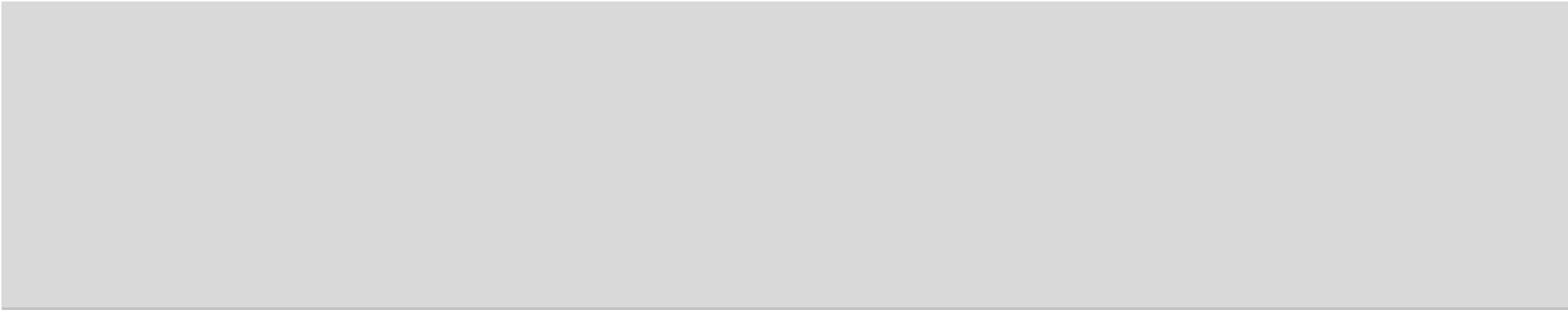


Patent Owner Masimo's Trial Hearing Demonstratives

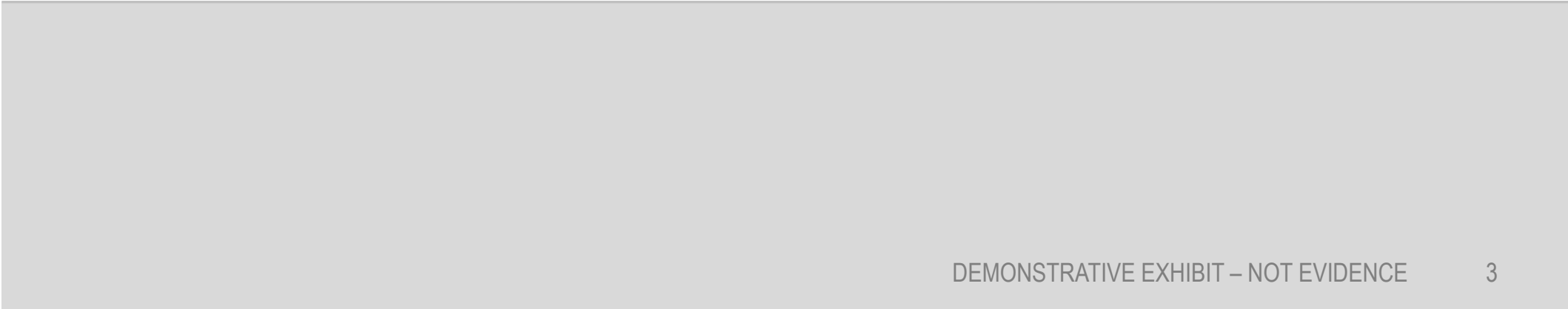
Apple Inc. v. Masimo Corp.
IPR2024-00290
U.S. Pat. No. 8,190,223

Abbreviations

Pet.	Petition
POPR	Patent Owner's Preliminary Response
Inst.	Institution Decision
POR	Patent Owner's Response
Reply	Petitioner's Reply
Sur-Reply	Patent Owner's Sur-Reply



Background



DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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'223 Patent

(12) **United States Patent**
Al-Ali et al.

(54) **NONINVASIVE MULTI-PARAMETER
PATIENT MONITOR**

(75) Inventors: **Ammar Al-Ali**, Tustin, CA (US); **Joe Kiani**, Laguna Niguel, CA (US); **Mohamed Diab**, Mission Viejo, CA (US); **Greg Olsen**, Irvine, CA (US); **Roger Wu**, Irvine, CA (US); **Rick Fishel**, Orange, CA (US)

(73) Assignee: **Masimo Laboratories, Inc.**, Irvine, CA (US)

(10) Patent No.: **US 8,190,223 B2**

(45) Date of Patent: **May 29, 2012**

FIG. 2

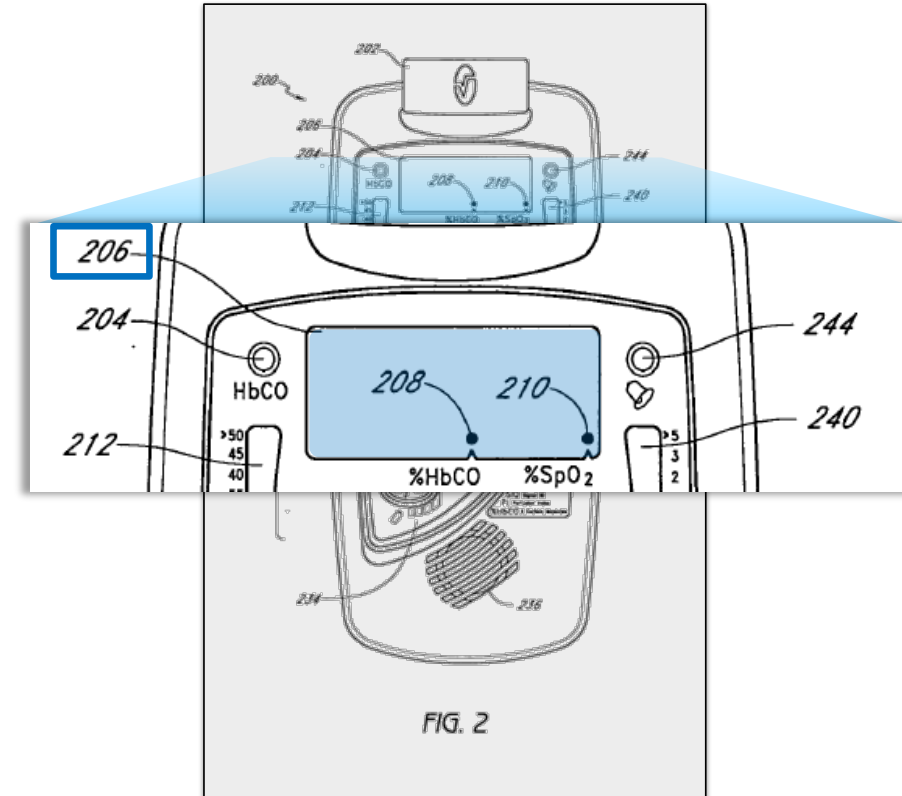
Priority Date:
Mar. 1, 2005



Masimo rainbow® technology led to the need to display more parameters

Purpose Of The Invention

- ⌚ Inventors sought a way to show multiple parameters in limited display space without sacrificing patient safety
- ⌚ Replace one parameter with a second parameter when value:
 - Indicates a worsening state of a patient
 - Alarms
 - Above or below a designated range



Purpose Of The Invention



EX2031, 1.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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'223 Patent

ABSTRACT

Embodiments of the present disclosure include a handheld multi-parameter patient monitor capable of determining multiple physiological parameters from the output of a light sensitive detector capable of detecting light attenuated by body tissue. For example, in an embodiment, the monitor is capable of advantageously and accurately displaying one or more of pulse rate, plethysmograph data, perfusion quality, signal confidence, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO₂"), fractional arterial oxygen saturation ("SpaO₂"), or the like. In an embodiment, the monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate.

Despite the success of read through motion oximeter systems, there is a need to provide patient monitors capable of displaying multiple physiological parameters, other than or in addition to SpO₂, plethysmograph waveforms, or pulse rates. For example, in accessing a patient's condition, caregivers often desire knowledge of other blood constituents, including for example, a percent value for arterial carbon monoxide saturation ("HbCO") or a percent value for methemoglobin saturation ("HbMet") or the like.

In an embodiment, the display of a noninvasive multi-parameter patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display area or real estate. In an embodiment, a user may cycle different param-

Claim 1

A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying **a measured value of a first physiological parameter** of body tissue of a monitored patient in a first display area or displaying **a measured value of a second physiological parameter** of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information

wherein in the common display area, **the display of one of the measured values of the first or second physiological parameter is replaced with the other of the measured values based on an occurrence of an event**, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

Example Of Changes – Claim 13

A patient monitor capable of measuring at least two physiological parameters,

the patient monitor comprising a display capable of displaying **a measured value of a first physiological parameter** of body tissue of a monitored patient in a first display area or displaying **a measured value of a second physiological parameter of the body tissue in a second display area** where the first display area and the second display area comprise at least some common display area capable of displaying information,

wherein **the common display area changes** from displaying one of the measured values of **the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event**, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient,

wherein an aspect of the display **changes** to illustrate a **change** in the severity of one of the measured values of the first or second physiological parameters, wherein the aspect that **changes** comprises a display size.

Petitioner's Grounds

Ground	Claims	Basis for Rejection
1A	1-4, 6, 11-18, 20-22	§103: Naghavi-Hochstedler-Burnes
1B	19, 27-28, 32, 34, 36-37, 42-43	§103: Naghavi-Hochstedler-Burnes-Hayashi
1C	42-44	§103: Naghavi-Hochstedler-Burnes-Hayashi-Mortz

Claim Construction

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Claim Construction

“measured value”

Claims 1-4, 6, 11-22, 27-28, 32, 34, 36-37, and 42-44

“changes”

Claims 13, 28

“replaced”/“replaces”/“replacing”

Claims 1, 15, 18, 21, 27

“first” and “second”

Claims 1-4, 6, 11-22, 27-28, 32, 34, 36-37, and 42-44

All Claims: Measured Value

Measured Value

value of a parameter currently detected
and determined by the monitor

All Claims: Measured Value

⌚ Claim 19:

“measured values of the first and second physiological parameters are **determined using an output signal of a light sensitive detector capable** of detecting light attenuated by the body tissue”

⌚ Other claims consistent:

- an invasively ***measured value*** (Claims 5, 23);
- a non-invasively ***measured value*** (Claim 6); and
- glucose (Claim 7)

All Claims: Measured Value

- ⊙ Each claim recites replacing/changing the display of a ***measured value*** based on an event or occurrence
 - approaches or crosses a threshold (Claims 1, 13, 27, 28);
 - is alarming (Claim 15);
 - is more critical than the other (Claim 18); or
 - otherwise indicating a worsening state of a patient (Claim 21)
- ⊙ Thus, monitors must ***currently*** measure the parameter value

All Claims: Measured Value

Specification:

Sensor that “produces sufficient data for the determination of HbCO, HbMet, Hbt and SpO2, SpO2 only, SpO2 and HbMet, any combination of the foregoing or other parameters, or the like”

Device determines “the many parameters capable of being measured by the monitor”

Claims 1, 15, 18, 21, 27: “Replaced”/“Replaces”/“Replacing”

Measured Value Of First Parameter “Replaced” By Measured Value Of A Second Parameter

The measured value of the first parameter is removed from the display and the measured value of the second parameter is displayed in its place

Claims 1, 15, 18, 21, 27: “Replaced”/“Replaces”/“Replacing”

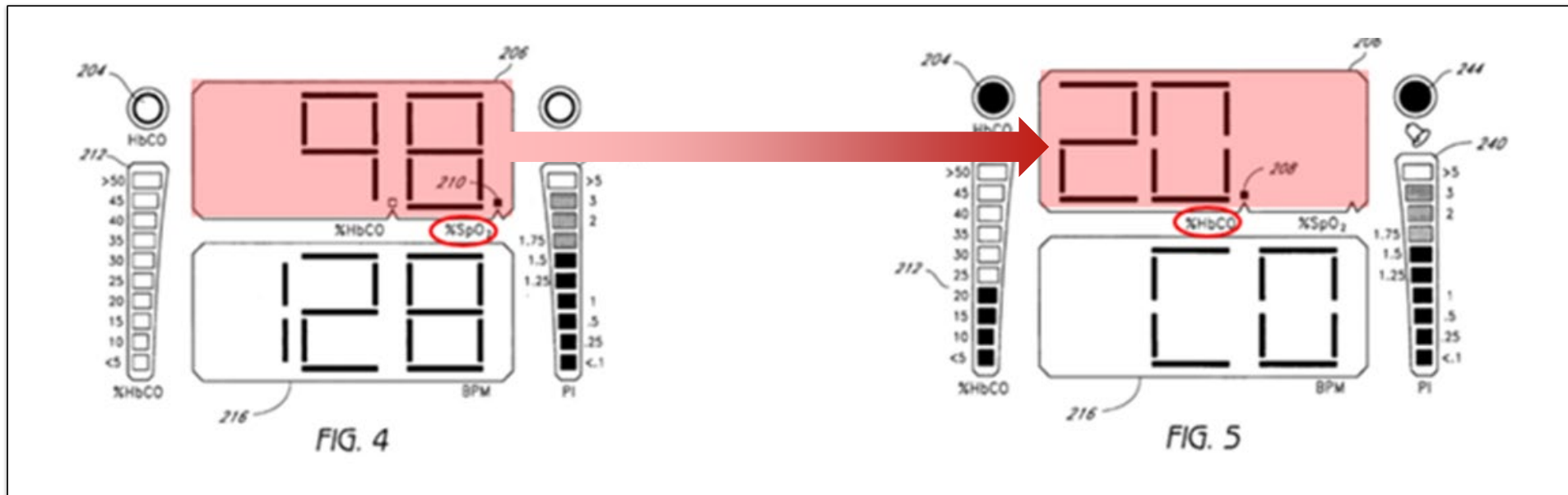
Plain and Ordinary Meaning of “Replace”: “take the place of”

“In an embodiment, the four LED’s may also change color as the battery charge decreases, and the final LED may begin to flash to ***indicate that the caregiver should replace the batteries.***”



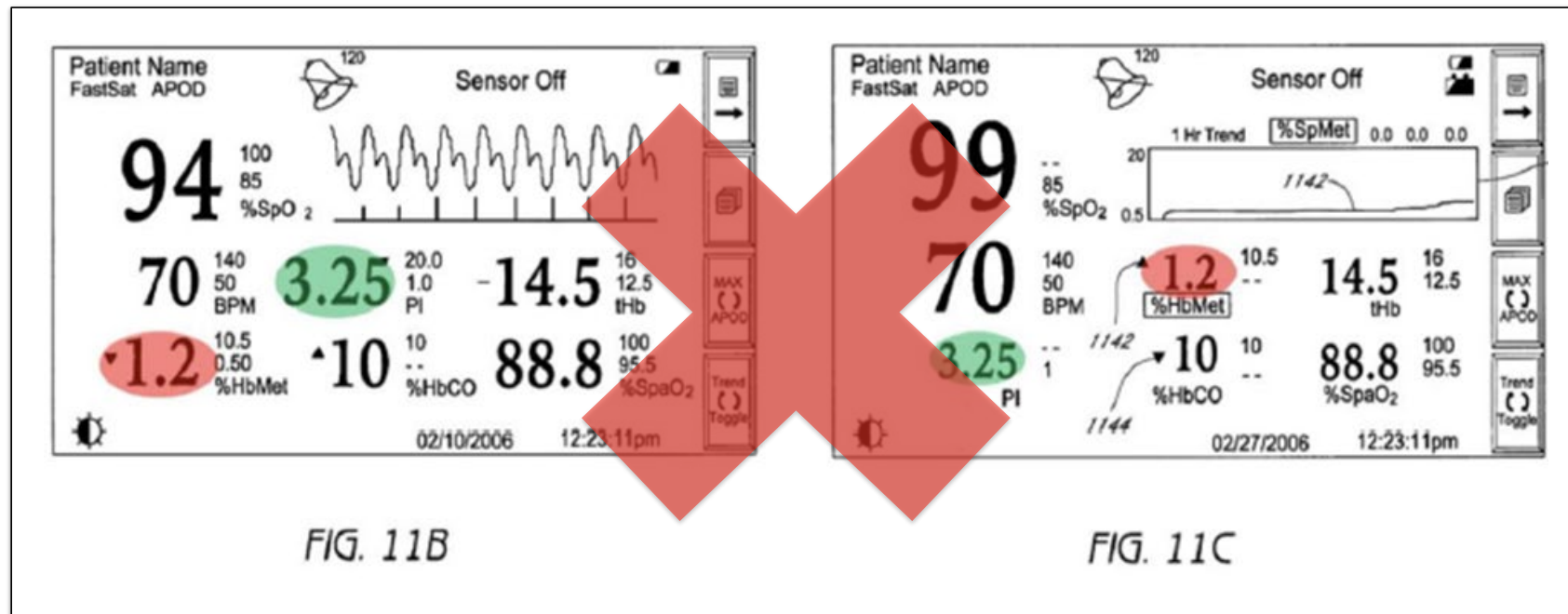
Claims 1, 15, 18, 21, 27: “Replaced”/“Replaces”/“Replacing”

Figures show SpO2 value **replaced** by HbCO value



Claims 1, 15, 18, 21, 27: “Replaced”/“Replaces”/“Replacing”

Specification explains monitor “may advantageously employ enlargement or reorganization”



File History Of The '223 Patent

⌚ Examiner distinguished:

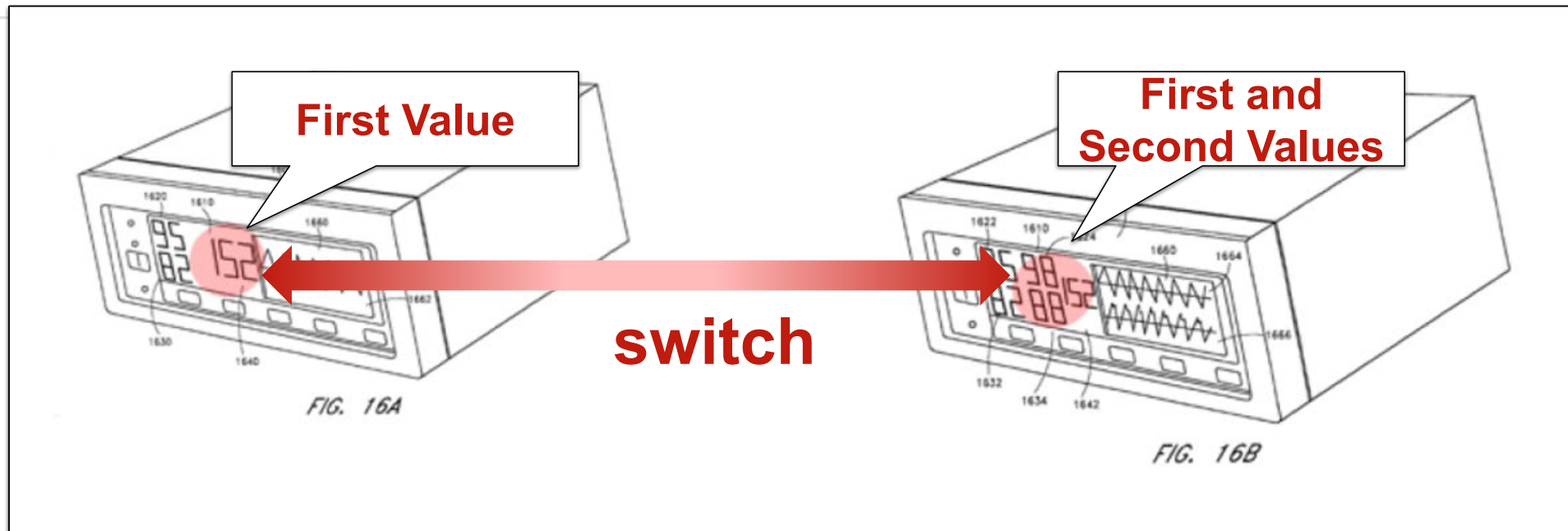
- **replacing** the first value with a second value (Claim 21)
from
- **switching** display to show both first value **and** second value (Al-Ali)

⌚ Notice of Intent to Issue a Reexamination Certificate:

- “Al-Ali does not replace the first value, but **switches** from displaying the first value to displaying the first and second values”

File History Of The '223 Patent

Switch display to show both first value *and* second value is not **replacing** (Al-Ali)



File History Of The '223 Patent

Replacement of a measured value **removes** it from the display

Examiner:

“when an alarm condition is detected, Al-Ali **switches** from displaying one parameter to displaying all of the parameters to allow the user to better view the conditions that caused the alarm”

“there would be no motivation to simply replace the first parameter with the second, as it would contradict the direct teaching in the reference of allowing the user to see the entirety of the patient’s condition”

Claims 13, 28: “Changes”

Changes

Same construction as “replace”

The measured value of the first parameter is removed from the display and the measured value of the second parameter is displayed in its place

Claims 13, 28: “Changes”

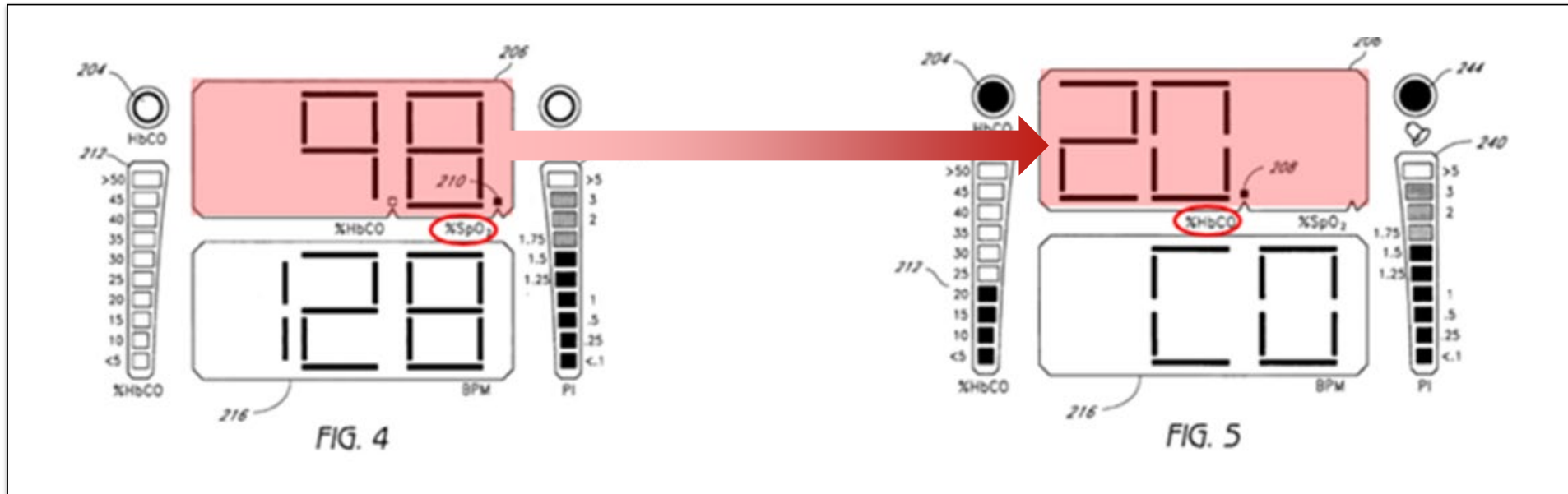
Plain And Ordinary Meaning Of “Change”: “to replace with another”

- ⦿ Consistent with the plain and ordinary meaning of “change”
- ⦿ Examples:
 - flat tire “changed”
 - lightbulb “changed”



Claims 13, 28: “Changes”

Claims align with specification: “common display area ***changes from*** displaying ***one*** of the measured values of the first ***or*** second physiological parameter to displaying ***the other*** of the measured values”



Claims 13, 28: “Changes”

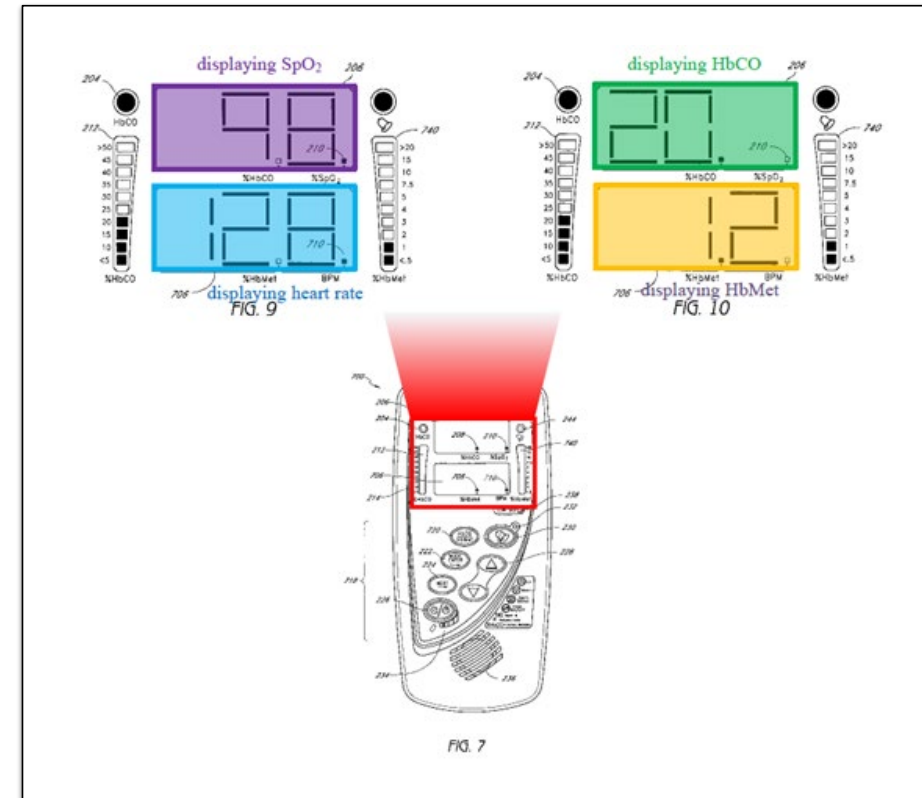
Claim 28:

“a user input button, the activation of which causes the display to **change from** displaying the measured value of the first blood parameter **to** displaying the measured value of the second blood parameter”

Claim terms “change from . . .to”
is consistent with the “replaced” limitations

All Claims: “First” And “Second”

- ⦿ All claims recite display of a “first” parameter and “second” parameter
- ⦿ All claims require at least two measured values, each of a ***different*** parameter
- ⦿ Undisputed by Apple



Claim Construction

POSITA Would Understand Claims Require

- 1) displaying the measured value of the first parameter
- 2) then replacing the value with a second measured value of a second parameter that the device is currently monitoring, but not displaying

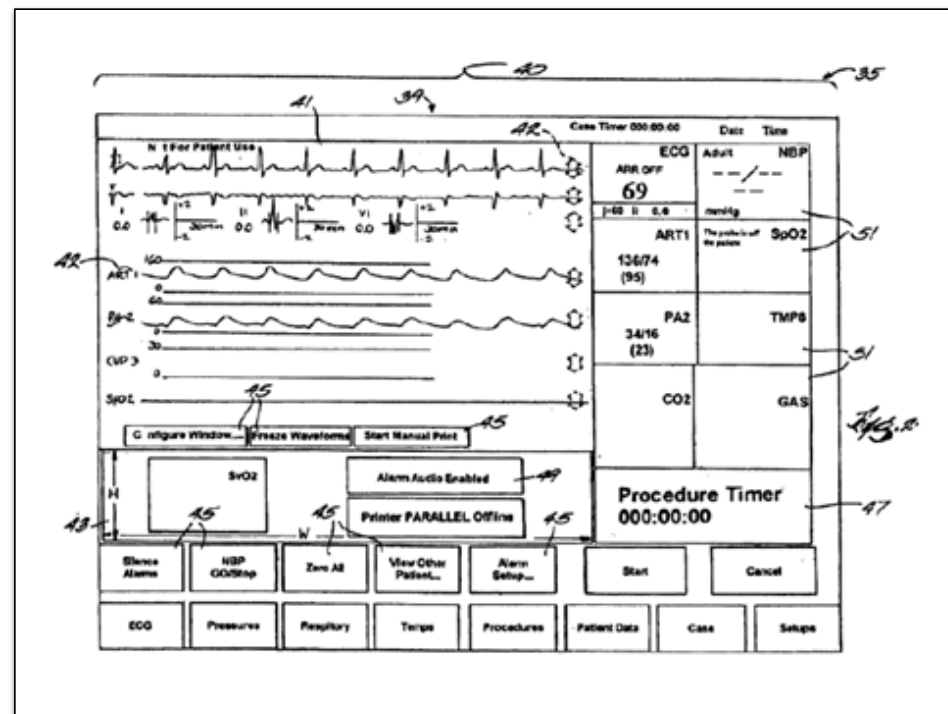
Naghavi + Hochstedler + Burnes

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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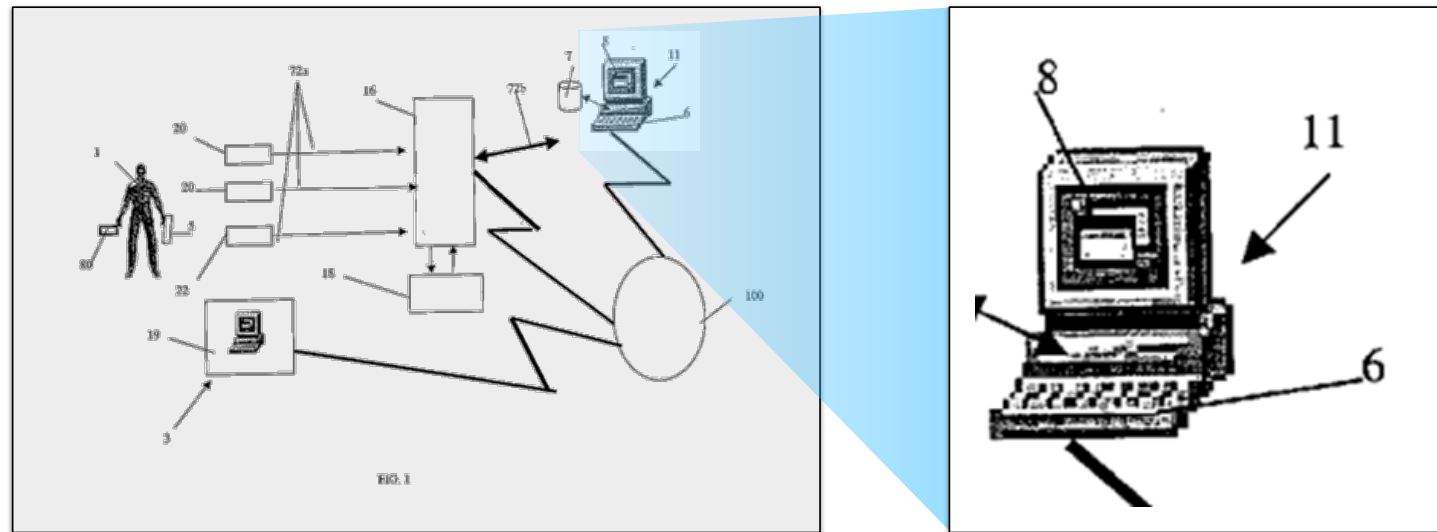
Hochstedler

- ⊗ U.S. Patent No. 6,707,476 – “Automatic Layout Selection For Information Monitoring System.”
- ⊗ Graphical user interface for patient monitoring system that uses a “CRT display, flat panel display, or similar device.”



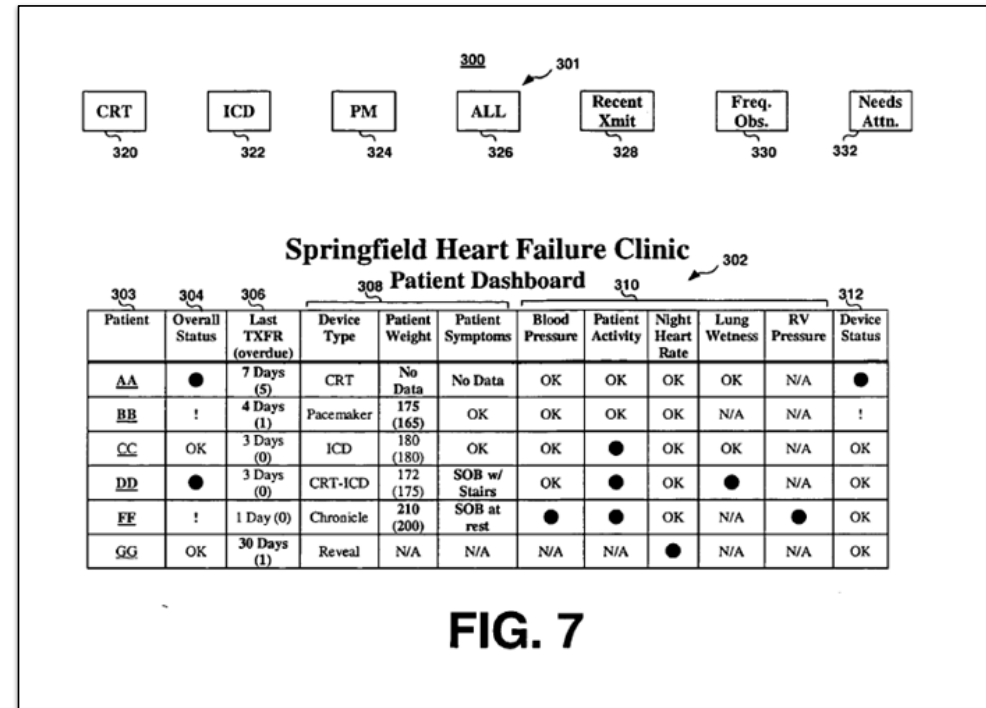
Naghavi

- ⌚ U.S. Patent Pub. No. 2002/0184055 - “System And Method For Healthcare Specific Operating System”
- ⌚ Personal healthcare management system including a large display, such as a computer screen



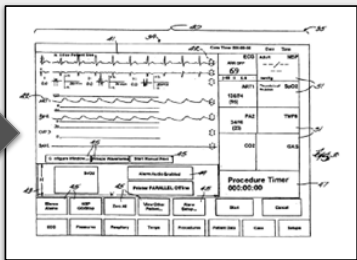
Burnes

- U.S. Patent Pub. No. 2006/0064020 - “Clinic Dashboard Monitor”
- “[R]emote patient monitoring system including a graphical user interface (GUI) that displays a summary table of categorized parameter values for multiple patients simultaneously”
- Shows all values, even those unmeasured (“N/A” or “No Data”)

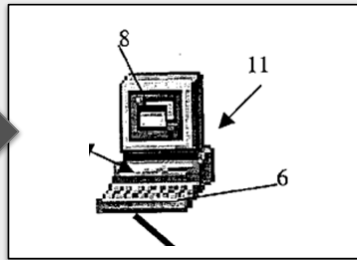


Patent Is Distinct From The Art

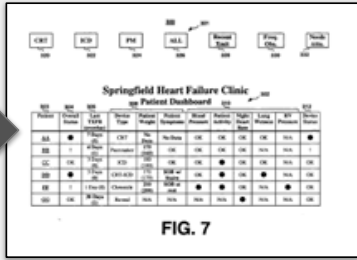
Hoschstedler:



Nagavi:

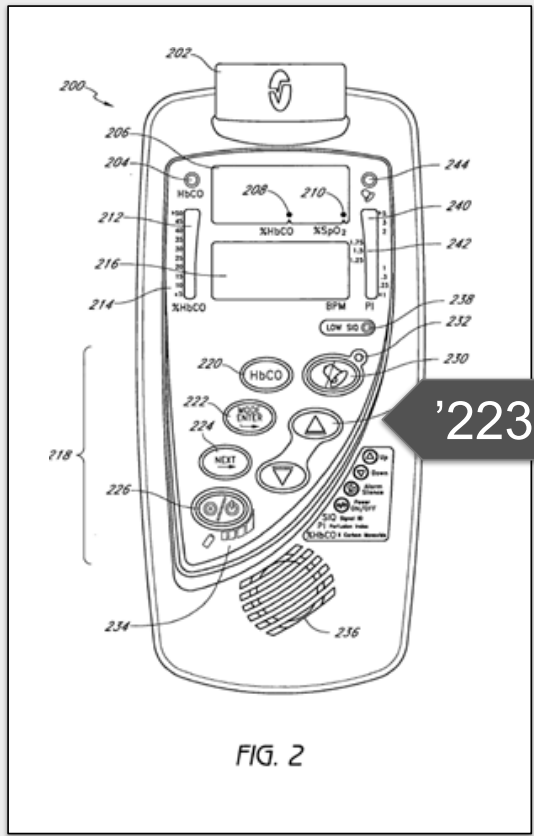


Burnes:



VS

'223 Patent



EX1004, Fig. 2; EX1005, Fig. 1; EX1006, Fig. 7; EX1001, Fig. 2.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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The Prior Art Does Not Disclose Replacing
(Or Changing) One Parameter For Another

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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Example Claim Language

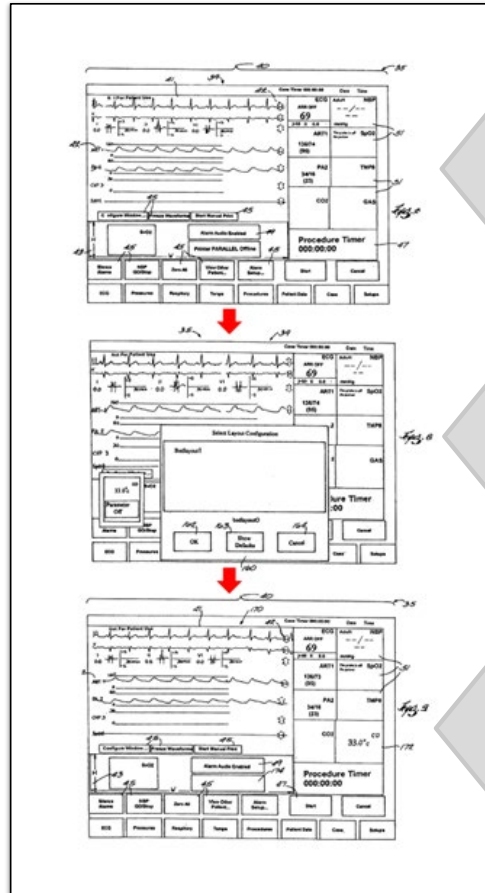
Claim 1:

“wherein in the common display area, the display of one of the measured values of the first or second physiological parameter *is replaced* with the other of the measured values based on an occurrence of an event . . .”

Claim 13:

“wherein the common display area *changes from displaying* one of the measured values of the first or second physiological parameter *to displaying* the other of the measured values based on an occurrence of an event . . .”

Hochstedler Does Not Disclose Or Suggest Replacing (Or Changing)



Hochstedler discloses blank boxes for unmonitored parameters

Changes display because active capabilities (parameters measured) have changed

Hochstedler system switches from Fig. 2 to Fig. 9 only “once a selection from the dialog box . . . has been made”

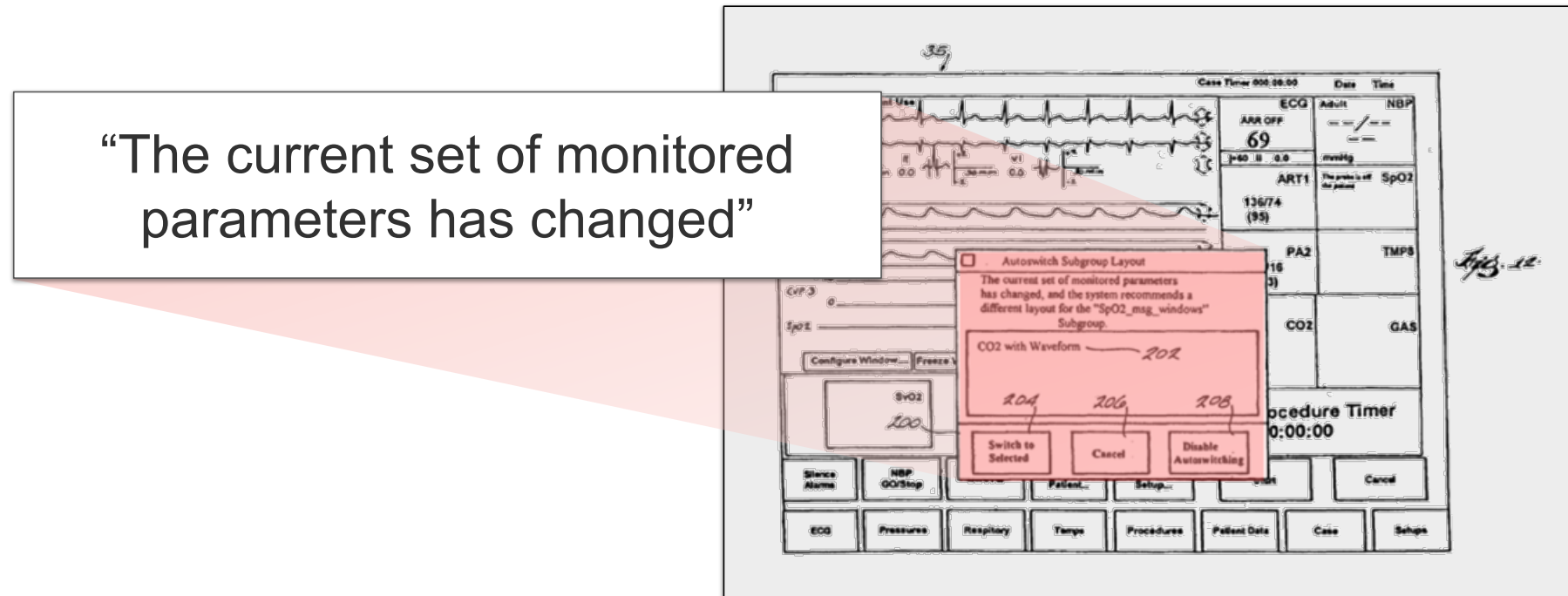
POR, 30-34; Sur-Reply, 12-14, 18-20; EX1004, 2:43-45, 5:61-65, 6:61-7:5, 8:30-33, Figs. 2, 8, 9; EX2042, ¶¶95-99.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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Hochstedler Does Not Disclose Or Suggest Replacing (Or Changing)

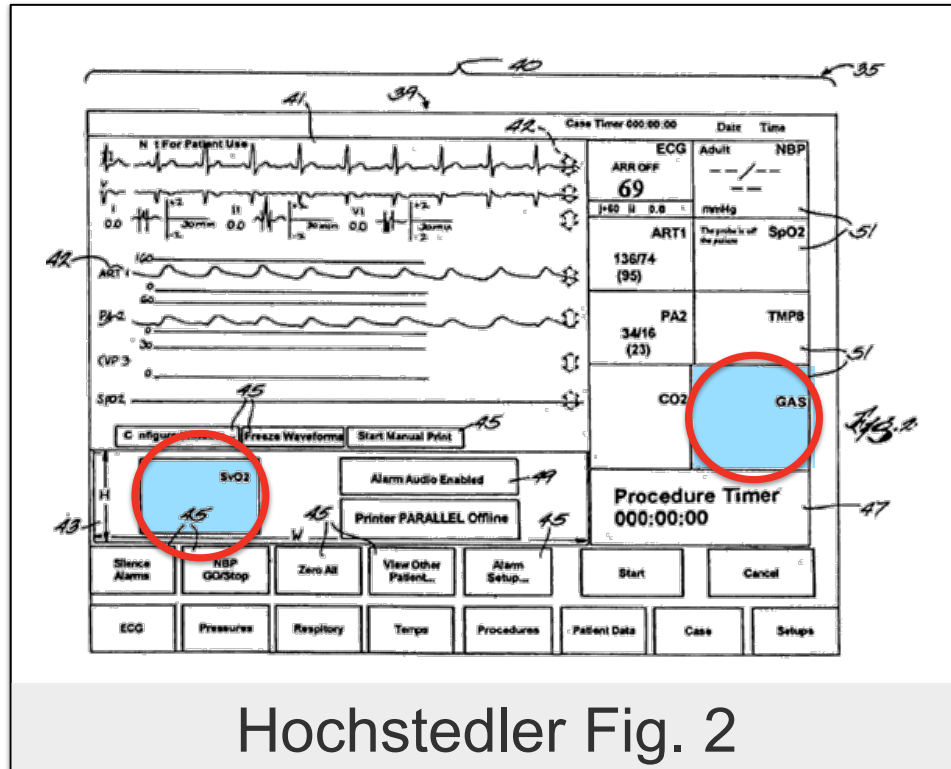
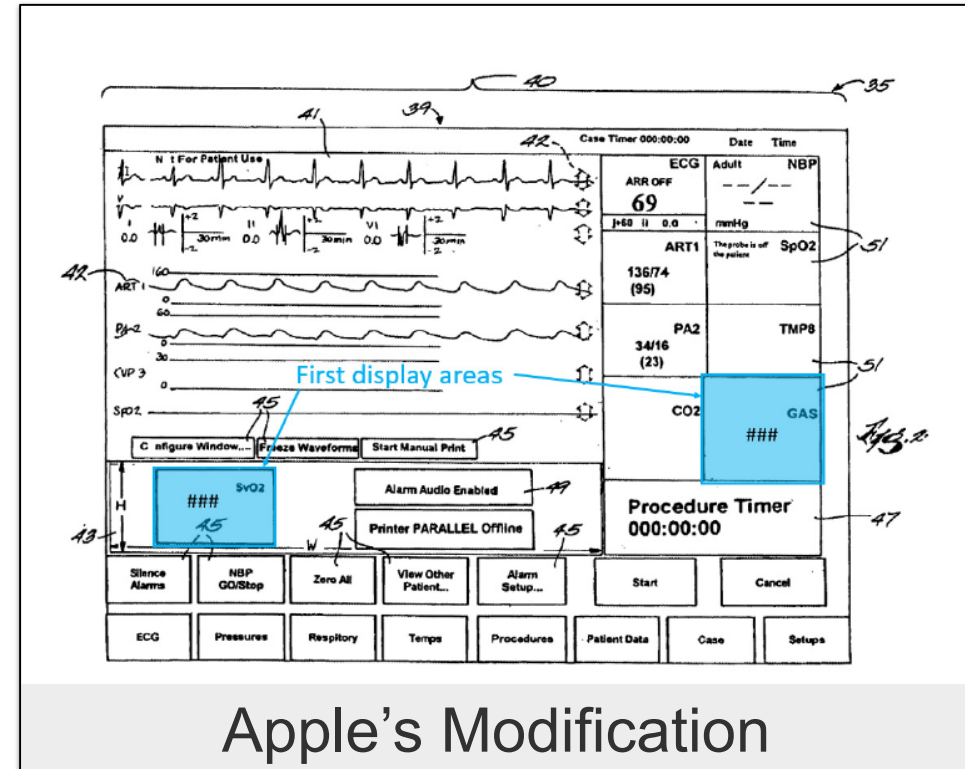
Display changes only when monitored parameters have changed



Hochstedler Does Not Display Two Different Measured Values In The Same Display Area

- ⦿ Hochstedler discloses displaying all measured values at the same time
- ⦿ Apple modifies Hochstedler's figures (Figs. 2, 9, and 13) to attempt to show limitation, but modification is not supported by reference

Apple Modified Hochstedler's Fig. 2 To Add Measured Values “###”



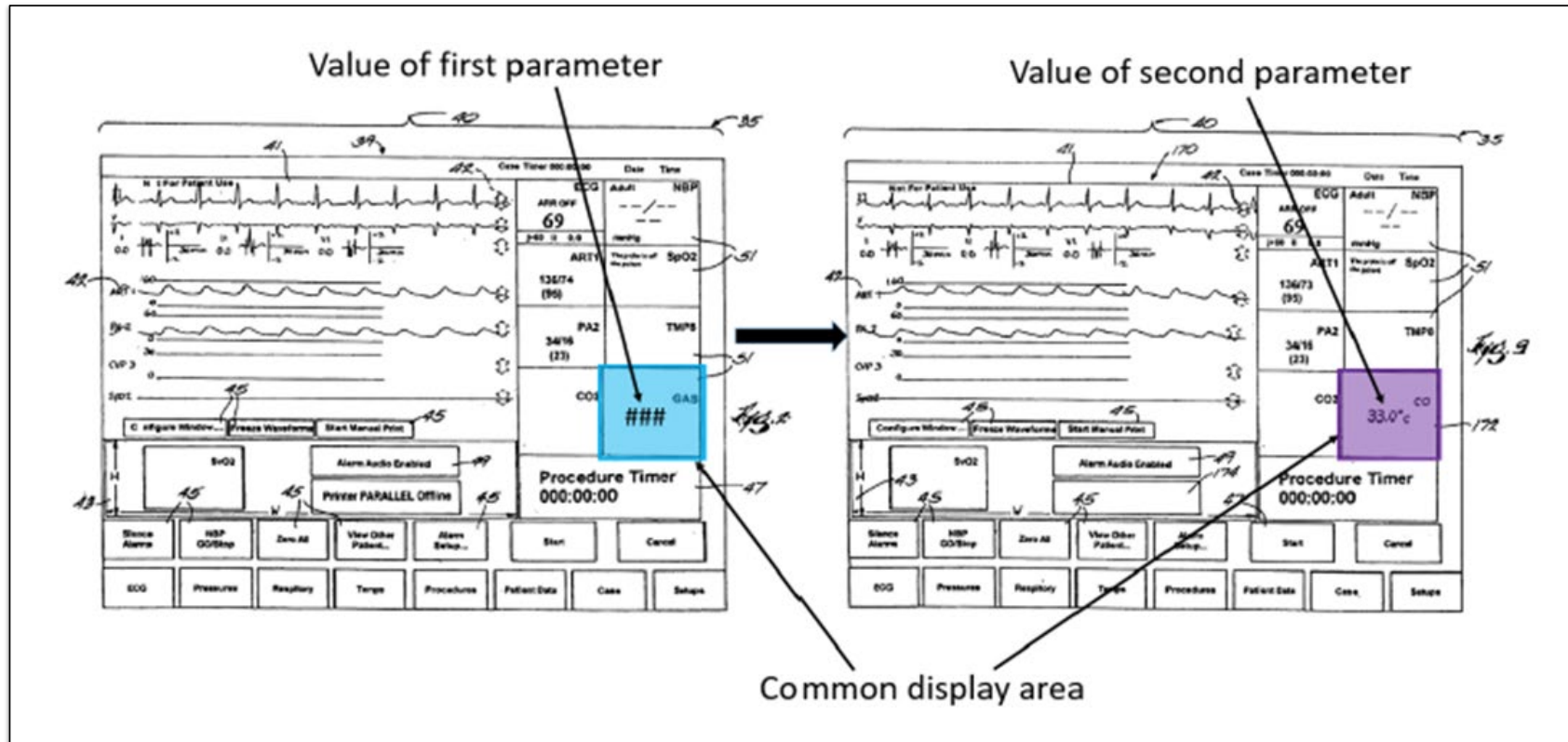
Pet., 6, 20, 23-24, 26-27; POR, 29; Reply, 16-17; Sur-Reply, 12-13, 18-20; EX1003, ¶¶69; EX1004, Fig. 2; EX2042, ¶103.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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Apple's Modified Figures Suggest Replacing A Measured Value

Hochstedler Does Not Change As Apple Proposes

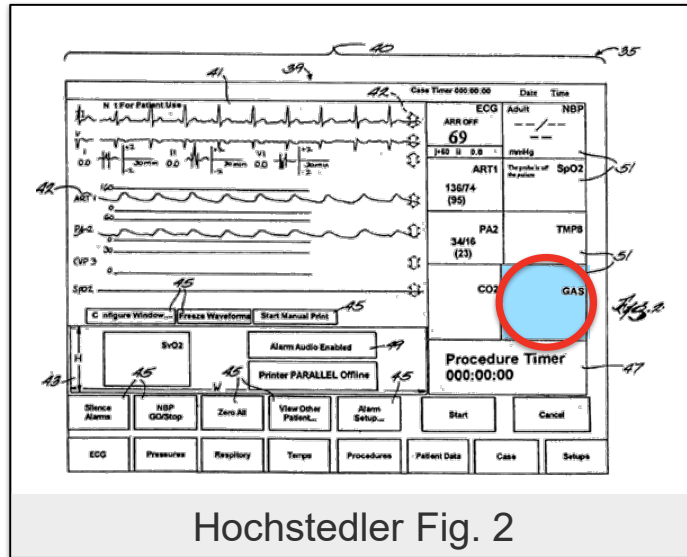
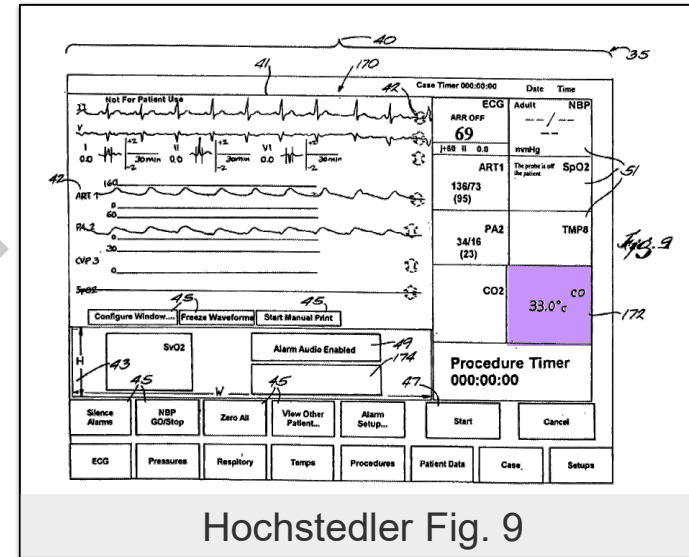


Pet., 26; POR, 29; Sur-Reply, 12-14, 18-20; EX1004, Figs. 2, 9; EX2042, ¶¶103-104.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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Hochstedler's Actual Figures Do Not Disclose A Replacement Of Measured Values



- ⊙ Both Fig. 2 and Fig. 9 display **all parameters measured** at each time
- ⊙ No measured but **undisplayed** parameters – GAS is blank means nothing measured
- ⊙ Fig. 2 layout switches to Fig. 9 layout system after **capabilities** change (e.g., sensors added or removed)

The Prior Art Does Not Disclose Monitoring An Undisplayed Parameter

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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Apple's New Theory On Replacement

- ⦿ Board noted in the Institution Decision that Apple relied on Hochstedler only as disclosing the claimed replacement of a measured value

- Apple:

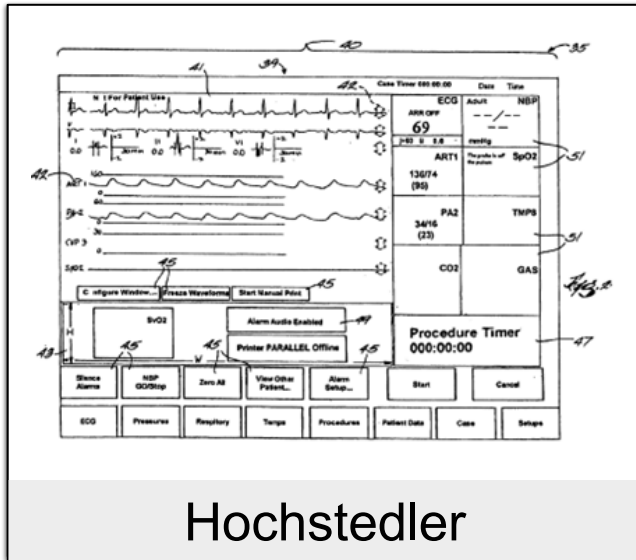
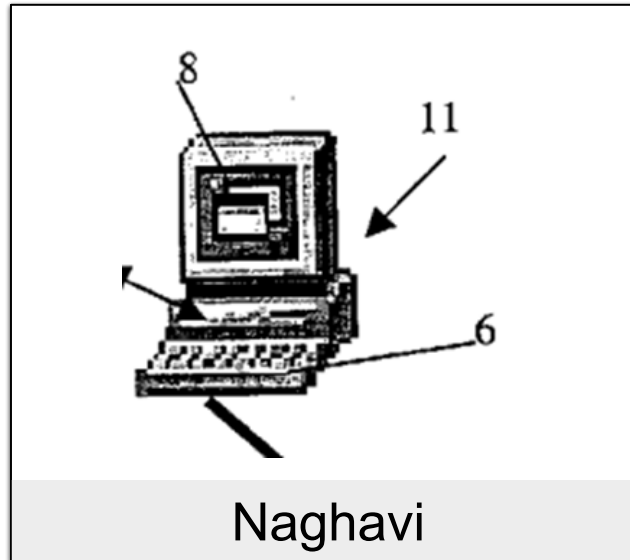
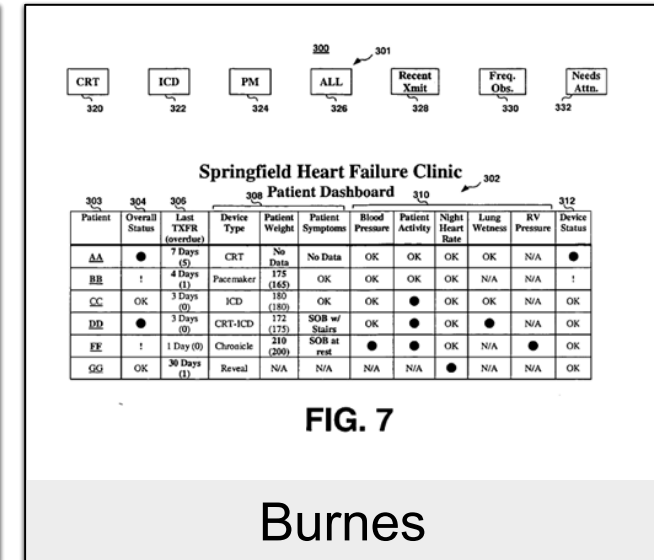
“relies on Hochstedler for the specific GUI changes that show replacement of one measured value of a parameter for another, not Naghavi or Burnes.”

- ⦿ Apple, in its Reply, contends that the ***combination*** of references discloses this limitation

Prior Art, Alone Or In Combination, Does Not Disclose Replacement Of Measured Values

- ⦿ Apple required to identify at least one reference that disclosed replacing display of one measured value for another
 - *Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194 (Fed. Cir. 2014)
- ⦿ Proper construction of “replacing” measured values requires a parameter that is monitored, but not displayed
- ⦿ Hochstedler, Naghavi, and Burnes display all measured values of parameters, no parameters are measured but undisplayed

All Art Discloses Large Screens With Sufficient Real Estate To Display All Parameters



POR, 37-40; EX1004, 1:8-10; EX1005, Abstract, Fig. 1, ¶¶11, 58; EX1006, Abstract, ¶¶5, 33, 36, Fig.7; EX2042, ¶¶109, 112-116.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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Burnes Discloses Displaying All Parameters

- ⊙ **Burnes:** displays “summary data for multiple patients simultaneously”
 - Displays non-monitored parameters (“N/A” or “No Data”)
- ⊙ Presents **more** information from multiple patients simultaneously, not replacement

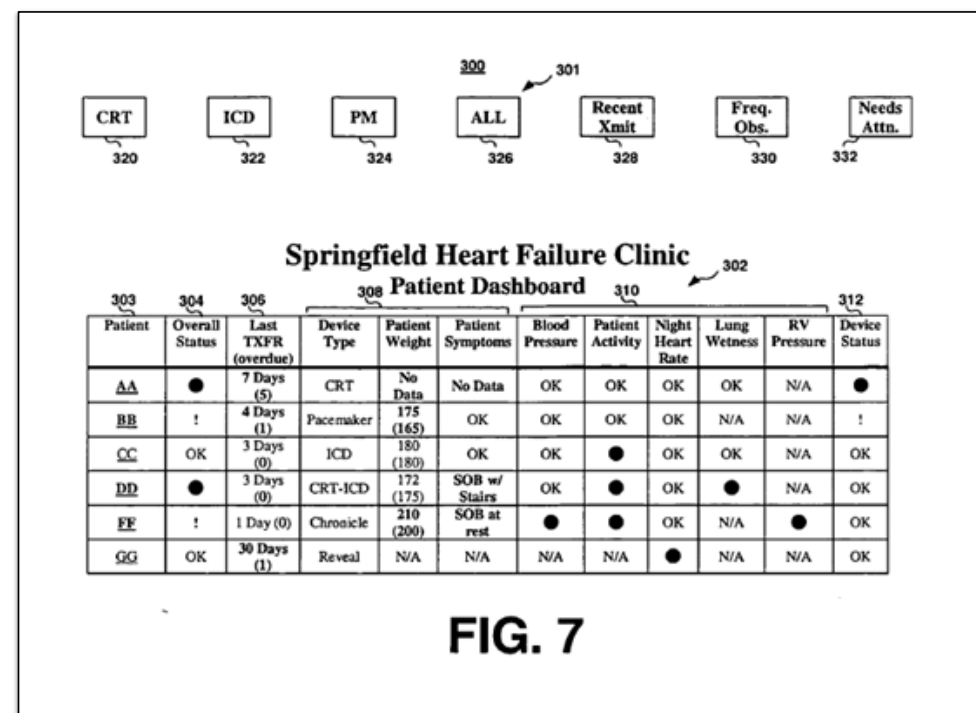
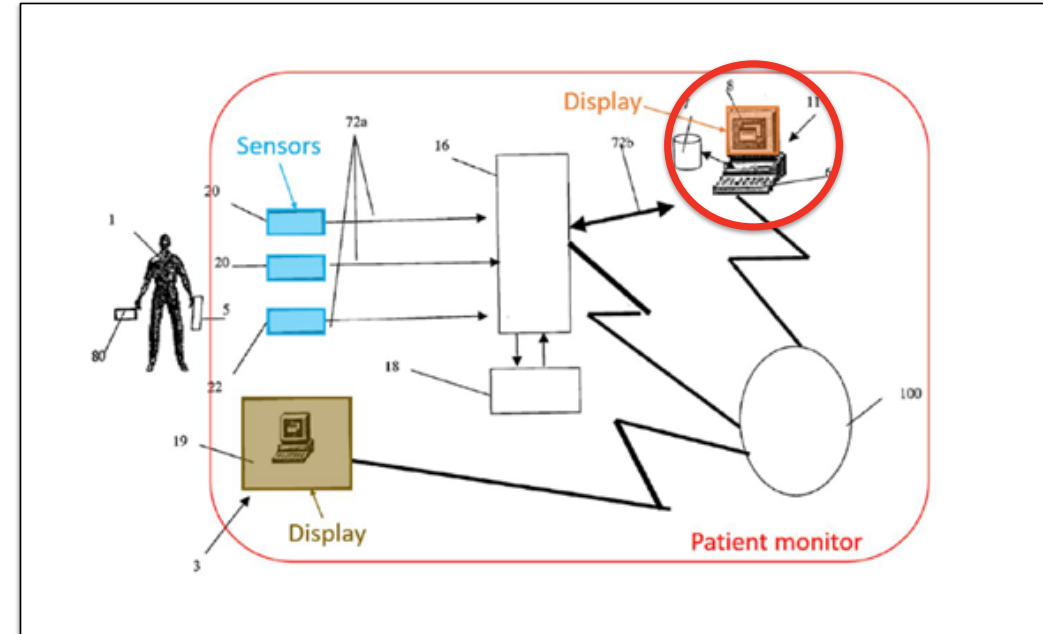


FIG. 7

Naghavi Discloses Displaying All Parameters

Naghavi discloses:

- ⊕ “easy-to-access” system; and
- ⊕ a “user friendly GUI” with “a **single** visual display of displayed items comprising menus, health objects, icons, and options”



Rearranging Parameters Is Not Replacing One Parameter With Another

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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New Replacing Theory Based On Naghavi Does Not Disclose Replacing (Or Changing)

- ⌚ Apple theory raised in Reply: Rearranging icons on a screen (Naghavi) discloses replacement
- ⌚ Argument not in Petition
 - Institution Decision:

“Petitioner, however, relies on Hochstedler for the specific GUI changes that show replacement of one measured value of a parameter for another, ***not Naghavi or Burnes.***” (Inst., 21)

- ⌚ Petition relied on Naghavi ***only*** to argue that the replacement is “based on the occurrence of an event” (Pet., 27)

New Replacing Theory Based On Naghavi Does Not Disclose Replacing (Or Changing)

Rearranging does not meet replacing or changing limitations

- ⌚ Proper construction requires removing one parameter to display another
- ⌚ Examiner rejected argument similar to Apple's during reexam
- ⌚ No expert has opined that Naghavi's reference to rearranging icons discloses replacing measured values

A POSITA Would Not Have Been Motivated To Combine Naghavi, Hochstedler, and Burnes

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

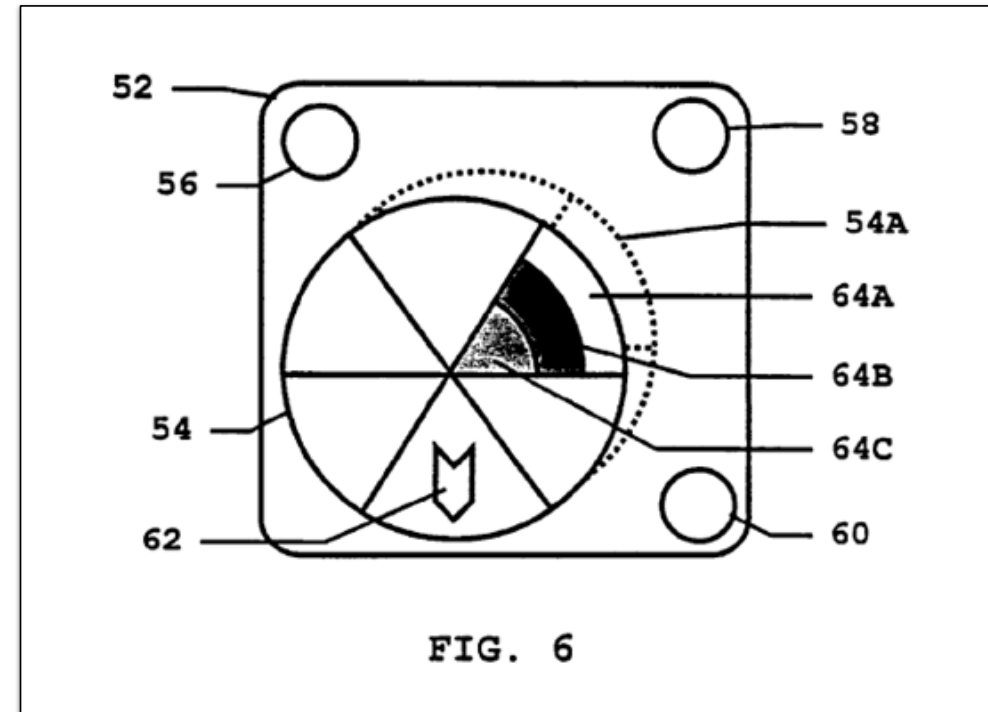
52

Apple's Proposed Motivations To Combine

- ⦿ All of Apple's motivations to combine assume measured but undisplayed parameters
 - ⦿ (1) allows GUI to change with needs of user and stage of medical treatment and display “clinically relevant information”
 - ⦿ (2) prioritizes display of important info over “less relevant” information
 - ⦿ (3) provide a display that best suits the condition of the patient
 - ⦿ (4) relieve the data analysis burden on clinicians
 - ⦿ (5) known technique by known system to yield predictable results
- ⦿ No such teaching in the references

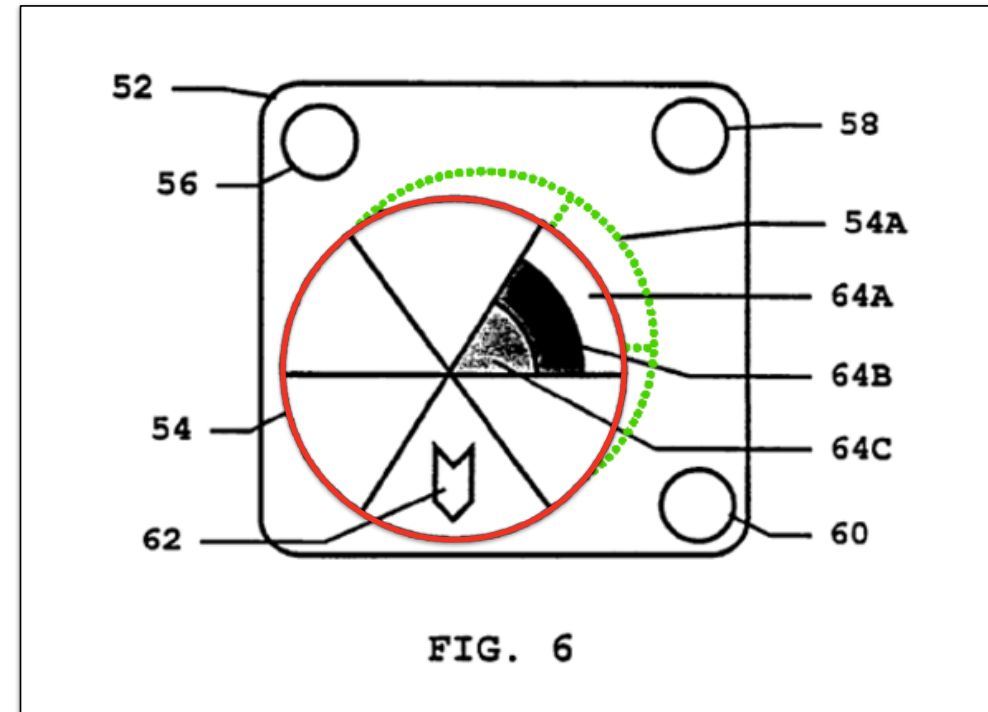
Malmborg

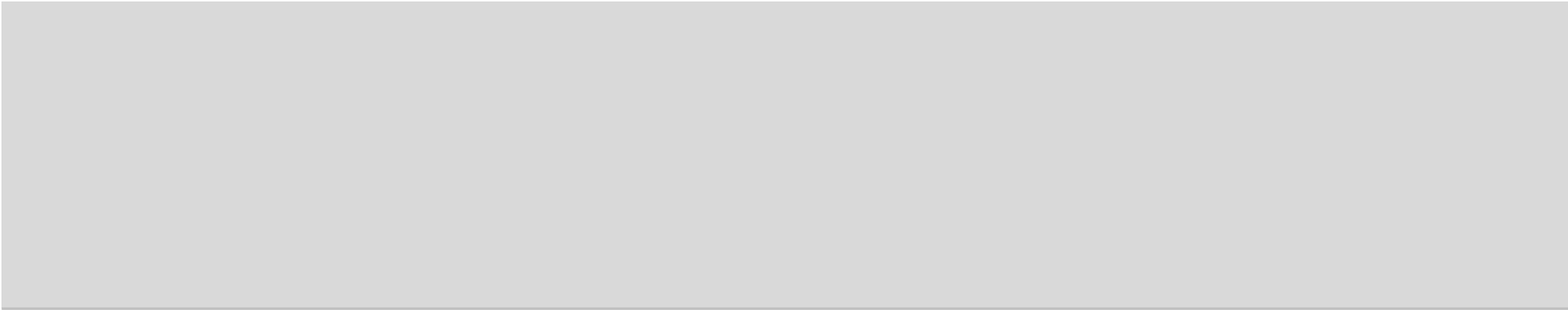
- ⌚ Newly identified in reply
- ⌚ Apple – complete removal of one parameter value from a display, and introduction of a newly displayed parameter value in its place, was well-known (citing Malmborg)
- ⌚ Malmborg is not part of any combination in the IPR



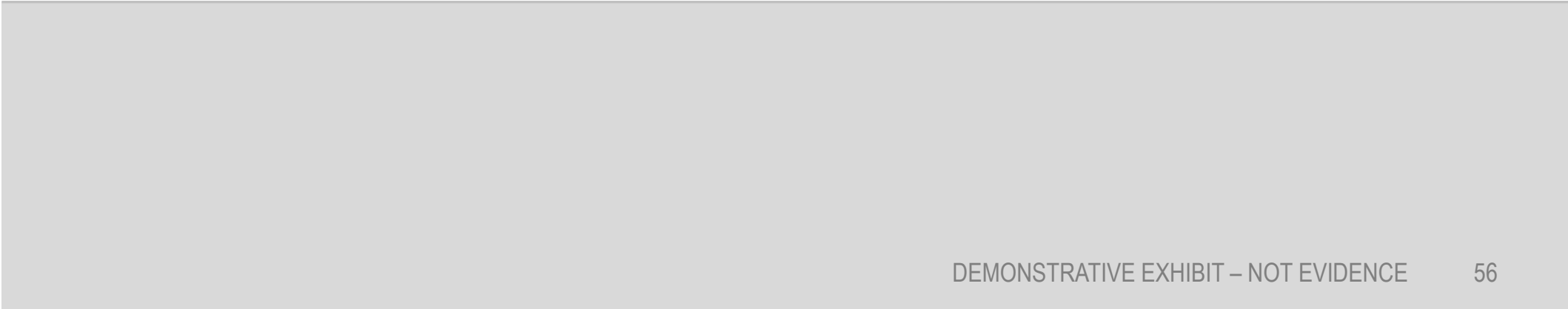
Malmborg

- ⌚ Apple does not explain
 - How Malmborg shows replacing a measured value was “well-known”
 - Why Malmborg matters to the instituted combination
- ⌚ Even if Malmborg is considered, Malmborg does not disclose replacing
 - Discloses windows with colors “superimposed upon one another” where both are visible





Claim 4



DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

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Claim 4

Claim 4:

“the common display area is configured to default to displaying one of the measured values of the first or second physiological parameters.”

Apple argues Hochstedler’s GUI provides an example of a default layout

- ⦿ Claim 4 does not require a default layout
- ⦿ Hochstedler does not describe default layouts
 - Describes default settings and default weights based on algorithm