

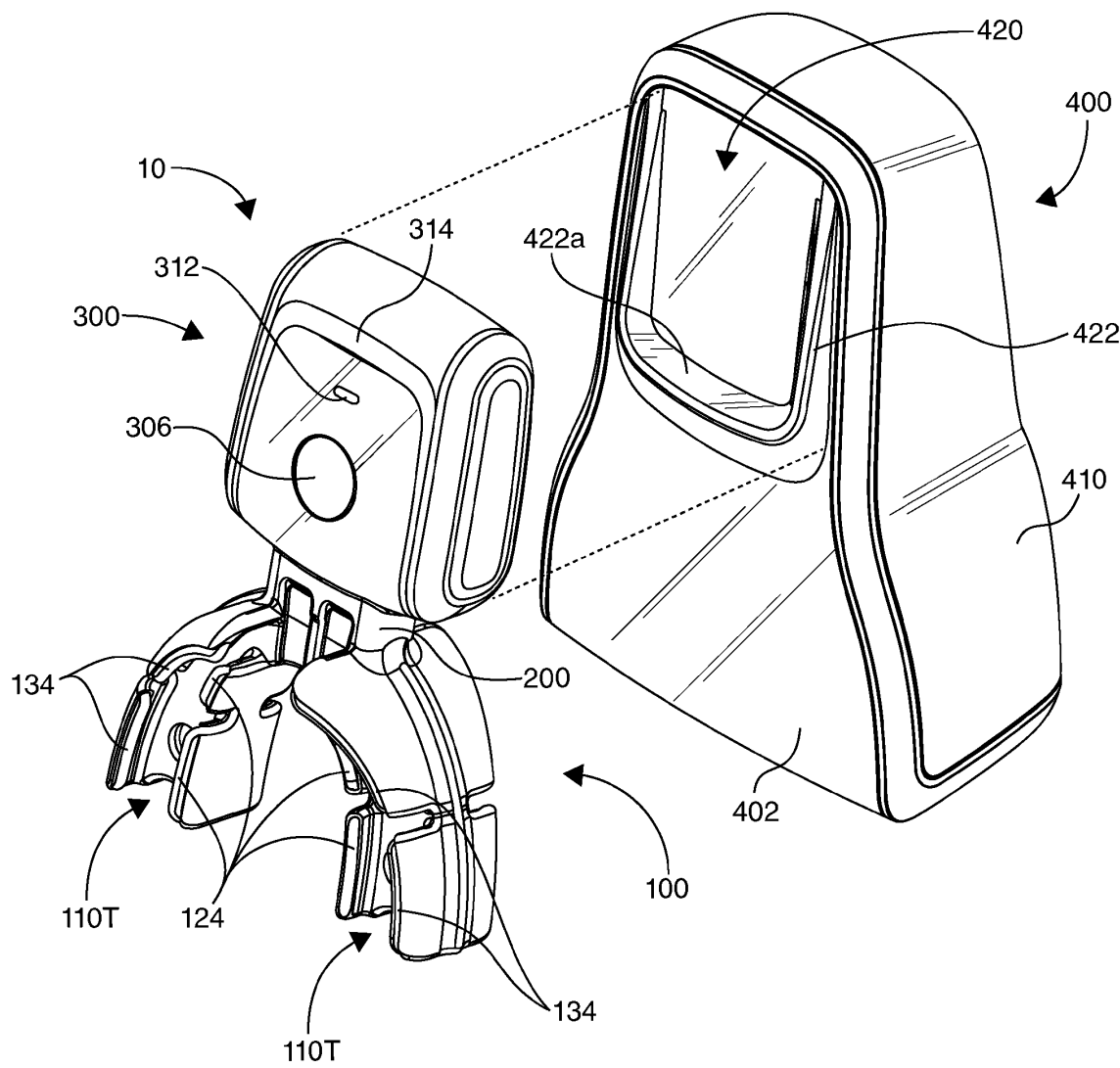


Fig.1

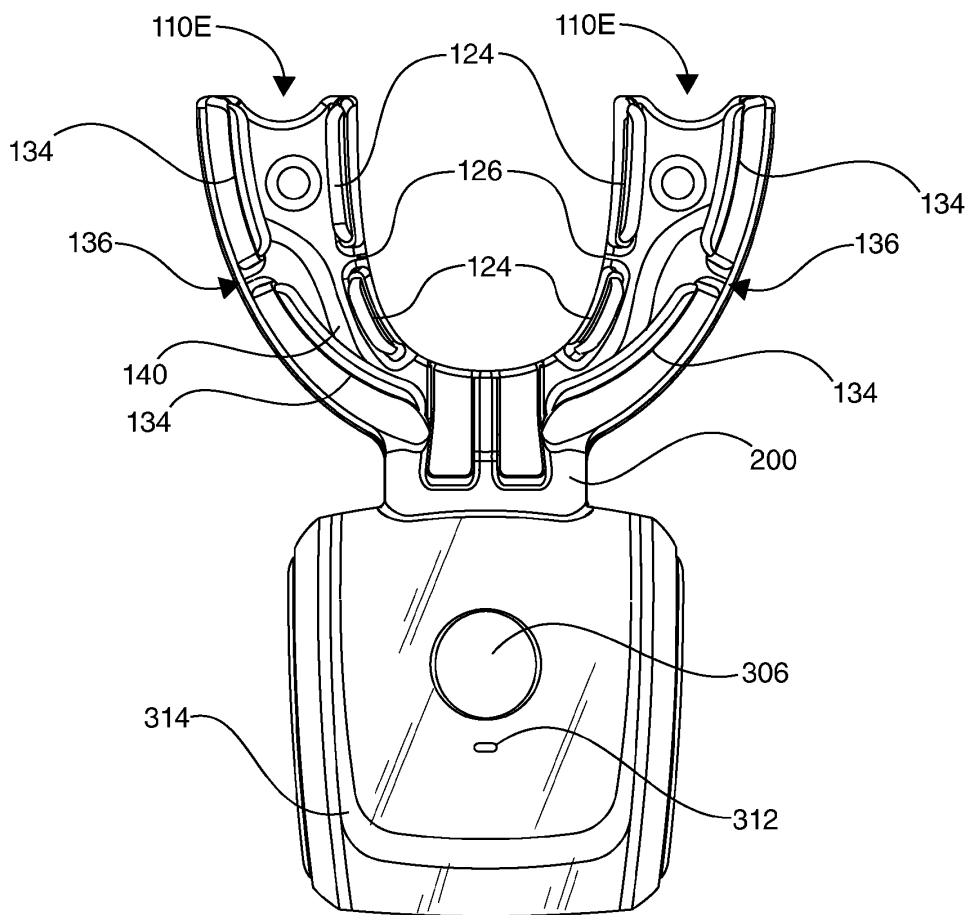


Fig.2

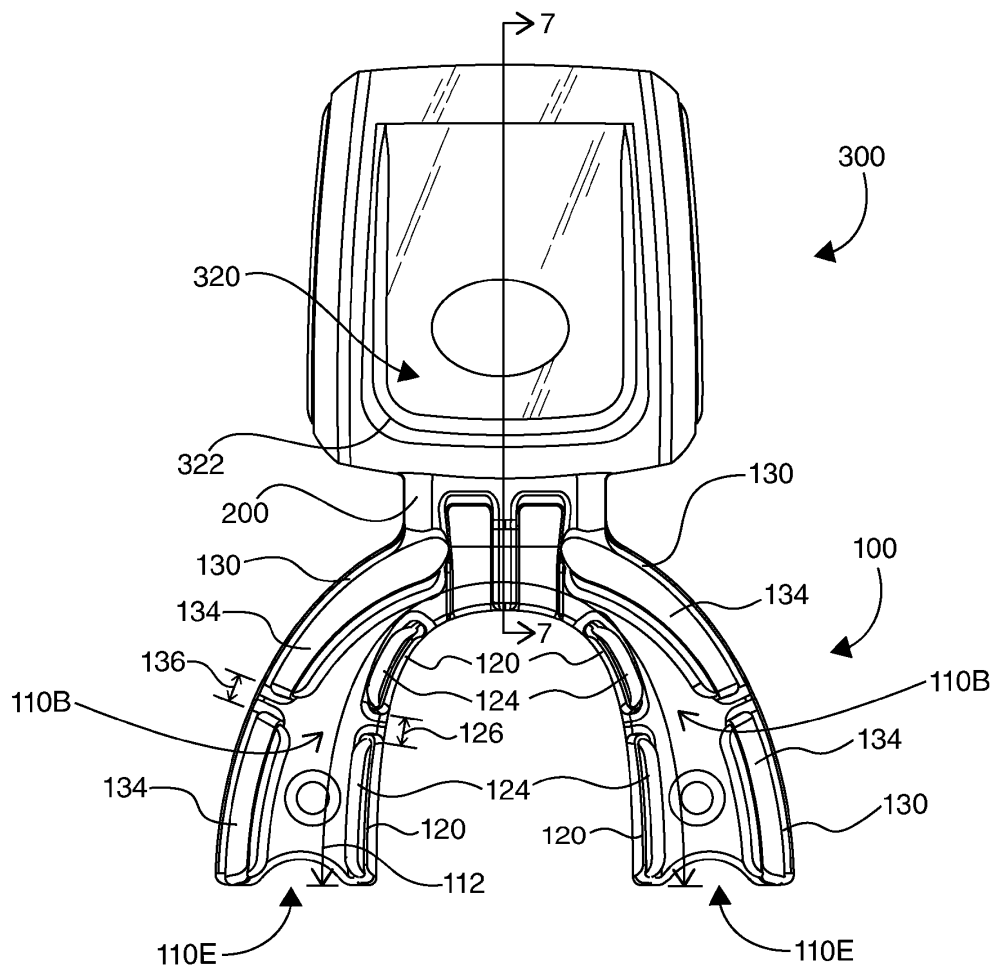


Fig.3

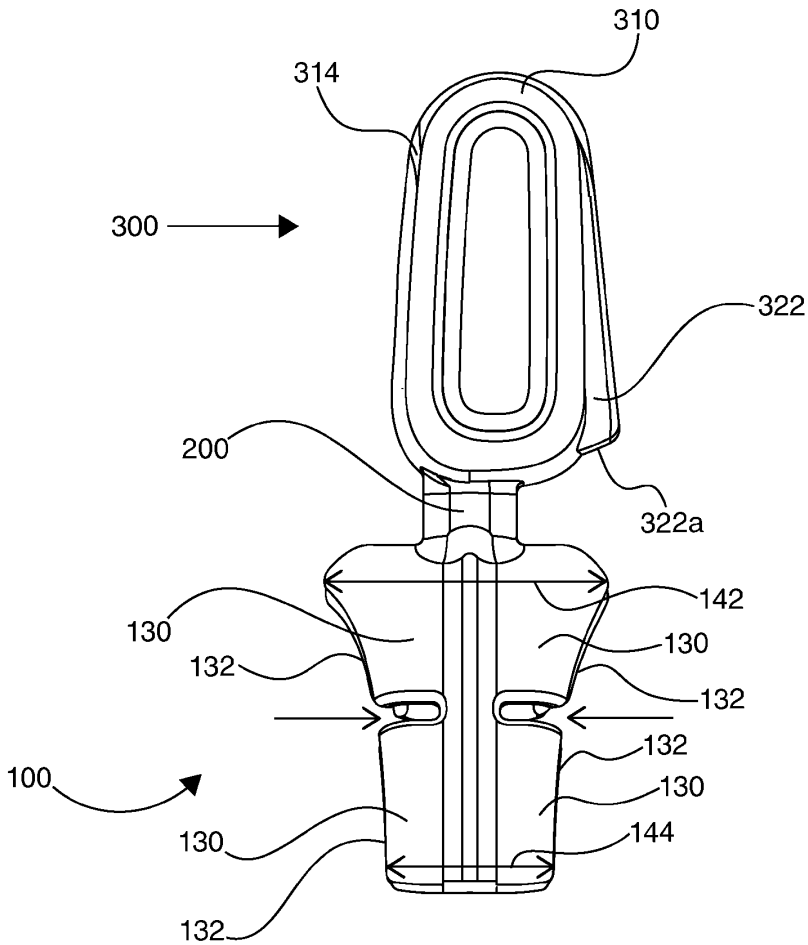


Fig.4

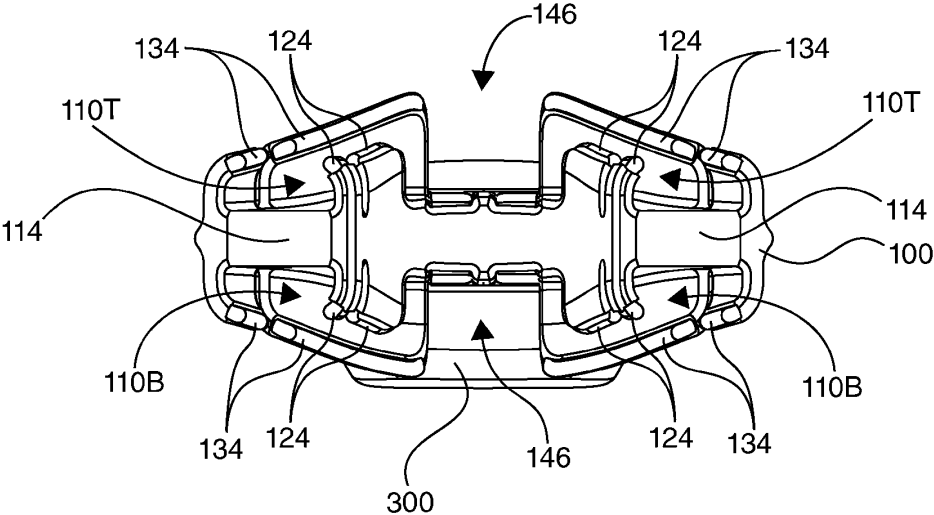


Fig.5

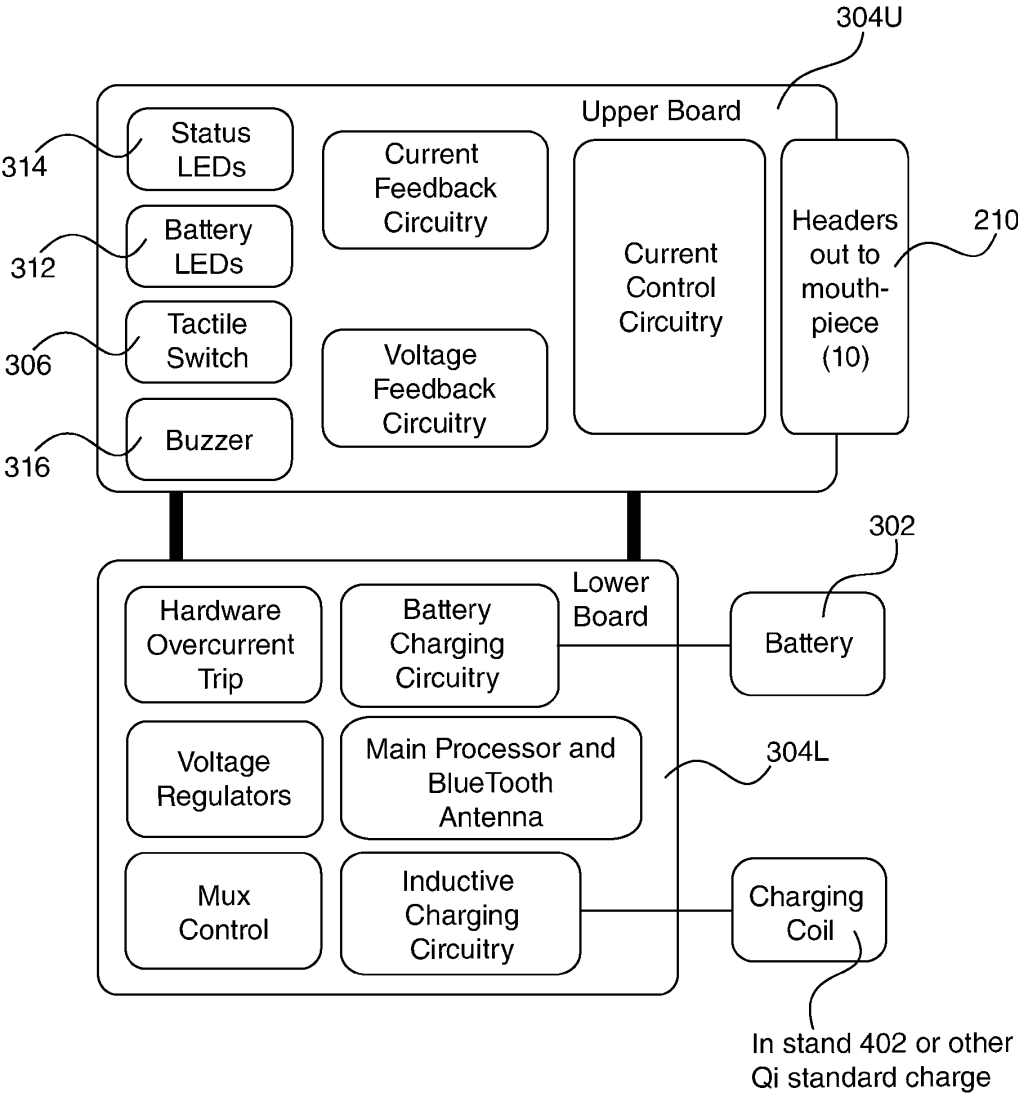


Fig.6

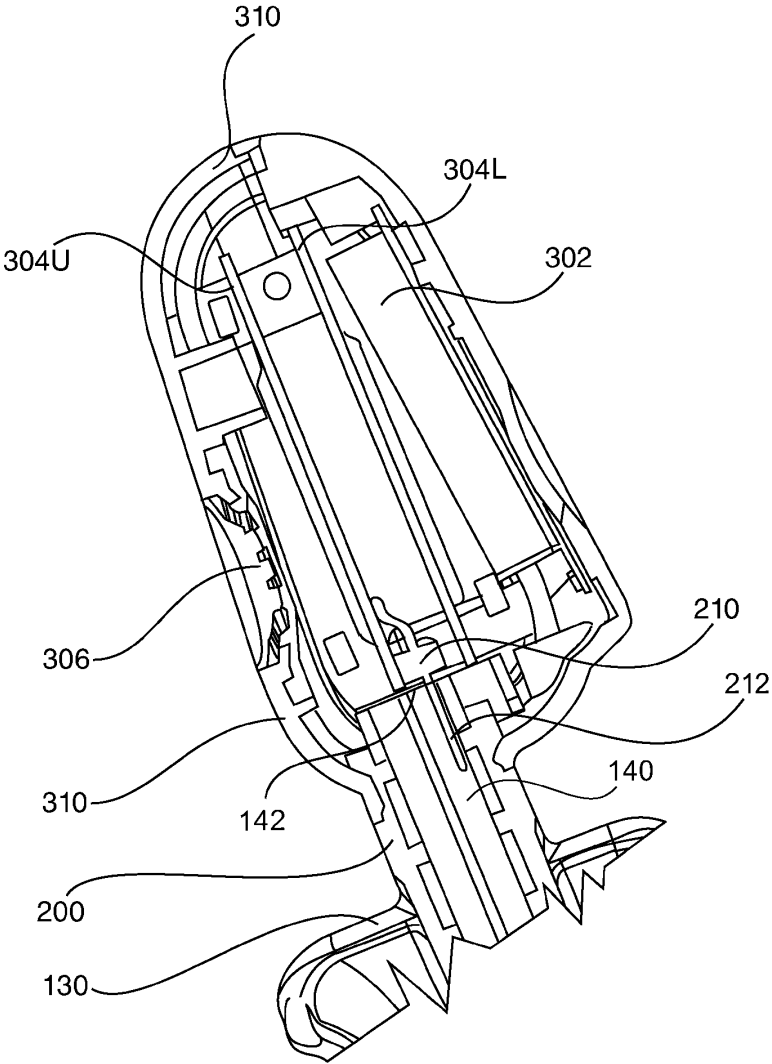


Fig.7

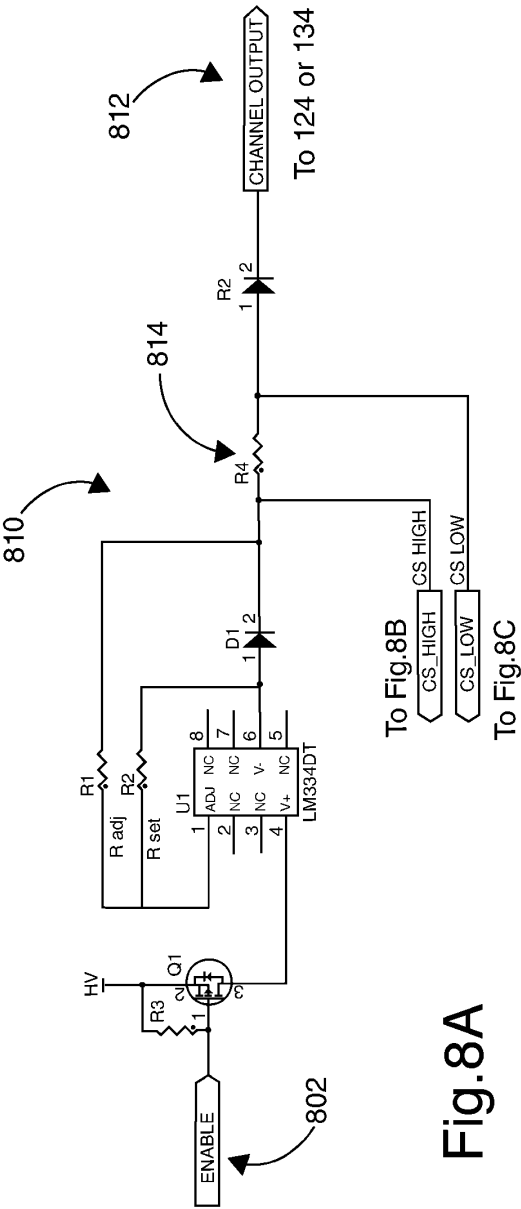


Fig. 8A

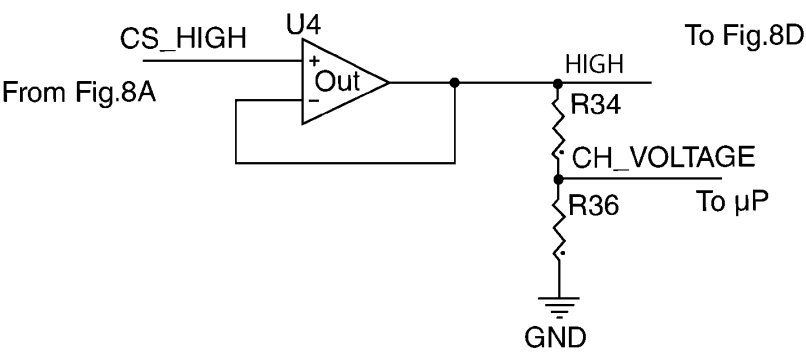


Fig.8B

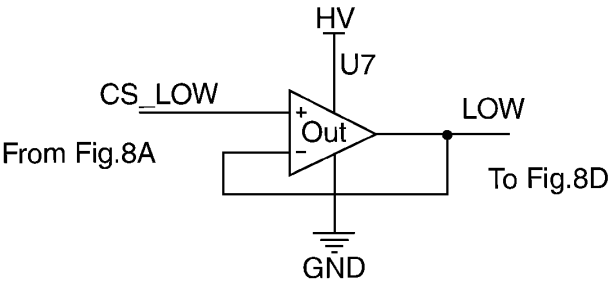


Fig.8C

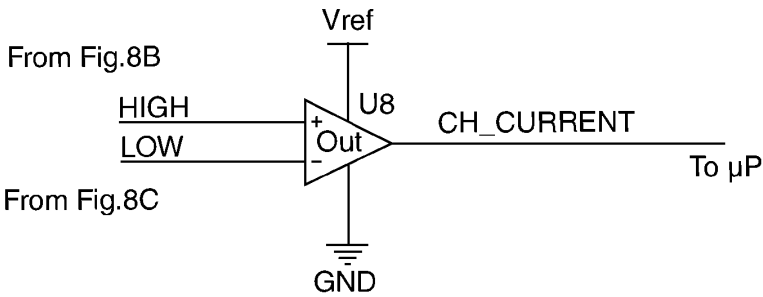


Fig.8D

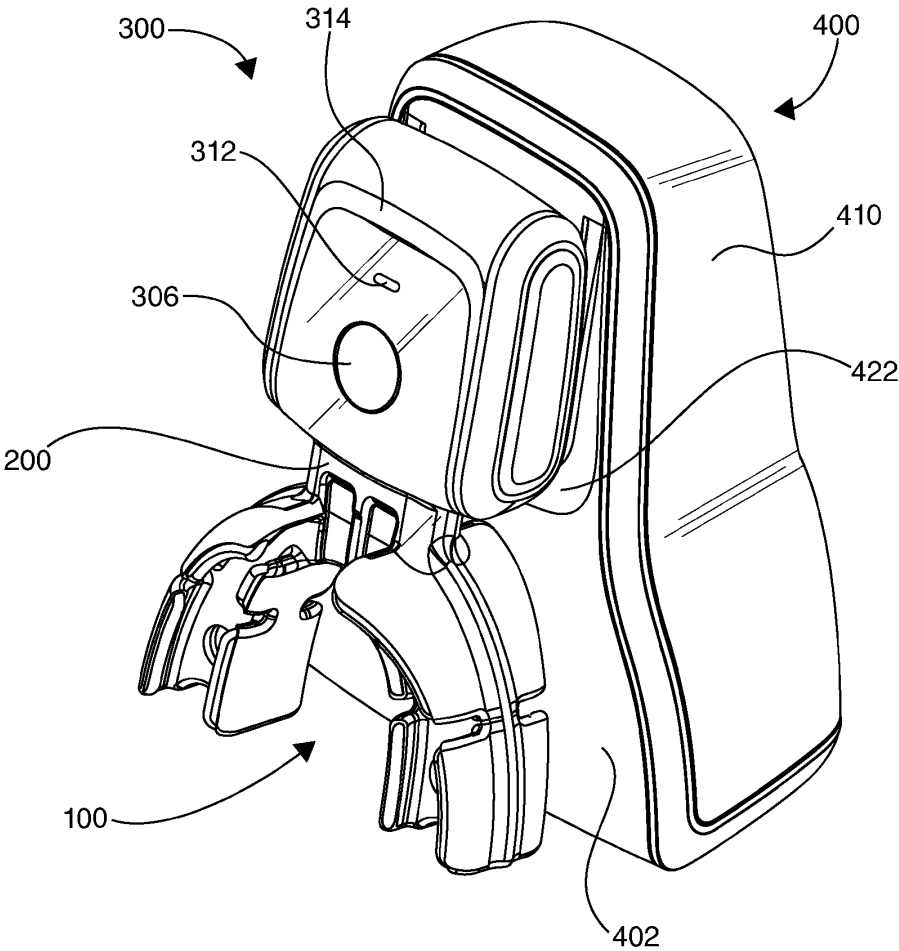


Fig.9

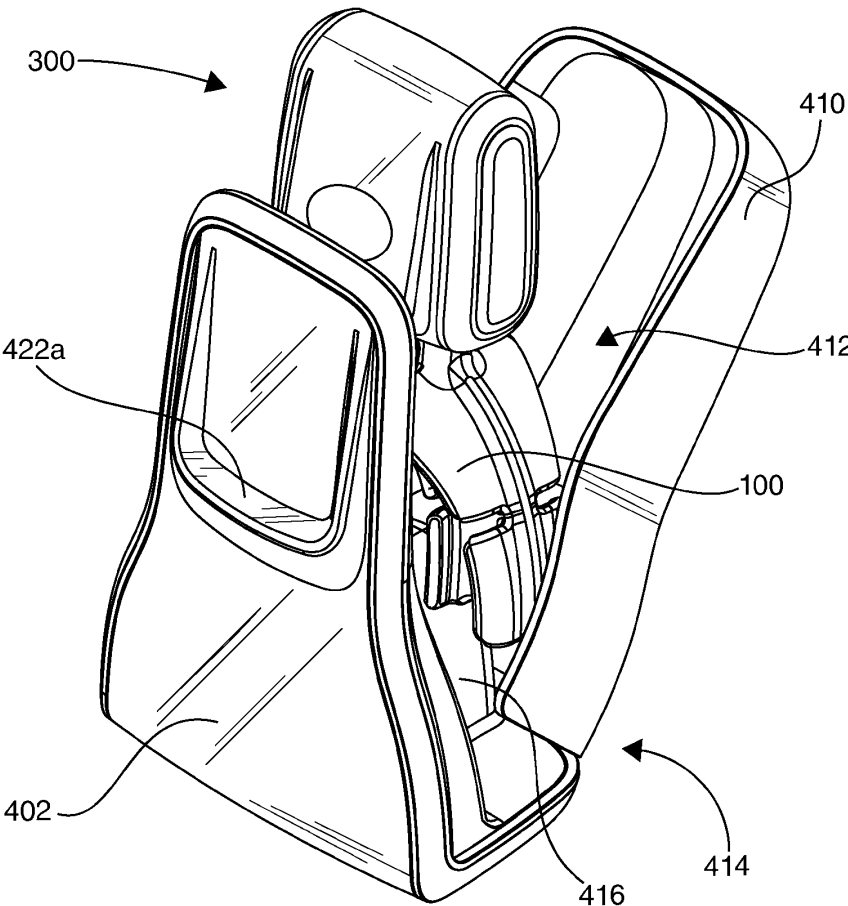


Fig.10

Device State	Treatment Indicator Light	Battery Indicator Light	Audible Feedback	
			Tone/Sequence	Persistence
OFF	Off	Off	3 falling tones	One time on transition
READY	On-White	Off	3 rising tones (From OFF) 1 tone (From all other states)	One time on transition
RUN	On-Blue	Off	2 rising tones	One time on transition
OPEN	Flashing-Blue	Off	5 rise and 5 fall tones (alternating)	Repeats at 10 second intervals for first 30 seconds, then at 30 second intervals.
COMPLETE	Flashing-White	Off	Short melody greater than 2 seconds	One time on transition
LOW BATTERY ¹	Off (From READY) Flashing-White (From COMPLETE)	Flashing-Amber	2 falling tones (From READY) Off (From COMPLETE)	One time on transition / repeat on button press if in READY state
CRITICAL BATTERY	Flashing-Red	Flashing-Amber	4 short tones	One time on transition
CHARGING ²	Off	Flashing-White (charging) On-White for 10 minutes ⁴ (Charging complete)	2 rising tones	One time on transition
FAULT ³	Flashing-Red	Off	4 short tones	One time on transition
BLE Paired (Service App)	No change	No change	No change	

Fig.11

Parameter	Description	Default Value	Min Value	Max Value	Increment	Units
UDI_DEVICE_IDENTIFIER	Unique device identifier - Device Identifier	FTPU	14	14	n/a	Characters (Numeric only)
UDI_MANUFACTURING_DATE	Unique device identifier - Manufacturing Date	FTPU	6	6	n/a	Characters (Numeric only)
UDI_SERIAL_NUMBER	Unique device identifier - Serial Number Identifier	FTPU	6	6	n/a	Characters (Numeric only)
PATIENT_ID	Unique ID number	-	-	100	n/a	Characters (Numeric only)
DENTIST_ID	Unique ID number	-	-	100	n/a	Characters (Numeric only)
HYGIENIST_ID	Unique ID number	-	-	100	n/a	Characters (Numeric only)
TREATMENT_DURATION	Duration of current delivery (SRS 3.05)	1200	1	1800	1	Seconds
INACTIVITY_DURATION_READY	Duration of inactivity before powering off when in READY state (SRS 2.03)	60	1	1200	1	Seconds
INACTIVITY_DURATION_OPEN	Duration of inactivity before powering off when in OPEN state.	300	1	1200	1	Seconds
INACTIVITY_DURATION	Duration of inactivity before powering off in COMPLETE, LOW BATTERY or FAULT states.	180	1	1200	1	Seconds
CHANNEL_1	Individual Channels On=1, Off=0	1	0	1	1	-
CHANNEL_2	Individual Channels On=1, Off=0	1	0	1	1	-
CHANNEL_3	Individual Channels On=1, Off=0	1	0	1	1	-
CHANNEL_4	Individual Channels On=1, Off=0	1	0	1	1	-
CHANNEL_5	Individual Channels On=1, Off=0	1	0	1	1	-
CHANNEL_6	Individual Channels On=1, Off=0	1	0	1	1	-
CHANNEL_7	Individual Channels On=1, Off=0	1	0	1	1	-

Fig.12A

Parameter	Description	Default Value	Min Value	Max Value	Increment	Units
CHANNEL_8	Individual Channels On=1, Off=0	1	0	1	1	-
POWER_MODE	Power mode in OFF state, Low Power Mode=1, Power Off Mode=0	1	0	1	1	-
MIN_CURRENT_PERCENT	Percentage of minimum total current threshold based on the sum of the target current for all currently enabled channels	75	0	100	1	%
MIN_CURRENT_TIME	Duration for which the sum of total current across all channels is below the MIN_CURRENT_PERCENT of target to trigger an efficacy fault	30	1	120	1	Seconds

Fig.12B

Reference	Counter	Description	Increment Condition	Reset Condition	Cleared by User Reset
1	Manual Power On	Number of times the device has been powered on using the push-button.	Transition from OFF to READY states	Firmware Update	Yes
2	Automatic Power On	Number of times the device transitions to READY without a button press	Removed from the charger; transition from CHARGING to READY	Firmware Update	Yes
3	Manual Power Off	Number of times the device has been powered off using the push-button.	Transition to OFF from READY, COMPLETE, RUN, OPEN, LOW BATTERY, or FAULT states by push-button press.	Firmware Update	Yes
4	Automatic Power Off	Number of times the device powered off due to being removed from the charging base or inactivity before or after a treatment	Transition to OFF due to inactivity in the READY, COMPLETE, OPEN, LOW BATTERY, CRITICAL_BATTERY or FAULT states	Firmware Update	Yes
5	Critical Battery Power Off	Number of times the device entered the CRITICAL_BATTERY state.	Transition from any state to CRITICAL BATTERY	Firmware Update	Yes
6	Recharges Initiated	Number of times that the user placed the device onto the charging base	Transition to CHARGING state	Firmware Update	Yes
7	Completed recharges	Number of times charging was completed	Charging chip indicates to micro that charging is complete	Firmware Update	Yes
8	Treatments Started	Number of times the user started a treatment	Transition from READY to RUN states	Firmware Update	Yes
9	Successfully Completed Treatments	Number of times the user completed a treatment	Transition from RUN to COMPLETE states	Firmware Update	Yes
10	Open Circuits	Number of times open circuit conditions occurred	Transition from RUN to OPEN states	Firmware Update	Yes
11	Low Battery	Number of times low battery occurred	Transition to LOW BATTERY states	Firmware Update	Yes
12	Faults	Number of times faults occurred	Transition to FAULT state	Firmware Update	Yes
13	Efficacy Faults	Number of times an efficacy fault occurred	Transition to FAULT state from RUN state due to total current delivered being less than MIN_CURRENT_PERCENT of target	Firmware Update	Yes
14	Overcurrent Faults	Number of times a fault occurred due to overcurrent delivery	Transition to FAULT state from RUN state due to an overcurrent condition	Firmware Update	Yes
15	Total Minutes of Treatment Delivered	Total minutes of treatment delivered	Each minute during RUN state	Firmware Update	Yes
16	Bluetooth Connects	Number of times Bluetooth device has connected to the device	Each time a Bluetooth connection occurs	Firmware Update	Yes

Fig.13A

Reference	Counter	Description	Increment Condition	Reset Condition	Cleared by User Reset
17	Cumulative Charge	Cumulative charge delivered (pAs) for each channel over the device lifetime.	Increment at the end of each treatment to add cumulative charge delivered on each channel.	Firmware Update	No
18	Device Up-time	Cumulative time that the device has been powered on over the device lifetime.	Increment anytime the device microprocessor is powered on, including when the device state is OFF in Low Power Mode.	Persists for device lifetime	No
19	Time Since Power On	Cumulative time that the device has been powered on since the last microprocessor power off.	Increment anytime the device microprocessor is powered on, including when the device state is in Low Power Mode.	Resets on each microprocessor power off into OFF State	No

Fig.13B

Recorded Events	Event Data	Description
Power On	[Automatic, Manual]	Transition from OFF to READY; transition from CHARGING to READY (automatic)
Treatment Started	[Voltage Levels for all channels]	Transition from READY to RUN
Battery Level (Start)	[Battery Voltage Level]	Battery level on transition from READY to RUN
Charge Delivered	[Treatment duration in seconds, Total charge delivered for each channel (coulombs)]	Transition from: RUN to any state other than OPEN; OPEN to any state other than RUN
Open Circuit		Transition from RUN to OPEN
Treatment Resumes		Transition from OPEN to RUN
Treatment Completed	[Voltage Levels for all Channels]	Transition from RUN to COMPLETE; voltage should be recorded just prior to transitioning from RUN state while current is still being delivered
Battery Level (Completed)	[Battery Voltage Level]	Battery level on transition from RUN to COMPLETE
Power Off	[Type: Inactivity, Button Press, Critical Battery]	Transition to OFF
Low Battery	[Battery Voltage Level]	Transition to LOW BATTERY
Critical Battery	[Battery Voltage Level]	Transition to CRITICAL BATTERY
Charging Initiated	[Battery Voltage Level]	Transition to CHARGING
Charging Complete	[Battery Voltage Level]	Charging chip signals to micro that battery charging is complete
Overcurrent Fault	[Current level for all channels, Voltage level for all channels]	Transition to FAULT due to overcurrent condition
Efficacy Fault	[Voltage Levels for all channels, Current level for all channels]	Transition to FAULT state from RUN state due to total current delivered being less than MIN_CURRENT_PERCENT of target
Other Fault	[Fault Code]	Transition to FAULT for reasons other than lack of efficacy, critical battery or overcurrent
Bluetooth Device Connected	[MAC Address of iPad] (if available)	Each time a Bluetooth device connects successfully
Bluetooth Device Disconnected	[MAC Address of iPad] (if available)	Each time a connected Bluetooth device disconnects
Current Date & Time	[Current date and time; precision of at least 1 second]	Upon receipt of the date and time from a Bluetooth device (e.g. Service App)

Fig.14

Operating Function		User Task (s)		Device Response
<i>High level operating functions that involve user interaction with the device</i>		<i>One or more user interactions with a device to achieve a desired result</i>		<i>Device interaction to complete the task (from the user's perspective)</i>
1	Prepare device for use	1.1	Remove device from packaging (first time use), carrying case, or charger	(If removed from charger and device is powered on) Device gives user audible and visual indication that device is ready to start a treatment. The device plays a tone and the treatment indicator light turns on (white)
2	Power on	2.1	(If needed) Press and hold the button to turn on device	Device powers on, gives user audible and visual indication that the device is ready to start a treatment. The device plays a tone and the treatment indicator light turns on (white).
3	Insert mouthpiece into mouth	3.1	Insert the mouthpiece into the mouth	None
4	Perform treatment	4.1	Press the button to start the treatment	Device gives audible and visual indication of starting treatment. The device plays a series of tones and the treatment indicator light changes to blue (on). Device begins delivering current and timing treatment duration.
		4.2	(If needed) Temporarily remove/reinsert the mouthpiece during treatment	Device pauses/resumes treatment and gives audible and visual indication. While paused, the device plays a series of tones (repeating periodically) and the treatment indicator light changes to flashing blue. When treatment resumes, the device plays a series of tones and the treatment indicator light changes to blue (on).
		4.3	Wait for treatment to complete	Device completes current delivery cycle and gives No audible and visual indication

Fig. 15A

Operating Function		User Task (s)		Device Response
				that the treatment is complete. The device plays a series of tones and the treatment indicator light changes to flashing white
5	Remove mouthpiece from mouth	5.1	Remove the mouthpiece from the mouth	None
6	Power off	6.1	(If needed) Press and hold button to turn off or allow device to automatically turn off after short time	Powers off when user presses and holds button, or automatically turns off after short period of time
7	Clean mouthpiece	7.1	Rinse the mouthpiece with water	None
		7.2	optional) If the mouthpiece is not clean, scrub with soft toothbrush and hand soap	None
8	Charge device	8.1	Plug charger into wall outlet	None
		8.2	Place device onto the charger	Device indicates charging status via audible and visual indication. The device plays a series of tones and the battery indicator light flashes white, indicating charging (or turns on white indicating charging complete).
9	Store mouthpiece	9.1	(optional) Place the mouthpiece in the carrying case	None
10	Respond to low battery	10.1	Place device onto the charger when the device indicates low battery (see 8.2)	Device indicates low battery condition and charging status via audible and visual indication. The device battery indicator light flashes amber, indicating a low battery condition. When the device is placed on the charger, the device plays a series of tones and the battery indicator light changes

Fig.15B

Operating Function		User Task (s)		Device Response
				to flashing white, indicating charging.
11	Respond to critical battery	11.1	Place device onto the charger when the device indicates critical battery (see 8.2)	Device indicates critical battery condition and charging status via audible and visual indication. The device plays a series of tones and the treatment indicator light changes to flashing red. The battery indicator light flashes amber, indicating a low battery condition. When the device is placed on the charger, the device plays a series of tones, the treatment indicator light turns off, and the battery indicator light changes to flashing white, indicating charging.
12	Respond to faults	12.1	Contact treating dentist for evaluation or a replacement device.	Device indicates fault condition via audible and visual indication. The device plays a series of tones and the treatment indicator light changes to flashing red.

Fig.15C

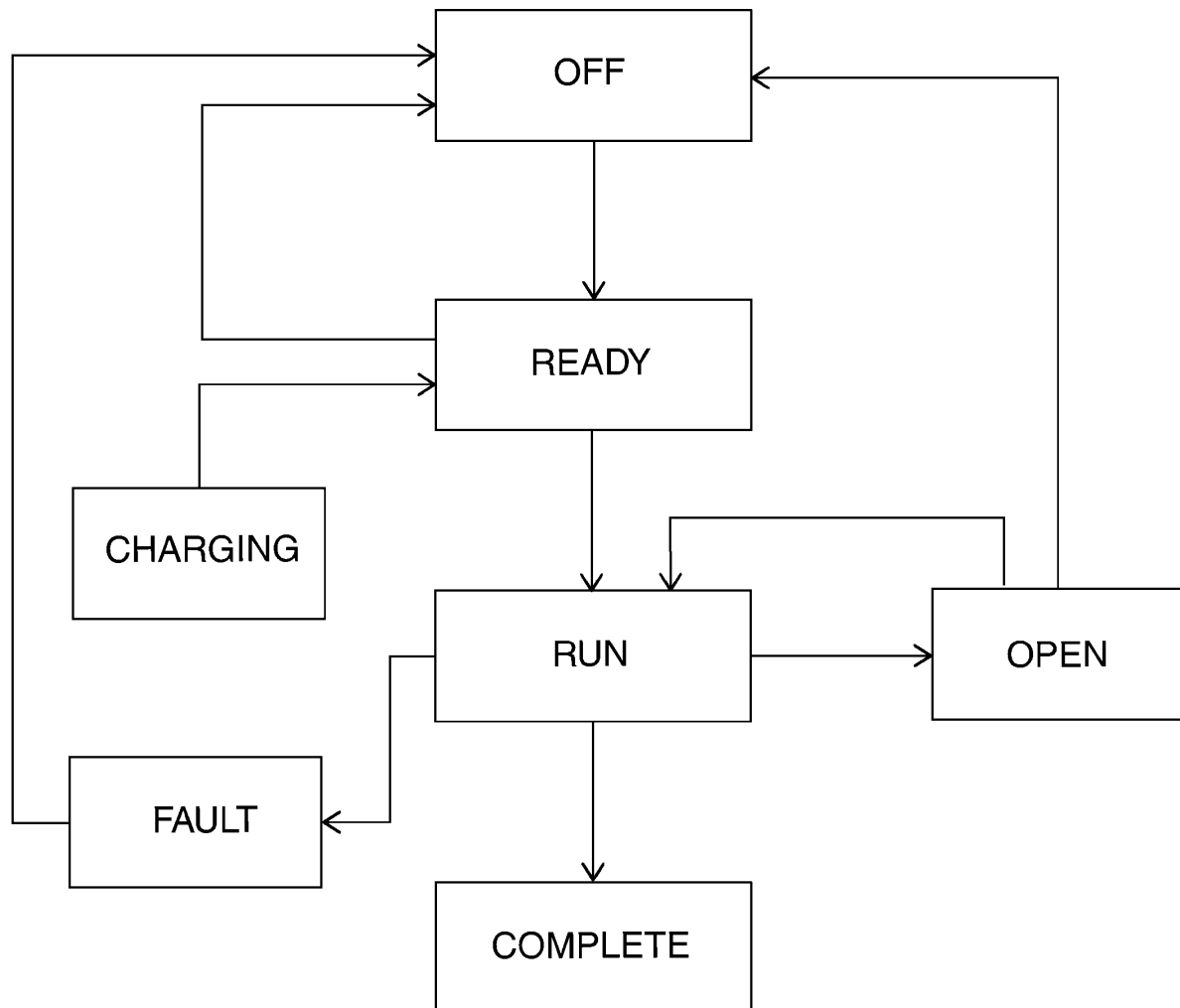


Fig.16

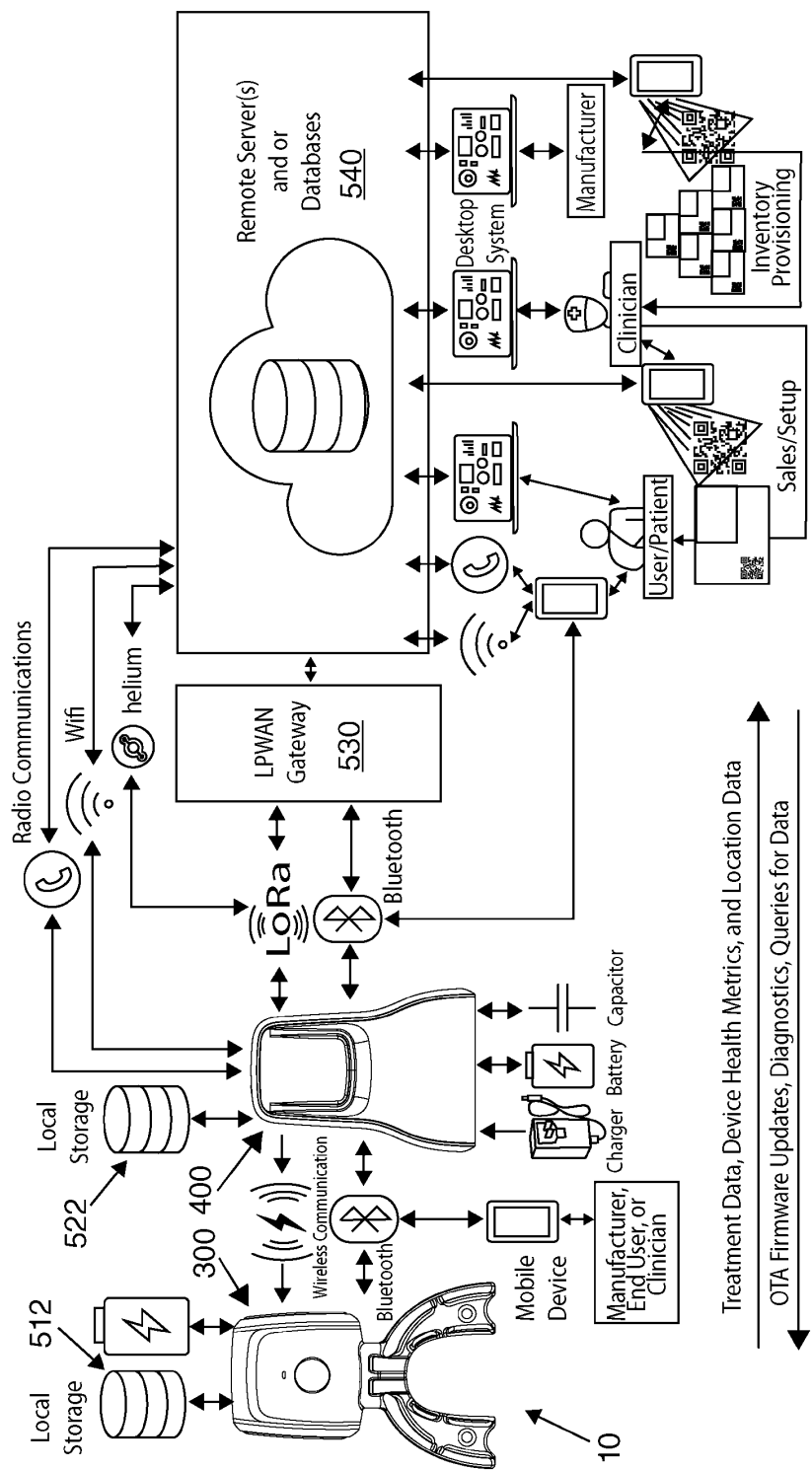


Fig.17A

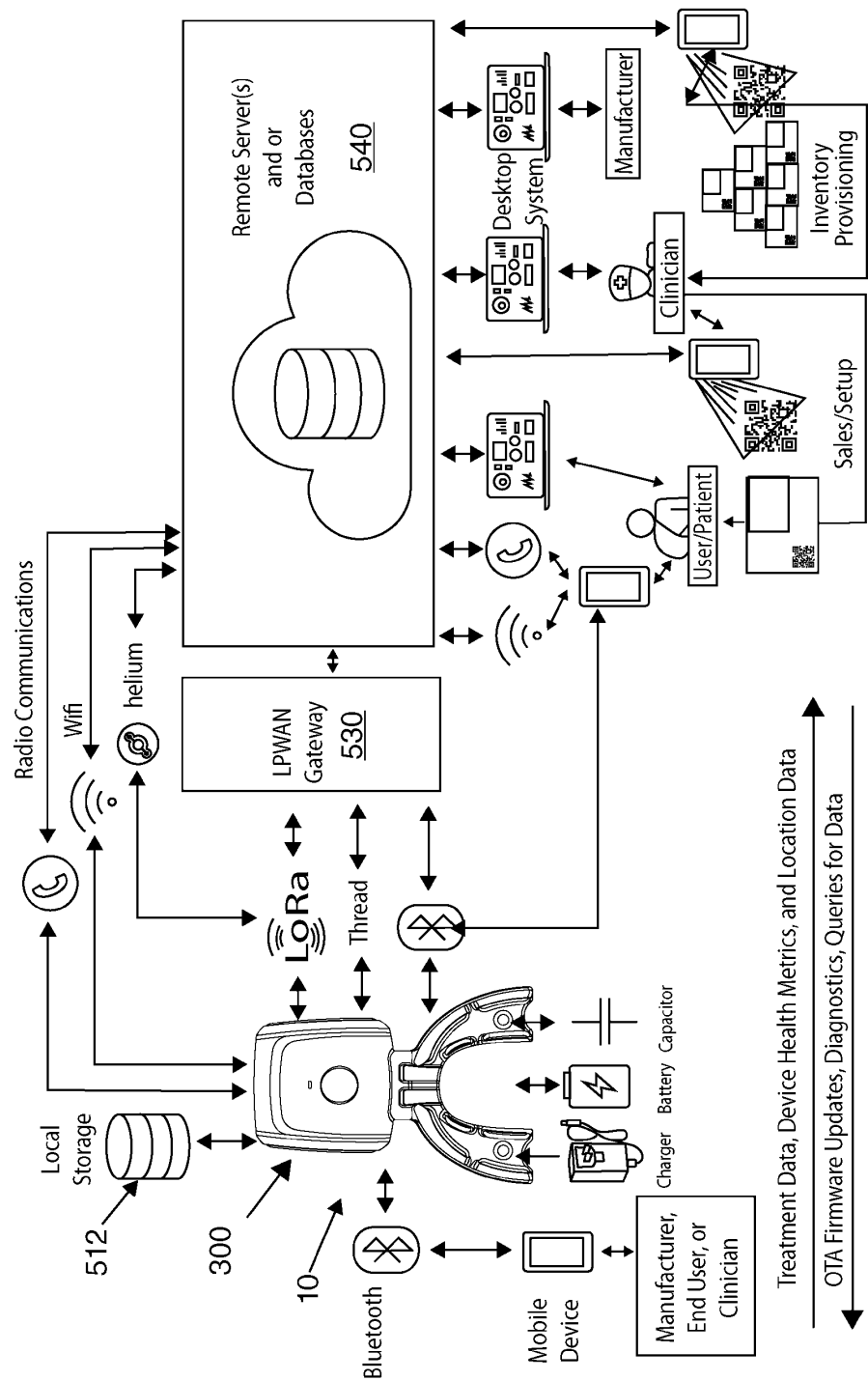


Fig.17B

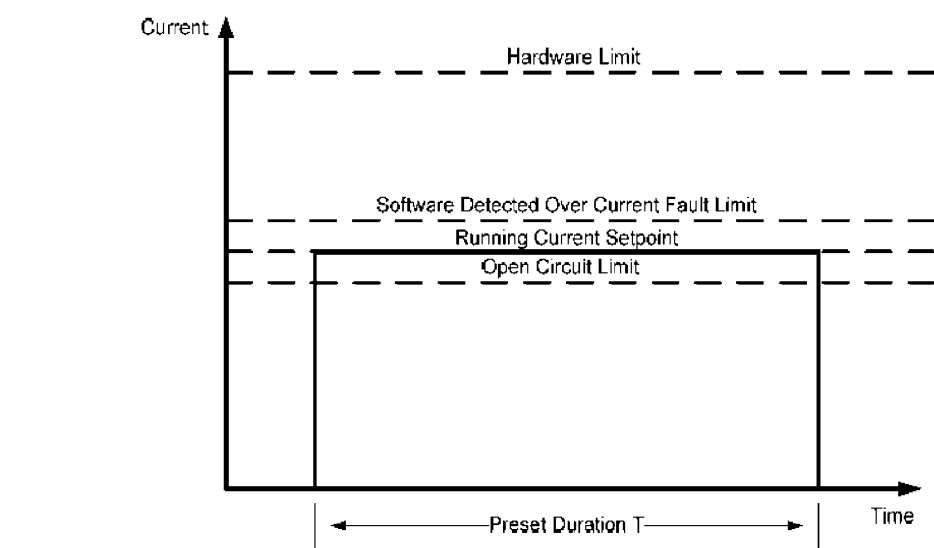


FIG. 18