</p>	<p>6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21</p> <p><i>E.g.</i>, ’474 Patent: Fig. 3, Fig. 4, Fig. 5, 3:21-48, 4:1-10, 5:34-61, 6:1-15, 8:24-31, 11:8-54, 13:57-67, cls. 1-25</p> <p><i>See also</i> Asserted Patents</p> <p><u>Exemplary Extrinsic Evidence:</u> Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant’s arguments in the Opening Brief.</p>	<p>asserted claim 18 of the ’474 patent are indefinite.</p>
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	Therefore, indefinite at least for the failure to disclose adequate structure under § 112(f) <u>Exemplary Extrinsic Evidence:</u> Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions. Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff's arguments.		
<p>“controller”</p> <p><u>’652 Patent:</u></p> <p>“[is/further] configured to”</p> <ul style="list-style-type: none"> • “control the operation of the blood component separation device and the blood draw pump” • “calculate (1) a volume of anticoagulant in the collected plasma 	<p>Indefinite; Governed by means-plus-function interpretation under 35 U.S.C. § 112(f) ⁴</p> <p><u>’652 Patent:</u></p> <p>Function:</p> <ul style="list-style-type: none"> • control the operation of the blood component separation device and the blood draw pump • calculate (1) a volume of anticoagulant in the collected 	<p>Not indefinite</p> <p>Plain and ordinary meaning</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><i>E.g.</i>, ’652 Patent: Fig. 3, Fig. 4, 2:61-3:47, 5:26-33, 8:1-28, cls. 11, 13, 14, 18</p> <p><i>E.g.</i>, ’416 Patent: Fig. 3, Fig. 4, Fig. 5, 3:6-33, 3:51-61, 5:18-6:2, 8:9-15, 8:60-67, 9:48-58, 10:58-66, 13:1-41, 14:50-62, 15:40-45, cls. 17, 18, 19, 20, 21, 25, 26, 30</p>	<p><u>’652 Patent:</u> Claims 11, 13, 14, and 18</p> <p>In view of its construction, Terumo submits that at least asserted claims 11-19 of the ’652 patent are indefinite.</p>

⁴ Terumo asserts that, to the extent any other limitation such as those in the asserted dependent claims further defines the function of the controller, regardless of whether or not the controller is explicitly mentioned, the proposed constructions and arguments raised here similarly apply to those dependent claims.

<p>component as the plasma component is being collected in the plasma container, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component”</p> <ul style="list-style-type: none"> • “stop the blood draw pump when a target volume of pure plasma is collected within the plasma container” • “monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source” • “monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood” • “determine the subject’s hematocrit based, at least in part, upon on the monitored volume of red blood cells collected 	<p>plasma component as the plasma component is being collected in the plasma container, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component</p> <ul style="list-style-type: none"> • stop the blood draw pump when a target volume of pure plasma is collected within the plasma container • monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source • monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood • determine the subject’s hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the subject 	<p><i>E.g.</i>, ’926 Patent: Fig. 3, Fig. 4, 3:3-56, 5:9-41, 6:19-26, 7:7-17, 8:17-36, 8:55-9:18, cls. 8, 13, 14, 15, 22, 23, 24, 26</p> <p><i>E.g.</i>, ’934 Patent: Fig. 3, Fig. 4, Fig. 5, 3:12-63, 5:24-38, 5:58-6:39, 7:55-63, 8:13-20, 9:55-63, 10:60-11:15, 12:28-39, 14:55-62, 15:1-5, cls. 8, 9, 11, 12, 15, 16, 20, 22, 23, 25, 26, 30</p> <p><i>E.g.</i>, ’124 Patent: Fig. 3, Fig. 4, 3:12-39, 3:55-67, 5:15-23, 5:40-47, 6:26-33, 7:14-24, 7:25-43, 8:25-41, 9:4-12, 9:17-25, cls. 11, 13, 14, 18</p> <p><i>E.g.</i>, ’916 Patent: Fig. 3, Fig. 4, 3:9-35, 3:59-63, 5:15-23, 5:40-56, 8:17-44, 9:47-67, cls. 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21</p> <p><i>E.g.</i>, ’474 Patent: Fig. 3, Fig. 4, Fig. 5, 3:21-48, 4:1-10, 5:34-61, 6:1-15, 8:24-31, 11:8-54, 13:57-67, cls. 1-25</p> <p><i>E.g.</i>, ’873 Patent: Fig. 3, Fig. 4, 3:12-39, 3:55-67, 5:40-47, 6:23-33, 7:14-24, 8:17-42, 9:13-25, cls. 13, 14, 17, 18, 19, 22, 24, 25, 27, 30</p> <p><i>E.g.</i>, ’204 Patent: Fig. 3, Fig. 4, Fig. 5, 3:34-58, 4:14-18, 5:46-65,</p>	<p>’416 Patent: Claims 17-20, 25-26, and 30.</p> <p>In view of its constructions, Terumo submits that at least asserted claims 17-21 and 24-30 of the ’416 Patent are indefinite</p> <p>’926 Patent: Claims 8, 13, 14, 23, and 26</p> <p>In view of its construction, Terumo submits that at least asserted claims 8-30 of the ’926 patent are indefinite.</p> <p>’934 Patent: Claims 8, 9, 11, 23, and 26</p> <p>In view of its construction, Terumo submits that</p>
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<p>within the blood component separation device and a volume of whole blood withdrawn from the subject”</p> <p><u>’416 Patent:</u> “[is/is further/further] configured to”</p> <ul style="list-style-type: none"> • “control the operation of the blood component separation device and the first pump” • “calculate (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor, (2) a target collection volume based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, (3) a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma container, and (4) a 	<p><u>’416 Patent:</u> Function:</p> <ul style="list-style-type: none"> • control the operation of the blood component separation device and the first pump • calculate (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor, (2) a target plasma collection volume based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, (3) a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma container, and (4) a volume of pure plasma collected within the plasma container equals the target plasma collection volume • stop the first pump when the calculated volume of pure plasma collected within the plasma container equals the target plasma collection volume 	<p>6:14-25, 8:12-44, 9:19-29, 10:10-20, 11:58-12:21, 13:41-14:32, 15:44-53, cls. 1, 8, 9, 10, 11, 13, 22, 23, 24, 25, 26, 27</p> <p><u>Exemplary Extrinsic Evidence:</u> Plaintiff reserves the right to rely on the knowledge of a POSITA, an expert in the field, and/or other extrinsic evidence as needed in response to Defendant’s arguments in the Opening Brief.</p>	<p>at least asserted claims 8-11, 13, 15-19, and 21-29 of the ’934 Patent are indefinite</p> <p><u>’124 Patent:</u> Claims 11, 13, 14, and 18</p> <p>In view of its construction, Terumo submits that at least asserted claims 11-20 of the ’124 patent are indefinite..</p> <p><u>’916 Patent:</u> Claims 1-4, 6-7, 10-16, 17-21</p> <p>In view of its proposed construction, Terumo submits that at least asserted claims 1-7 and 10-22 of the ’916 patent are indefinite.</p>
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<p>volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component”</p> <ul style="list-style-type: none"> • “stop the first pump when the calculated volume of pure plasma collected within the plasma container equals the target plasma collection volume” • “return, after collecting at least a portion of the target plasma collection volume, fluid remaining within the blood component separation device via the first line” • “calculate an intravascular deficit based, at least in part on, the volume of pure plasma collected and a volume of the contents of the blood component separation device returned to the donor” • “return a volume of saline to the donor to 	<ul style="list-style-type: none"> • return, after collecting at least a portion of the target plasma collection volume, fluid remaining within the blood component separation device via the first line • calculate an intravascular deficit based, at least in part on, the volume of pure plasma collected and a volume of the contents of the blood component separation device returned to the donor • return a volume of saline to the donor to obtain a target intravascular deficit • monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source • monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood • determine the donor's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device 	<p><u>’474 Patent</u>: Claims 1–6, 9–16, 18–25</p> <p>In view of its construction, Terumo submits that at least asserted claims 1-6 and 9-26 of the ’474 patent are indefinite.</p> <p><u>’873 Patent</u>: Claims 13, 14, 17–19, 22, 24, 25, 27, and 30</p> <p>In view of its proposed construction, Terumo submits that at least asserted claims 13-30 of the ’873 patent are indefinite.</p> <p><u>’204 Patent</u>: Claims 1, 8–9, 11, 13, 22–25, 27</p>
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<p>obtain a target intravascular deficit”</p> <ul style="list-style-type: none"> • “monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source” • “monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood” • “determine the donor's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the donor” <p><u>’926 Patent:</u> “[is/is further] configured to”</p> <ul style="list-style-type: none"> • “control the operation of the blood component separation device” 	<p>and a volume of whole blood withdrawn from the donor</p> <p><u>’926 Patent:</u> Function:</p> <ul style="list-style-type: none"> • control the operation of the blood component separation device • [calculate] (1) [calculate] a volume of anticoagulant to be collected with plasma component in the plasma container, the volume of anticoagulant to be collected with the plasma component based, at least in part on [the/a] hematocrit of the donor, (2) [calculate] a target volume of pure plasma to collect in the plasma container based, at least in part, on the weight of the donor, and (3) [calculate] a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma • calculate the volume of anticoagulant before 	<p>In view of its proposed construction, Terumo submits at least asserted claims 1, 3-9, 11-14, 22, 23-25, 27-30 of the ’204 patent are indefinite.</p>
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<ul style="list-style-type: none"> • “[calculate] (1) [calculate] a volume of anticoagulant to be collected with plasma component in the plasma container, the volume of anticoagulant to be collected with the plasma component based, at least in part on [the/a] hematocrit of the donor, (2) [calculate] a target volume of pure plasma to collect in the plasma container based, at least in part, on the weight of the donor, and (3) [calculate] a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma” • “calculate the volume of anticoagulant before withdrawing whole blood from the donor” • “calculate the target volume of pure plasma before withdrawing whole blood from the donor” 	<p>withdrawing whole blood from the donor</p> <ul style="list-style-type: none"> • calculate the target volume of pure plasma before withdrawing whole blood from the donor • program the blood processing device with an end point based, at least in part, on the target collection volume <p><u>’934 Patent:</u> Function:</p> <ul style="list-style-type: none"> • control the operation of the blood component separation device and the first pump • [calculate] (1) [calculate] a donor plasma volume based, at least in part, on [a/the] weight and height of the donor and [a/the] hematocrit of the donor, (2) [calculate] a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, and (3) [calculate] [a volume of plasma component collected within the plasma collection 	
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<ul style="list-style-type: none"> • “program the blood processing device with an end point based, at least in part, on the target collection volume” <p><u>’934 Patent:</u> “[is/is further] configured to”</p> <ul style="list-style-type: none"> • “control the operation of the blood component separation device and the first pump” • “[calculate] (1) [calculate] a donor plasma volume based, at least in part, on [a/the] weight and height of the donor and [a/the] hematocrit of the donor, (2) [calculate] a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, and (3) [calculate] [a volume of plasma component collected within the plasma collection container/ a target collection volume]” 	<p>container/ a target collection volume]</p> <ul style="list-style-type: none"> • stop the first pump when the calculated volume of plasma component collected within the plasma collection container equals the target plasma volume to collect • calculate a volume of anticoagulant to be collected with the plasma component in the plasma collection container • configured to stop the first pump when the volume of pure plasma collected within the plasma collection container equals the target plasma collection volume • program the blood processing device with a blood processing end point based, at least in part, on the target collection volume <p><u>’124 Patent:</u> Function:</p> <ul style="list-style-type: none"> • control the operation of the blood component separation device and the blood draw pump 	
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<ul style="list-style-type: none"> • “stop the first pump when the calculated volume of plasma component collected within the plasma collection container equals the target plasma volume to collect” • “calculate a volume of anticoagulant to be collected with the plasma component in the plasma collection container” • “configured to stop the first pump when the volume of pure plasma collected within the plasma collection container equals the target plasma collection volume” • “program the blood processing device with a blood processing end point based, at least in part, on the target collection volume” <p><u>’124 Patent:</u> “[is/ further] configured to”</p>	<ul style="list-style-type: none"> • calculate (1) a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the subject, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component • stop the blood draw pump when a target volume of pure plasma is collected within the plasma container • monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source • monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood • determine the subject's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device 		
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<ul style="list-style-type: none"> • “control the operation of the blood component separation device and the blood draw pump” • “calculate (1) a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the subject, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component” • “stop the blood draw pump when a target volume of pure plasma is collected within the plasma container” • “monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source” • “monitor a number of rotations of an anticoagulant pump to determine a volume of 	<p>and a volume of whole blood withdrawn from the subject</p> <p><u>’916 Patent:</u> Function:</p> <ul style="list-style-type: none"> • control operation of the system • receive at least a donor’s weight and hematocrit • receive donor parameters electronically from a control system • receive the donor’s weight and hematocrit electronically • determine the target volume for plasma product comprising raw plasma and anticoagulant • determine [a/the] target volume for plasma product [comprising raw plasma and anticoagulant] [and/or raw plasma] [based at least in part on the [weight/donor weight] and hematocrit/based at least in part on the donor parameters]] • determine the target volume for plasma product and/or raw plasma based at least in part on the donor weight 	
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<p>anticoagulant introduced into the whole blood”</p> <ul style="list-style-type: none"> • “determine the subject’s hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the subject” <p><u>’916 Patent:</u> “[is programmed/is configured/programmed] [to]”</p> <ul style="list-style-type: none"> • “control operation of the system” • “receive at least a donor’s weight and hematocrit” • “receive donor parameters electronically from a control system” • “receive the donor’s weight and hematocrit electronically” • “determine the target volume for plasma product comprising raw plasma and anticoagulant” 	<ul style="list-style-type: none"> • determine the target volume for plasma product and/or raw plasma based at least in part on the donor hematocrit • control the system to operate [a draw and return cycle/draw and return phases/a plurality of draw and return cycles] to withdraw [the] whole blood from the donor and separate the whole blood into the plasma product and the second blood component • return the second blood component to the donor • establish a current value of the hematocrit of the donor and a new target volume for plasma product and/or raw plasma • control the system to operate a subsequent draw and return cycle • determine the target volume for plasma product and/or raw plasma before a start of a first draw and return cycle • determine a target volume for plasma product and/or raw plasma by receiving the target volume for plasma 	
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<ul style="list-style-type: none"> • “determine [a/the] target volume for plasma product [comprising raw plasma and anticoagulant] [and/or raw plasma] [based at least in part on the [weight/donor weight] and hematocrit/based at least in part on the donor parameters]]” • “determine the target volume for plasma product and/or raw plasma based at least in part on the donor weight” • “determine the target volume for plasma product and/or raw plasma based at least in part on the donor hematocrit” • “control the system to operate [a draw and return cycle/draw and return phases/a plurality of draw and return cycles] to withdraw [the] whole blood from the donor and separate [the] whole blood into the plasma product and the 	<ul style="list-style-type: none"> • product and/or raw plasma from the control system • determines the target volume for plasma product and/or raw plasma by calculating the target volume for plasma product and/or raw plasma • repeat draw and return [phases/cycles] until the target volume of plasma product and/or raw plasma is collected • perform the draw and return phases at least three times • initiate a final return of the second blood component when (1) a measured volume of plasma product in the plasma collection container reaches the target volume for plasma product and/or (2) a volume of raw plasma in the plasma collection container reaches the target volume for raw plasma • control the system to collect the plasma product in the plasma product collection container until [the plasma product in the plasma product collection container/a collected volume of plasma product] reaches 	
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<ul style="list-style-type: none"> • second blood component” • “return the second blood component to the donor” • “establish a current value of the hematocrit of the donor and a new target volume for plasma product and/or raw plasma” • “control the system to operate a subsequent draw and return cycle” • “determine the target volume for plasma product and/or raw plasma before a start of a first draw and return cycle” • “determine a target volume for plasma product and/or raw plasma by receiving the target volume for plasma product and/or raw plasma from the control system” • “determines the target volume for plasma product and/or raw plasma by calculating the target volume for plasma 	<p>the [determined target volume/target volume for plasma product and/or raw plasma]</p> <ul style="list-style-type: none"> • determine a volume of whole blood to be drawn in a final draw phase which is different than a volume drawn in a prior draw phase <p><u>’474 Patent:</u> Function:</p> <ul style="list-style-type: none"> • control operation of the system • receive at least a donor’s weight, [height,] [sex] and hematocrit • receive [the donor’s weight and hematocrit/donor parameters] electronically • determine a target volume for plasma product [comprising raw plasma and anticoagulant] [and/or raw plasma] [based on the donor’s total blood volume and/or the donor’s plasma volume / based at least in part on the donor parameters and on the donor’s total blood volume and/or the donor’s plasma volume] 	
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<p>product and/or raw plasma”</p> <ul style="list-style-type: none"> • “repeat draw and return phases until the target volume of plasma product and/or raw plasma is collected” • “perform the draw and return [phases/cycles] at least three times” • “initiate a final return of the second blood component when (1) a measured volume of plasma product in the plasma collection container reaches the target volume for plasma product and/or (2) a volume of raw plasma in the plasma collection container reaches the target volume for raw plasma” • “control the system to collect the plasma product in the plasma product collection container until [the plasma product in the plasma product collection container/a collected volume of 	<ul style="list-style-type: none"> • control the system to operate [a draw and return cycle/draw and return phases/a plurality of draw and return cycles] to withdraw the whole blood from [the/a] donor and separate the whole blood into the plasma product and the second blood component • return the second blood component to the donor • establish a current value of the hematocrit of the donor and a new target volume for plasma product and/or raw plasma • control the system to operate a subsequent draw and return cycle • determine the target volume for plasma product and/or raw plasma before a start of a first draw and return cycle • determine the target volume for plasma product based an anticoagulant ratio • determine the donor's total blood volume based on multiple parameters selected from the group consisting of the weight, height, sex, age, and morphology of the donor 	
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<p>plasma product] reaches the [determined target volume/target volume for plasma product and/or raw plasma]”</p> <ul style="list-style-type: none"> • “determine a volume of whole blood to be drawn in a final draw phase which is different than a volume drawn in a prior draw phase” <p><u>’474 Patent:</u> “[is programmed/is configured/programmed] [to]”</p> <ul style="list-style-type: none"> • “control operation of the system” • “receive at least a donor’s weight, [height,] [sex] and hematocrit” • “receive [the donor’s weight and hematocrit/donor parameters] electronically” • “determine a target volume for plasma product [comprising raw plasma and anticoagulant] [and/or raw plasma] [based on 	<ul style="list-style-type: none"> • repeat draw and return phases until the target volume of plasma product and/or raw plasma is collected • perform the draw and return [phases/ cycles] at least three times • initiate a final return of the second blood component when (1) a measured volume of plasma product in the plasma collection container reaches the target volume for plasma product and/or (2) a volume of raw plasma in the plasma collection container reaches the target volume for raw plasma • control the system to collect the plasma product in the plasma product collection container until [the plasma product in the plasma product collection container reaches the determined target volume/ a collected volume of plasma product reaches the target volume for plasma product and/or raw plasma] • determine a volume of whole blood to be drawn in a final draw phase which is different 	
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<p>the donor's total blood volume and/or the donor's plasma volume / based at least in part on the donor parameters and on the donor's total blood volume and/or the donor's plasma volume]"</p> <ul style="list-style-type: none"> • "control the system to operate [a draw and return cycle/draw and return phases/a plurality of draw and return cycles] to withdraw the whole blood from [the/a] donor and separate the whole blood into the plasma product and the second blood component" • "return the second blood component to the donor" • "establish a current value of the hematocrit of the donor and a new target volume for plasma product and/or raw plasma" • "control the system to operate a subsequent draw and return cycle" • "determine the target volume for plasma 	<p>than a volume drawn in a prior draw phase</p> <ul style="list-style-type: none"> • determine a target volume for plasma product and/or raw plasma by receiving the target volume for plasma product and/or raw plasma from the control system • determines the target volume for plasma product and/or raw plasma by calculating the target volume for plasma product and/or raw plasma • determine the target volume for plasma product and/or raw plasma based at least in part on the donor weight • determine the target volume for plasma product and/or raw plasma based at least in part on the donor hematocrit • determine the donor's total blood volume based on the weight and height of the donor • determine the donor's total blood volume before whole blood is withdrawn from the donor during a donation • determine the target volume for plasma product comprising raw plasma and anticoagulant 	
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<p>product and/or raw plasma before a start of a first draw and return cycle”</p> <ul style="list-style-type: none"> • “determine the target volume for plasma product based an anticoagulant ratio” • “determine the donor's total blood volume based on multiple parameters selected from the group consisting of the weight, height, sex, age, and morphology of the donor” • “repeat draw and return phases until the target volume of plasma product and/or raw plasma is collected” • “perform the draw and return [phases/ cycles] at least three times” • “initiate a final return of the second blood component when (1) a measured volume of plasma product in the plasma collection container reaches the target volume for plasma product and/or (2) a 	<p><u>’873 Patent:</u> Function:</p> <ul style="list-style-type: none"> • control the operation of the blood component separation device and the blood draw pump • calculate a volume of pure plasma collected within the plasma collection container based, at least in part, on a volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the subject • calculate a volume of pure plasma to be collected within the plasma collection container based, at least in part, on a volume of plasma component to be collected within the plasma collection container, a ratio of anticoagulant to be added to the withdrawn whole blood, 	
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<p>volume of raw plasma in the plasma collection container reaches the target volume for raw plasma”</p> <ul style="list-style-type: none"> • “control the system to collect the plasma product in the plasma product collection container until [the plasma product in the plasma product collection container reaches the determined target volume/ a collected volume of plasma product reaches the target volume for plasma product and/or raw plasma]” • “determine a volume of whole blood to be drawn in a final draw phase which is different than a volume drawn in a prior draw phase” • “determine a target volume for plasma product and/or raw plasma by receiving the target volume for plasma product and/or raw 	<p>and a hematocrit of the subject</p> <ul style="list-style-type: none"> • calculate a percentage of anticoagulant in the collected plasma component • calculate a percentage of anticoagulant to be collected in the plasma component • calculate a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the subject • calculate a volume of anticoagulant to be collected in the collected plasma component based, at least in part, upon the hematocrit of the subject • pure plasma to be collected within the plasma collection container based, at least in part, upon the volume of anticoagulant to be collected in the collected plasma component • monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source • monitor the operation of an anticoagulant pump to 	
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<p>plasma from the control system”</p> <ul style="list-style-type: none"> • “determines the target volume for plasma product and/or raw plasma by calculating the target volume for plasma product and/or raw plasma” • “determine the target volume for plasma product and/or raw plasma based at least in part on the donor weight” • “determine the target volume for plasma product and/or raw plasma based at least in part on the donor hematocrit” • “determine the donor's total blood volume based on the weight and height of the donor” • “determine the donor's total blood volume before whole blood is withdrawn from the donor during a donation” • “determine the target volume for plasma product comprising raw 	<p>determine a total volume of anticoagulant introduced into the system</p> <ul style="list-style-type: none"> • control the plasma collection process to collect a target volume of pure plasma and/or a target volume of plasma component [within the plasma collection container] <p><u>’204 Patent:</u> Function:</p> <ul style="list-style-type: none"> • control the operation of the blood component separation device and the first pump • calculate a target plasma amount to collect based, at least in part, on the donor's total blood volume and a hematocrit of the donor • stop collecting plasma when the [target plasma amount/target amount of plasma] to collect has been collected into [a/the] plasma collection container • stop collecting the plasma component when the [target plasma amount/target amount of plasma] to collect has been collected into the plasma collection container 	
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<p>plasma and anticoagulant”</p> <p><u>’873 Patent:</u> [is/is further/further] configured to</p> <ul style="list-style-type: none"> • “control the operation of the blood component separation device and the blood draw pump” • “calculate a volume of pure plasma collected within the plasma collection container based, at least in part, on a volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the subject” • “calculate a volume of pure plasma to be collected within the plasma collection container based, at least in part, on a volume of plasma component to be 	<ul style="list-style-type: none"> • calculate the donor's total blood volume • return, after collecting at least a portion of the target plasma amount to collect • receive individual characteristics of the donor <p>Structure: Insufficient disclosure of corresponding structure that performs the claimed functions</p> <p>Therefore, indefinite at least for the failure to disclose adequate structure under § 112(f).</p> <p><u>Exemplary Intrinsic Evidence:</u></p> <p><u>’652 Patent:</u> 2:61-3:7; 3:10-22; 3:43-51; 5:1-9; 5:25-33; 6:8-; 7:1-9; 8:9-; 9:2-10; FIG. 3.</p> <p><u>’416 Patent:</u> FIG. 3; 3:5-33; 3:43-61; 5:18-6:2; 7:49-57; 8:7-15; 8:57-67; 9:48-58; 10:58-11:5; 11:51-57; 13:36-40; 13:64-14:3; 14:50-57; 15:40-45.</p> <p><u>’926 Patent:</u> FIG. 3; 3:3-25; 3:52-60; 5:9-17; 5:34-41; 6:18-26; 7:7-17; 8:18-23; 9:10-18.</p>	
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<p>collected within the plasma collection container, a ratio of anticoagulant to be added to the withdrawn whole blood, and a hematocrit of the subject”</p> <ul style="list-style-type: none"> • “calculate a percentage of anticoagulant in the collected plasma component” • “calculate a percentage of anticoagulant to be collected in the plasma component” • “calculate a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the subject” • “calculate a volume of anticoagulant to be collected in the collected plasma component based, at least in part, upon the hematocrit of the subject, the volume of pure plasma to be collected within the plasma collection container based, at least in part, 	<p>’934 Patent: FIG. 3; 3:12-39; 3:59-64; 5:24-6:8; 6:23-29; 7:55-63; 8:13-20; 8:65-67; 9:55-60; 10:63-11:1; 11:56-62; 13:41-45; 13:66-14:3; 14:55-62; 15:46-51</p> <p>’124 Patent: 3:12-25; 3:28-; 3:56-67; 5:15-23; 5:39-47; 6:23-; 7:16-24; 8:25-; 9:18-25; FIG. 3.</p> <p>’916 Patent: FIG. 3; 3:9-38; 3:57-64; 5:40-47; 6:23-34; 7:16-24; 8:25-38; 9:17-25.</p> <p>’474 Patent: FIG. 3; 3:20-48; 3:57-4:10; 5:34-6:19; 6:35-45; 8:24-31; 9:9-16; 9:64-10:7; 11:7-21; 11:63-12:8; 13:52-56; 14:8-19; 14:63-15:11; 15:56-61.</p> <p>’873 Patent: FIG. 3; 3:12-39; 3:55-67; 5:40-47; 6:23-33; 7:14-24; 8:22-38; 9:13-25.</p> <p>’204 Patent: FIG. 3; 3:34-61; 4:12-22; 5:46-6:57; 8:26-44; 9:19-29; 10:10-20; 11:21-35; 12:13-21; 13:65-14:2; 14:24-31; 15:12-24; 16:2-7.</p> <p><u>Exemplary Extrinsic Evidence:</u></p> <p>All intrinsic evidence cited above for this term is hereby incorporated as extrinsic evidence if the above cited intrinsic evidence would not</p>	
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<p>upon the volume of anticoagulant to be collected in the collected plasma component”</p> <ul style="list-style-type: none"> • “monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source” • “monitor the operation of an anticoagulant pump to determine a total volume of anticoagulant introduced into the system” • “control the plasma collection process to collect a target volume of pure plasma and/or a target volume of plasma component [within the plasma collection container]” <p><u>’204 Patent:</u> [is further] configured to</p> <ul style="list-style-type: none"> • “control the operation of the blood component separation device and the first pump” 	<p>qualify as intrinsic evidence for the relevant patent.</p> <p>Terumo may rely on a declaration or testimony from Dr. Jason Acker or another qualified expert in support of its claim construction positions.</p> <p>Terumo reserves the right to rely on the knowledge of a POSITA, any evidence cited by Plaintiff, and/or any evidence needed in response to Plaintiff’s arguments.</p>		
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<ul style="list-style-type: none">• “calculate a target plasma amount to collect based, at least in part, on the donor’s total blood volume and a hematocrit of the donor”• “stop collecting plasma when the [target plasma amount/target amount of plasma] to collect has been collected into [a/the] plasma collection container”• “stop collecting the plasma component when the [target plasma amount/target amount of plasma] to collect has been collected into the plasma collection container”• “calculate the donor’s total blood volume”• “return, after collecting at least a portion of the target plasma amount to collect”• “receive individual characteristics of the donor”			
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Dated: February 3, 2026

/s/ John M. Caracappa

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CERTIFICATE OF SERVICE

I hereby certify that all counsel of record who are deemed to have consented to electronic service are being served this 3rd day of February, 2026, with a copy of this document via the District Court's ECF/CM electronic filing system.

/s/ John M. Caracappa
John M. Caracappa
Counsel for Defendant