Attachment 1

stryker

Product specifications for

LIFEPAK® 35 monitor/defibrillator

The following specifications are for a portable, multi-parameter monitor/defibrillator:

1. Operating modes

1.1	AED Mode: For automated ECG analysis and a prompted treatment protocol for patients in cardiac arrest. Patient monitoring also available.
1.2	Manual Mode: For performing manual defibrillation, synchronized cardioversion, noninvasive pacing, and patient monitoring.
1.3	Standby Mode: The monitor/defibrillator is turned off, but still has power supplied and can transmit records and start auto-tests.
1.4	User Test Mode: For performing daily shift checks and monthly tests, manually starting a self-test, and viewing test logs.
1.5	Auto Test Mode: For automatic self-test that the device performs daily when not in use.
1.6	Archive Mode: For accessing stored patient information.
1.7	Setup Mode: For viewing current setup options on the device, updating setup options and software using the LIFENET System, and adjusting the current date and time.
1.8	Service Mode: For authorized personnel to perform diagnostic tests and calibrations.

2. User interface

2.1	Controls

2.1.1.	Critical Therapy controls are grouped together in a logical orientation such as: Power On, Charge, Shock, and Analyze hard buttons; Manual Therapy Selections -Defibrillation, Synchronized Cardioversion, and Pacing Pacing Controls - Rate, Current, and Pause CPR Controls - Timer, Metronome On/Off, cprINSIGHT On/Off
2.1.2.	Critical controls are color coded to enable clear visibility and to help the user distinguish each control for rapid access.
2.1.3.	All critical measurement controls are dedicated to single function soft keys on the touchscreen to provide for fast, unambiguous access. These controls include LEAD, SIZE, NIBP and 12- LEAD.
2.1.4.	Additional operational controls are dedicated to single function soft keys on the touchscreen to provide for fast, unambiguous access. These controls include TRANSMIT, PRINT, EVENTS, DISPLAY MODE, CODE SUMMARY and HOME SCREEN.
2.1.5.	All controls are accessible on the front panel of the device while operating the unit in all typical settings, including patient treatment and transport (i.e., equipped with carrying case).
2.1.6.	All controls operate with a single press except the ON control, which requires the user to push and hold the ON button for a few seconds to turn the device off to prevent turning off the device inadvertently.
2.1.7.	The SYNC control is located separate from the primary defibrillation controls to prevent accidental activation during cardiac arrest.

2.2 Audible prompts

2.2.3.	Volume settings are adjustable for CPR metronome, alarms, QRS beep, voice prompts and tones; some tones can be silenced with one push of a button.

2.3 Patient connection

2.3.1.	Patient connections: All patient connections except Therapy and ECG Connectors are visible and accessible on the front panel of the device while operating the unit in all typical settings, including patient treatment and transport (i.e., equipped with carrying case) or when housed on a closed shelf.
2.3.2.	Therapy cable offers a solid, positive connection to device that is not vulnerable to shock or impact; it is easily inserted or removed with a gloved hand without the need for additional tools for quick replacement during patient use in case it becomes damaged.
2.3.3.	ECG cable offers a solid connection and easy removal without side-to-side tension to preserve integrity of cable.
2.3.4.	CO2 connector accepts sensors for intubated and non-intubated patient applications, without additional adapters, to maximize clinical functionality. CO2 monitoring activates automatically when a sensor is connected.
2.3.5.	SpO2/SpCO/SpMet all use a common connection and include lock out for incompatible sensors. SpO2/SpCO/SpMet monitoring activates automatically when a proper sensor is connected.
2.3.6.	NIBP connector is self-locking and can be easily removed with one hand.
2.3.7.	P1/P2/P3 connector is available from the front of the device.

2.4 Display

2.4.1.	The device active viewing area is 264 mm (10.4 in) diagonal; 158 mm (6.2 in) wide x 210 mm (8.3 in) high.
2.4.2.	The device display is dual-mode color backlit display with a resolution of 768 x 1024 pixels.
2.4.3.	The primary mode is a black background with color waveforms and text data. Waveforms and values are automatically color synchronized to real-time display of patient data to facilitate assessment at a glance (e.g., blue pulse oximetry waveform matched with blue pulse oximetry value; green ECG waveform matched with green heart rate).
2.4.4.	A secondary mode is black parameter and real-time patient data on a white background for clear viewing in bright sunlight. The user may toggle between primary and secondary viewing modes with each mode available in less than one second.
2.4.5.	The device displays a minimum of six seconds of patient ECG and alphanumeric characters for patient parameter values, device instructions and prompts.
2.4.6.	The device provides the option to display one or two additional waveforms.
2.4.7.	The device can be set up for display of up to seven simultaneous waveforms (3 full length and four half length).
2.4.8.	The device includes a HOME SCREEN key which, when depressed, returns the display to normal patient monitoring mode without the need to cycle or backtrack through menus.
2.4.9.	The display displays status of one or two batteries (including installed, active, low, require replacement, remaining capacities), Bluetooth® connections and selected energy.

3. Defibrillator

3.1.	The device uses a biphasic truncated exponential waveform with the following characteristics:	
	3.1.1.	Voltage compensation to address varying patient impedance.
	3.1.2.	Variable duration based on patient impedance.
	3.1.3.	Escalating energy levels up to 360 joules to maximize clinical options and treat the widest range of patients. The full range of energy levels are accessible at any time (except internal defibrillation) in Manual Mode, as limited by pre-determined patient impedance ranges.
3.2	The device has the following energy accuracy:	
	3.2.1.	±1J or 10 percent of setting, whichever is greater, into 50 ohms.
	3.2.2.	±2 joules or 15 percent of setting, whichever is greater, into 25-175 ohms.

3. Defibrillator

3.3.	The device offers the following paddle options:
	3.3.1. Hands-free pacing/defibrillation/ECG electrodes.
3.4.	The therapy cable has a length of 2.4 meters (8 feet), not including electrode assembly.
3.5.	The charge time to 360 joules does not typically exceed 10 seconds.
3.6.	The device can monitor the patient ECG for a potentially shockable rhythm and alert the operator, even while in manual defibrillation/monitoring mode.

4. External defibrillation (AED)

4.1.	The device is capable of being set up to power on in the AED mode.
4.2.	The device can be set up to automatically and continuously monitor the patient ECG for a potentially shockable rhythm.
4.3.	Pediatric setting for AED mode – Pediatric Energy setting provided for AED mode with configurable defaults.
4.4.	The device allows the operator to configure the output energy delivery sequence to be used during advisory mode as 200/200/360 or 200/300/360 joules.
4.5.	During AED mode, when a shockable ECG rhythm is detected, the device can be ready to deliver a shock within 28 seconds with a fully charged battery installed.
4.6.	The device is capable of adjusting the AED protocol by providing the ability to adjust settings for energy protocol, auto analyze timing, motion detection, cprINSIGHT, pulse check, CPR time, initial CPR, pre-shock CPR, metronome parameters and stacked shocks to meet AHA, IEC and local protocols.
4.7.	AED mode is allowed only with a hands-free electrode system.
4.8.	The device allows switching from AED mode to manual mode with or without a password or not allowed based on local protocol.
4.9.	The device allows switching from AED mode to pacing.

5. Manual defibrillation mode

5.1.	The device operates in manual mode using adult and pediatric hands-free pacing/defibrillation/ ECG electrodes and internal paddles.
5.2.	The device can be set up to operate in manual mode when it is turned on.
5.3.	While in manual mode, the device allows the operator to select the following energy settings; 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325 and 360 joules or a user configurable sequence. 100 - 325 joules, inclusive, in 25 joule steps, and to 360 joules for all 3 shock levels.
5.4.	The device allows the operator to select energy, charge and shock from front panel controls
5.5	cprINSIGHT in both Manual and AED mode – allows for analysis of ECG rhythm during CPR.

6. Synchronized cardioversion

6.1.	The device allows for a shock to be automatically delivered that is synchronized to a patient's ECG.
6.2.	An indicator is shown on the ECG QRS where the shock will be delivered.
6.3.	The device allows adjustment of the shock delivery point by the use of an ECG size control.
6.4.	During synchronous cardioversion, the device begins energy transfer within 60 milliseconds of the QRS peak.

7. Pacer

7.1.	The device operates in demand and non-demand modes.
7.2.	The device allows the user to program a preferred/default starting mode.
7.3.	The device allows the operator to set the default rate and current values.

7. Pacer

7.4.	The device generates pacing pulses at a rate of 40 to 170 pulses per minute.
7.5.	The accuracy of the pacing output rate is within +/- 1.5 percent over the entire range.
7.6.	The device generates a monophasic, truncated exponential current pulse (20 +/- 1 ms).
7.7.	The device allows the operator to select the pacing output current from 0 to 200 mA.
7.8.	The device incorporates a pacing pause function which allows the operator to reduce the pacing rate by a factor of four, to allow assessment of the patient's underlying ECG rhythm.
7.9.	The pacing circuit includes automatic adjustment of the refractory period (function of rate) from 180 to 270 msec, +/- 3 percent, to ensure the delivered rate is consistent with the operator selected rate.

8. ECG monitor

8.1.	The device monitors patient ECG via the following means:	
	8.1.1.	Three (3) wire cables for 3-lead ECG monitoring.
	8.1.2.	Five (5) wire cables for 7-lead ECG monitoring.
	8.1.3.	Ten (10) wire cables for 12-lead ECG acquisition. The cable should be multi-segmented (main trunk, 4-wire section, 6-wire section) to facilitate multiple functionality and minimize replacement costs.
	8.1.4.	When the six chest electrodes are removed, the 10-wire cable functions as a 4-wire cable.
	8.1.5.	QUIK-COMBO® pacing/defibrillation/ECG electrodes for paddles monitoring.
8.2.	Lead selection; the device shall provide the following monitoring options:	
	8.2.	Lead selection; the device shall provide the following monitoring options:
	8.2.1.	Leads I, II, Ill with the 3-wire cable.
	8.2.2.	Leads I, II, Ill, AVR, AVL and AVF with the 4-wire cable (simultaneous acquisition).
	8.2.3.	Leads I, II, Ill, AVR, AVL, AVF and C with the 5-wire cable (simultaneous acquisition).
	8.2.4.	Leads I, II, Ill, AVR, AVL, AVF, VI, V2, V3, V4, V5 and V6 with the 10-wire cable (simultaneous acquisition). Leads A1, A2, and A3 with the 13-wire.
8.3.	The monitor allows the operator to adjust the ECG size using the following settings: 40, 30, 25, 20, 15, 10, 5, 2.5 mm/mV; (fixed at 10 mm/mV for 12-lead).	
8.4.	The monitor incorporates a continuous patient surveillance system, which, as a VF/VT alarm in manual mode, will monitor the patient via paddles lead or lead II for potentially shockable ECG rhythms and alert the operator to CHECK PATIENT if a shockable ECG rhythm is detected.	
8.6.	The device provides common mode rejection of at least 90 decibels at 50/60 hertz.	
8.7.	The device offers the following frequency response settings:	
	8.7.1	Monitoring electrodes: 0.5 to 40 hertz or 1.0 to 30 hertz (monitoring frequency response); 0.05 to 40 hertz or 0.05 to 150 hertz (diagnostic frequency response).
	8.7.2.	Paddles: 2.5 to 30 hertz.

9. 12-lead and 15-lead ECG algorithm

9.1.	The device incorporates University of Glasgow ECG Analysis Program, v30.4
9.2.	The analysis program includes interpretative statements to describe the 12-lead ECG, including statements such as, "Meets ST Elevation MI Criteria."
9.3.	The 12-lead ECG provides information related to leads disconnected and noisy ECG
9.4..	The report is displayed on screen for LP35 or can be printed.
9.5.	The device provides the option of printing the 12-lead ECG report at 25 millimeters per second or 50 millimeters per second.
9.6.	The 12-lead ECG report shall offer a 3-channel
9.7.	The device offers the option of printing automatically on the acquisition of a 12-lead.

9. 12-lead and 15-lead ECG algorithm

9.8.	The device includes trending of ST measurement after an initial 12-lead analysis and automatically generates a 12-lead ECG to alert the operator if any change in ST elevation or depression is detected.
9.9.	The 12-lead ECG is derived from ten (10) physical ECG leads rather than extrapolated from only five (5) leads to ensure clinical accuracy consistent with the established monitoring standard.
9.10.	The 12-lead ECG algorithm distinguishes between adult and pediatric patients using different algorithms established by user-input age.
9.11.	The 12-lead ECG algorithm distinguishes between male and female patients using different algorithms established by user-input gender.
9.12.	15 Lead ECG Analysis (measurements only; no new interpretive statements) – 12/15 Lead can be viewed on the device display; Measurements provided for up to 15 Leads

10. Pulse oximetry (SPO2), carbon monoxide (SpCO) and methemoglobin (SpMet) monitoring

10.1.	The device incorporates SPO2, SpCO and SpMet monitoring using Masimo® Rainbow® technology and compatible sensors.	
10.2.	Pulse oximetry (SPO2)	
	10.2.1.	The device measures, displays and stores SPO2 values in the range of 50 to 100 percent.
	10.2.2.	The device updates the SPO2 displayed value (on average) every 4, 8, 12 or 16 seconds.
	10.2.3.	The saturation accuracy of the SPO2 circuit shall be 70 to 100 percent.
	10.2.4.	The device display saturation rates from the SPO2 circuit to within ±2 digits without motion and ±3 with motion.
	10.2.5	Historical trended values can be displayed on screen or printed from CODE-STAT.
	10.2.6.	The device displays pulse rates from 25 to 239 pulses per minute.
	10.2.7.	The device displays pulse rates from the SPO2 circuit to within ±3 pulses per minute without motion and ±5 pulses per minute with motion.
	10.2.8.	The device has user-adjustable sensitivity and averaging time settings to compensate for low perfusion states and patient movement, respectively.
	10.2.9.	The device emits a pulse tone proportional to the displayed SPO2 value.
	10.2.10.	The device can be set up to turn SPO2 tone to off.
	10.2.11.	The device is capable of displaying an IR (pleth) waveform.
10.3.	Carbon monoxide (SpCO)	
	10.3.1.	The device measures, displays and stores SpCO values in the range of 0 to 40 percent.
	10.3.2	The device displays SpCO values to within ±3 digits accuracy.
	10.3.3.	Historical trended values shall be displayed on screen or printed from CODE-STAT .
10.4.	Methemoglobin (SpMet)	
	10.4.1.	The device measures, displays and stores SpMet in the range of 0 to 15 percent.
	10.4.2.	The display resolution is 0.1 percent for SpMet value from 0 to 10 percent and 1 percent for values from 10 to 15 percent.
	10.4.3.	The device displays SpMet circuit to within ±1% accuracy.
	10.4.4.	Historical trended values can be displayed on screen or on printed trending report.

11. Noninvasive blood pressure (NIBP)

11.1.1.	The device is capable of displaying blood pressure values in mmHg.
11.1.2.	The device measures systolic pressure in range: 30 to 255 mmHg.
11.1.3.	The device measures diastolic pressure in range: 15 to 220 mmHg.
11.1.4.	The device measures mean arterial pressure (MAP) in range: 20 to 235 mmHg.
11.1.5.	The device measures BP with accuracy of 3 mmHg or 2 % of the reading, whichever is greater.
11.1.6.	The device typically performs a blood pressure measurement in 20 seconds typical for adult STAT mode or 25 s typical (excluding inflation time) for adult Manual/Automatic mode.
11.1.7.	The device measures pulse rate in range: 30 to 240 pulses per minute.
11.1.8.	The device measures pulse rate with accuracy ±2 pulses per minute or ±2 percent, whichever is greater.
11.1.9.	The device offers a choice of initial cuff inflation pressures.
11.1.10.	The device can be set to perform automatic recurring measurements at the following set intervals: 2, 3, 5, 10, 15, 30 and 60 minutes.
11.1.12.	The device allows automatic cuff deflation in case of excessive pressure (greater than 290 Hg) or in case measurement time exceeds 120 seconds. For Neonate, it is 145 mmHg or 90 seconds.
11.1.13.	A range of disposable and reusable NIBP cuffs are available.
11.1.14.	NIBP cuffs are single bladder to facilitate placement independent of patient artery for rapid setup.
11.1.15.	Historical trended values shall be displayed on screen or printed from CODE-STAT.

12. Capnography (EtCO2 monitoring)

12.1.	The device incorporates capnography, using Medtronic® Microstream® technology.
12.2.	Capnography monitoring activates automatically upon connecting FilterLine® or Smart CapnoLine®.
12.3.	The device allows monitoring of intubated and non-intubated patients without the need for additional equipment, adapters or setup.
12.4.	The device does not have any CO2 sensors external to the device due to external sensor vulnerability to damage and high replacement cost.
12.5.	The device is capable of displaying CO2 value in kPa, volume percent or mmHg.
12.6.	The device does not use any separate water traps or filters; these should be integrated into the sensor to facilitate ease of use and setup.
12.7.	The device is specific to CO2 and not adversely affected by the presence of non-CO2 gases.
12.8.	The device uses disposable CO2 intubated and non-intubated sensors to eliminate risk of cross contamination between patients.
12.9.	The capnography option is compatible with Oridion FilterLine and Smart CapnoLine CO2 accessories and Medtronic Microstream™ Advance filter lines.
12.10.	The device measures CO2 pressure in range 0 to 99 mmHg (0 to13.2kPa). The device shall display CO2 waveform.
12.11.	The device measures CO2 with the following accuracy:
12.11.1.	0-80 breaths per minute: 0 to 38 mmHg ±2 mmHg, 39 to 99 mmHg ±5 percent of reading plus 0.08 for every 1 mmHg above 38 mmHg
12.11.2.	> 80 breaths per minute: 0 to 18 mmHg ±2 mmHg, 19 to 99 mmHg ± 4 mmHg or ± 12 percent of reading (whichever is higher)
12.12.	The device measures respiration rate in a range of 0 to 149 breaths per minute.
12.13.	The device measures respiration rate with the following accuracy:
12.13.1.	0 to 70 breaths per minute : ±1 breaths per minute
12.13.2.	71 to 120 breaths per minute: ±2 breaths per minute; 121 to 149: ±3 breaths/minute
12.14.	The time from first display of the device screen to when accurate EtCO2 measurements can be made of < 30 seconds, 18 s typical.

12. Capnography (EtCO2 monitoring)

12.15.	The rise time of the CO2 waveform is less than or equal to 190 milliseconds for 2 m FilterLine and less than or equal to 210 milliseconds for 4 m FilterLine.
12.16.	The response time of CO2 waveform, including the delay time and rise time:
12.16.1.	Less than or equal to 5.5 seconds with 200 cm tubing (includes delay time and rise time)
12.16.2.	Less than or equal to 7.4 seconds with 400 cm tubing (includes delay time and rise time)
12.17.	The device automatically compensates for ambient pressure changes.
12.18.	Historical trended values display on screen or on CODE-STAT printed report.
12.19.	The CO2 system can be easily calibrated by certified technicians through the service menu using standard procedures with known sample gas value.

13. Invasive pressure (IP)

13.1.	The device offers three channels of invasive pressure monitoring, with both waveform and numerics displayed. Channels will activate automatically once cables are connected. The device allows connection of the following sensors: Edwards Lifesciences - TruWave Disposable Pressure Transducer ICU Medical - Transpac IV Disposable Pressure Transducer
13.2.	The device includes a measurement range of –30 to +300mmHg in six selectable ranges.
13.3.	The device is capable of displaying readings in mmHg and includes waveform support.
13.4.	The device offers user-selectable labels of ART, PA, CVP, ICP and LAP for P1, or P2, or P3.
13.5.	The device has a bandwidth of DC to 30 hertz (<-3 decibels).
13.6.	The device has a numeric accuracy of ± 4 mmHg or 4 percent of reading, whichever is greater, inclusive of transducer error.
13.7.	Historical trended values display on screen or on CODE-STAT printed report.

14. Alarms

14.1.	The device incorporates individually selectable upper and lower alarm limits for each channel with default values set according to patient type selection.
14.2.	The user may select a range of silence periods for the alarms.
14.3.	The silence function applies only to the specific alarm that has been violated; new alarms will include an audible tone and are silenced separately.
14.4.	Audible tone is always provided for VF/VT alarm.
14.5.	The device incorporates a VF/VT alarm which activates continuous patient surveillance of potentially shockable ECG rhythms during manual mode operation with therapy electrodes and through standard ECG electrodes.
14.6.	Individually configurable patient alarms with Adult, Pediatric and Neonate default settings

15. Trending

15.1.	The device offers on-screen trending with choice of HR, PR (SpO2), PR (NIBP), SpO2 (percent), SpCO (percent), SpMet (percent), CO2 (EtCO2/FiCO2), RR (CO2), NIBP, IP1 , IP2, IP3, T1, T2, T3 or ST.
15.2.	The device includes up to eight hours of trend data.
15.3.	The device includes trending of ST measurement after an initial 12 -lead analysis. A 12-lead ECG will automatically print to alert the operator following a series of consistent ST elevations or depressions.
15.4.	Audible tone is always provided for VF/VT alarm.
15.5.	The device incorporates a VF/VT alarm which activates continuous patient surveillance of potentially shockable ECG rhythms during manual mode operation with therapy electrodes and through standard ECG electrodes.
15.6.	A printed trend summary is available from CODE-STAT.

16. Printer

16.1.	The device prints a continuous strip of the displayed patient information.
16.2.	The device supports an optional 100mm (3.9-inch) thermal recorder that is accessible from the back of the device. Paper shall be of standard roll format to facilitate replacement and minimize waste.
16.3.	The device prints at 25 mm/sec or 12.5mm/sec +/- 5 percent (measured in accordance with 60601-2-27, Section 201.12.1.101.7).
16.4.	The delay from display to printing is eight (+2/-0.5) seconds.
16.5.	The device allows the operator to set up automatic printing of waveform events as they occur, in any combination.
16.6.	The device offers the following frequency response settings for the printer:
16.6.1.	Monitoring frequency: 0.5 to 40 hertz
16.6.2.	Monitoring frequency: 1 to 30 hertz
16.6.3.	Diagnostic frequency: 0.05 to 40 hertz
16.6.4.	Diagnostic frequency: 0.05 to 150 hertz

17. Data management

17.1.	The device captures and stores patient data, events (including waveforms and annotations), continuous ECG waveform and diagnostic 12 -lead ECG reports in internal memory.
17.1.1.	Auto transmit reports at power down – when the device powers down it will transmit any unsent records to the configured location.
17.2.	The device allows the operator to enter the following patient information:
17.2.1.	Last name
17.2.2.	First name
17.2.3.	Middle Name
17.2.4.	Incident ID
17.2.5.	Patient ID
17.2.6.	Age (and Birthdate)
17.2.7.	Sex
17.2.8.	Weight
17.3.	If patient age has been previously entered while acquiring a 12-lead ECG, that value is automatically entered in the age field. If the age has been previously entered into the patient information field, it will be used when acquiring the first 12-lead ECG without further user intervention.
17.4.	The device allows stored reports to be retrieved for transmission to a remote location. Transmitted reports must be received by a personal computer (PC) with appropriate software installed.
17.5.	The device provides a means to manage archived patient records. Access to these records in the device has optional password protection. Options to manage archived records shall include:
17.5.1.	Transmit archived patient records
17.5.2.	Print archived patient records
17.5.3.	Add demographic data to archived patient records
17.6.	The device shall be able to store and transmit, at least 50 patient records with the following characteristics:
17.6.1.	12-hour duration for each patient record
17.7.	The following continuous waveforms:
17.7.1.	15 channels of Leads ECG with a sampling rate of 125 samples/second
17.7.2.	1 channel of Paddles ECG with a sampling rate of 125 samples/second
17.7.3.	1 channel of Paddles ECG resistive impedance with a sampling rate of 125 samples/second

17. Data management

	17.7.4.	1 channel of Paddles ECG reactive impedance with a sampling rate of 125 samples/second
	17.7.5.	1 channel of CO2 at the maximum sampling rate of the CO2 module
	17.7.6.	1 channel of SpO2 plethysmograph at the maximum sampling rate of the fastest SpO2 module
	17.7.7.	3 channels of invasive blood pressure multiplexed for 125 samples/second for each channel
	17.7.8.	2 channels of chest compression waveforms (depth and force) at 31.25 samples/second
	17.7.9.	The numeric values for each physiological parameter at least once per second
	17.7.10.	At least 1000 waveform events per patient record
	17.7.11.	At least 40 12/15-lead reports per patient record
	17.7.12.	Manual-entry patient information for each record
17.8.	Memory is internal, rather than by removable cards, to eliminate replacement cost issues and to protect data integrity/patient confidentiality.	
17.9.	The device allows the operator to store the following report options:	
	17.9.1.	CODE SUMMARY™, CODE SUMMARY™ + continuous waveforms, or 12/15 Lead critical event record reports
	17.9.2.	Auto vital sign measurements every five minutes and whenever alarm limits are exceeded
	17.9.3.	12-lead ECG report
	17.9.4.	Continuous waveform: At least 12 hours of continuous ECG record
17.10.	Data management architecture	
	17.10.1	When transferring data, the device outputs data in a format compatible with hospital cardiology information systems, such as the Marquette MUSE CV® cardiovascular information system.
	17.10.2	The data transferred from the device can be transferred and managed using web-based distribution and management. The data center is managed by the manufacturer on a 7/24 basis.

18. Data transmission

18.1.	The device is capable of transmitting current and archived data records to the LIFENET® System or to post-event review products such as CODE-STAT™ data review software or DT EXPRESS™ data transfer software.	
	18.1.1	The device is capable of transmitting data records via a Bluetooth wireless connection to other Bluetooth devices.
	18.1.2.	The device is capable of transmitting data records via a direct cable connection to a PC or gateway.
18.2.	The device has a Bluetooth connectivity option that includes a configurable password prompt for protection	
18.3.	The device allows the operator to transmit the following report options:	
	18.3.1	12-lead ECG report: the diagnostic 12-lead ECG report
	18.3.2	CODE SUMMARY: includes patient information, trend data, event and vital sign log, and waveforms associated with events
	18.3.3	Trend summary: includes patient information, vital signs log and vital signs graphs
	18.3.4.	CODE SUMMARY and Continuous Report. Continuous report provides real-time waveform data, acquired when the device is powered on and electrodes are connected or other waveform data is displayed
18.4.	The device provides the option of transmitting 12-lead ECG reports to a personal computer installed with appropriate software via a direct cable or Bluetooth wireless connection.	
18.5.	The device and communication system supports the following 12-lead features:	
	18.5.1.	Alert at the receiving end that a 12-lead ECG has arrived
	18.5.2.	Transmission to multiple locations
	18.5.3	Auto forwarding of 12-lead ECG report

18. Data transmission

	18.5.4	Sharing of electronic 12-lead report via email
	18.5.5	Acknowledgement of successful transmission at the device
18.6.	The device is capable of streaming continuous, real-time patient data and waveforms to a remote provider through the LIFENET System using Wi-Fi or Cellular.	
	18.6.1.	The device is capable of streaming current patient data during patient monitoring in manual and AED mode.
18.7.	The device is capable of transmitting reports during an in-progress streaming session.	
18.8.	Continuous patient data streaming has the option to be turned on or off. Default transmission settings can be modified in the device setup mode.	
18.9.	The device has the capacity to stream the following data options:	
	18.9.1.	All available monitor parameter waveforms in manual and AED mode and advisory monitoring state
	18.9.2.	Heart rate/Pulse Rate via ECG, SpO2 and NIBP connections
	18.8.3.	SpO2, SpCO and SpMET data
	18.8.4.	EtCO2 pressure and respiration rate data
	18.8.5.	NIBP as combined mean value, systolic value and diastolic value
	18.9.6.	Invasive pressure (IP up to 3 channels) as combined mean value, systolic value and diastolic value
	18.9.7.	Temperature (up to 3 channels) in Celsius or Fahrenheit unit options
18.10.	The device has an available streaming cancel option to discontinue the transmission of data.	
18.11.	The device can display the progress of user-initiated streaming sessions and streaming session success and/or failure prompts.	

19. Power

19.1.	Battery options: The device operates using lithium-ion, rechargeable batteries.	
19.2.	The device operates with one or two batteries; it operates from only one battery at a time, monitors the state of each battery and automatically switches to the second battery when a replace battery condition is detected for the first battery, without interruption of functional operation	
19.3.	Operating time: Two new, fully charged lithium-ion batteries provide the following prior to shutdown at 20°C (68°F):	
	19.3.1.	Monitoring typical 543 minutes, minimum 340 minutes
	19.3.2.	Pacing typical 497 minutes, minimum 320 minutes
	19.3.3.	Defibrillation (360 joules) typical 573 shocks, minimum 400 shocks
19.4.	Capacity after low battery warning	
	19.4.1.	Monitoring typical 48 minutes, minimum 12 minutes
	19.4.2.	Pacing typical 42 minutes, minimum 10 minutes
	19.4.3.	Defibrillation (360 joules) 16 typical shocks, minimum six shocks
19.5.	The device displays battery icons at the top display area for each battery placed in the device. The battery icons indicate the state of battery charge and which of the two batteries is being used to supply power to the device. Low/ Replace battery status is indicated with a low battery icons, warning message, and audible tone.	

20. Maintenance

20.1.	Each time the monitor/defibrillator is powered on, it performs internal self-tests to check that internal electrical components and circuitry work properly.
20.2.	The defibrillator stores the results of all user-initiated self-tests in a test log.
20.3.	When the defibrillator is on and a problem is detected that requires immediate service, such as a malfunctioning charging circuit, the service LED is illuminated, and a technical alarm is provided.

20. Maintenance

20.4.	The defibrillator performs an automatic self-test daily at 3 a.m. (time is configurable) if not in use. During the automatic self-test, the defibrillator turns itself on (ON LED illuminates) briefly, completes self- test, stores the self-test results in a test log and turns itself off.
20.5.	The device is capable of a manually initiated auto test that includes charging and discharging the defibrillator.
20.6.	The device has provision to transfer the test log report to a PC by a cable or by wireless means.
20.7.	The device has provisions to upgrade for future AHA specifications.
20.8.	The device offers a replaceable shock-absorbing handle.

21. Physical characteristics

21.1.	The device does exceed the following weight limits:	
	21.1.1.	Full-featured monitor/defibrillator with new roll of paper and two batteries installed 7.14 kilograms (15.75 pounds)
	21.1.2.	Lithium-ion battery: 0.5 kilograms (1.2 pounds)
	21.1.3.	Accessory bags: 1.59 kilograms (3.5 pounds)
21.2.	The device does exceed the following dimensions:	
	21.2.1.	Height: 35 centimeters (14.0 inches)
	21.2.2.	Width: 35 centimeters (13.8 inches)
	21.2.3.	Depth: 12.4 centimeters (4.9 inches)

22. Environmental conditions for operation as specified

22.1.	The device operates from 0° to 45°C (32° to 113°F). It operates from -10° to 0° C (14° to 32°F) or 45° to 55°C (113° to 131°F) for one hour after storage at room temperature.
22.2.	The non-operating temperature range of the device is -20° to +70°C (-4° to 158°F) except therapy electrodes and batteries.
22.3.	The device operates in relative humidity from 5 to 95 percent, non-condensing.
22.4.	The device operates from ambient to -382 to 4,572 meters (-1,253 to 15,000 feet) with NIBP: -152 to 3,048 meters (-500 to 10,000 feet).
22.5.	The device meets vibration per Random vibration for ground ambulances per EN 1789 clause 6.3.4.2 and 6.4.1 Random vibration for transportable EMS equipment per 60601-1-12 clause 10.1.3 b) Random vibration for pulse oximeters intended for use in the EMS environment per ISO 80601-2-61 clause 201.15.3.5.101.1 Sinusoidal vibration for ground ambulances per EN 1789 clause 6.3.4.2 and 6.4.1
22.6.	The device operates after five drops on each side from 0.5 meters onto a steel surface EN 1789: plus a 0.75 meter drop onto each of six surfaces.
22.7.	The device operates after a functional shock per IEC 60601-1-12, ISO 80601-2-55, and ISO 80601-2-61 shock requirements three shocks per face at 40 g, 11 ms half-sine pulses.
22.8.	The device operates after 1000 bumps at 15 g with pulse duration of 6 msec.
22.9.	The device can withstand an impact per IEC 60601-1:50 mm diameter, 500 g steel ball is dropped from 1.3 m
22.10.	The device is dust- and splash-proof (IP55) per IEC 60529.
22.11.	The device meets EMC emissions standards: EN 60601-1-2: General Requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
22.12.	The device withstands 60-hour exposure to the chemicals: betadine (10 percent povidone- iodine solution), coffee, cola, dextrose (5 percent glucose solution), electrode gel/paste (98 percent water, 2 percent Carbopol® 940), HCL (0.5 percent solution, pH=1), isopropyl alcohol and NaCI (0.9 percent solution).

23. Configuration settings

23.1.	To prevent unauthorized access to the setup and service menus, the device requires separate four-digit numeric security passcodes to be entered.			
23.2.	General: allows selection of the following:			
		Volume for alarms, tones, voice prompts		
		Auto vital signs vent: on or off		
		Line filter: 50 or 60 Hz		
		Adaptive brightness: on or off		
		Startup mode: AED or manual		
		Monitor AC power for readiness alert indicator: on or off		
23.3.	Manual Mode: allows selection of the following:			
		CPR time: 60 s, 120 s, or 180 s		
		Internal defibrillation energy: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 35, or 50 J		
		Voice prompts: on or off		
		Manual therapy access: direct, confirm, passcode, restricted		
		Charge tone with metronome: on or off		
		Energy Protocol:		
			Power on default: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 35, 50, 75, 90, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325, 360 J, or Automatic Protocol	
			Energy level 1: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 35, 50, 75, 90, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325, or 360 J	
			Energy level 2: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 35, 50, 75, 90, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325, or 360 J	
			Energy level 3: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 35, 50, 75, 90, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325, or 360 J	
23.4.	AED Mode: allows selection of the following			
		Auto analyze for stacked shocks: off or after shock		
		Motion detection: on or off		
		Pulse check: never, after second no shock advised, or after every no shock advised		
		AED waveform display: on or off		
		Adult Energy Protocol:		
			Energy level 1: 150, 175, 200, 225, 250, 275, 300, 325, or 360 J	
			Energy level 2: 150, 175, 200, 225, 250, 275, 300, 325, or 360 J	
			Energy level 3: 150, 175, 200, 225, 250, 275, 300, 325, or 360 J	
		Pediatric Energy Level		
			Energy level 1: 35, 50, 75, or 90 J	
			Energy level 2: 35, 50, 75, or 90 J	
			Energy level 3: 35, 50, 75, or 90 J	
23.5.	cprINSIGHT Analysis Technology: allows selection of the following:			
		Manual mode: on or off		
		AED mode: on or off		
		Precharge in manual mode: on or off		
23.6.	CPR Metronome: allows selection of the following:			
		Metronome in AED mode: on or off		
		Metronome rate: 100, 110, or 120 compressions per minute		
		Adult no airway C:V ration: 30:2, 15:2, 16:1, 12:1, 10:1, or continuous		

			Adult airway C:V ration: 30:2, 15:2, 16:1, 12:1, 10:1, or continuous
			Pediatric no airway C:V ration: 30:2, 15:2, 16:1, 12:1, 10:1, or continuous
			Pediatric airway C:V ration: 30:2, 15:2, 16:1, 12:1, 10:1, or continuous
			CPR timer: provided in Manual Mode with configurable time and metronome rate
23.7.	Pacing: allows selection of the following:		
			Rate: 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150, 155, 160, 165, or 170 ppm
			Current: 0, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, or 200 mA
			Mode: Non-demand or demand
			Internal pacemaker markers: on or off
23.8.	Monitoring: allows selection of the following:		
			Heart rate tone source: off, ECG, SpO2
			ECG setup:
			ECG frequency response: monitor or diagnostic
			Monitor frequency response: 1-30 Hz or 0.5 to 40 Hz
			Diagnostic frequency response: 0.05 to 40 Hz or 0.05 to 150 Hz
			CO2 setup:
			Units: mmHg, kPA, or %
			BTPS: on or off
			Temperature setup:
			Units: Fahrenheit or Celsius
			NIBP setup:
			Adult initial pressure: 80, 100, 120, 140, 160, or 180 mmHg
			Pediatric initial pressure: 80, 100, 120, 140, 160, or 180 mmHg
			Neonate initial pressure: 60, 80, 100, or 120 mmHG
			Interval – automatic measurements: off, 2, 3, 5, 10, or 15 minutes
23.9.	12/15 Lead: allows selection of the following:		
			Auto transmit: enable or disable
			Sweep speed: 25 or 50 mm/s
			Include interpretation results: enable or disable
			Format: standard or cabrera
23.10.	Medication Events: allows selection of the following: The Medication Events below can be edited, deleted, or additional events added (up to 40)		
			Medication 1: Adenosine, Amiodarone, Aspirin, Atropine, Bicarb, Dopamine, Epinephrine, Glucose, Heparin, Lidocaine, Morphine, Naloxone, Nitroglycerin, Thrombolytic, or Vasopressin
			Medication 2: same selections as Medication 1 above
			Medication 3: same selections as Medication 1 above
			Medication 4: same selections as Medication 1 above
			Medication 5: same selections as Medication 1 above
			Medication 6: same selections as Medication 1 above
			Medication 7: same selections as Medication 1 above
			Medication 8: same selections as Medication 1 above
			Medication 9: same selections as Medication 1 above
			Medication 10: same selections as Medication 1 above
			Medication 11: same selections as Medication 1 above

	Medication 12: same selections as Medication 1 above
	Medication 13: same selections as Medication 1 above
	Medication 14: same selections as Medication 1 above
	Medication 15: same selections as Medication 1 above

	Treatment Events: allows selection of the following: The Treatment Events below can be edited, deleted, or additional events added (up to 40)

	Treatment 1: Airway, CPR, IV Access, Oxygen, ROSC, or Transport
	Treatment 2: same selections as Treatment 1 above
	Treatment 3: same selections as Treatment 1 above
	Treatment 4: same selections as Treatment 1 above
	Treatment 5: same selections as Treatment 1 above
	Treatment 6: same selections as Treatment 1 above

	Quick Events: allows selection of the following:

		Quick Event 1: Medications or Treatments
		If Medications: Adenosine, Amiodarone, Aspirin, Atropine, Bicarb, Dopamine, Epinephrine, Glucose, Heparin, Lidocaine, Morphine, Naloxone, Nitroglycerin, Thrombolytic, or Vasopressin
		If Treatments: Airway, CPR, IV Access, Oxygen, ROSC, or Transport

23.10.9.	Quick Event 2: same selections as Quick Event 1 above
	Quick Event 3: same selections as Quick Event 1 above
	Quick Event 4: same selections as Quick Event 1 above
	Quick Event 5: same selections as Quick Event 1 above
	Quick Event 6: same selections as Quick Event 1 above
	Quick Event 7: same selections as Quick Event 1 above

	Quick Buttons: allows selection of the following:

		Quick Button 1:	
		Button enabled: on or off Button label: Medications or Treatments	
			If Medications: Adenosine, Amiodarone, Aspirin, Atropine, Bicarb, Dopamine, Epinephrine, Glucose, Heparin, Lidocaine, Morphine, Naloxone, Nitroglycerin, Thrombolytic, or Vasopressin
			If Treatments: Airway, CPR, IV Access, Oxygen, ROSC, or Transport
		Button timer: none, 1, 2, 3, 4, or 5 minutes	

	Quick Button 2: same selections as Quick Button 1 above
	Quick Button 3: same selections as Quick Button 1 above
	Quick Button 4: same selections as Quick Button 1 above

23.11.	Alarms: allows selection of the following:

	Alarms: on or off
	VF/VT Alarm: on or off
	Audio pause reminder alert tone: on or off

23.12.	Patient Record Access: allows selection of the following:

	Print/edit patient records in Archive Mode: enable or disable
	Archive mode password: must be least 6 characters and may contain Aa-Zz letters, numbers, or special characters

23.13.	Roll Printer: allows selection of the following:

	Code Summary format: none, event log, waveforms, event log and waveforms
	Autoprint events:

		Defibrillation: on or off
		Pacing: on or off
		Check patient: on or off
		SAS: on or off
		Patient alarms: on or off
		Events: on or off
		Initial rhythm: on or off
		12/15 Lead reports: on or off
23.14.	Transmission Sites: Up to 72 transmission sites can be configured with a site name and description. Each site has the following configuration options:	
		Default record type: Complete, Code Summary, or 12/15 Lead
		Record type locked: locked or unlocked
	Transmission: allows selection of the following:	
		Default site: none, or any of up to 72 configured sites
		Auto transmission at power off: on or off
		Hide transmitted records: on or off
		Bluetooth: enable or disable
		Wi-Fi: enable or disable
		Cellular: enable or disable
23.15.	Clock: allows selection of the following:	
		Clock mode: Elapsed time or Real time
		Time zone: (GMT-08:00) United States / Los Angeles, (GMT-11:00) U.S. Outlying Islands / Midway, (GMT-10:00) United States / Honolulu, (GMT-09:00) United States / Anchorage,(GMT-08:00) Mexico / Tijuana,(GMT-08:00) United States / Los Angeles,(GMT-07:00) Mexico / Chihuahua,(GMT-07:00) United States / Denver,(GMT-07:00) United States / Phoenix,(GMT-06:00) Canada / Regina,(GMT-06:00) Costa Rica,(GMT-06:00) Mexico / Mexico City,(GMT-06:00) United States / Chicago,(GMT-05:00) Colombia / Bogota,(GMT-05:00) United States / New York,(GMT-04:00) Barbados,(GMT-04:00) Brazil / Manaus,(GMT-04:00) Canada / Halifax,(GMT-04:00) Chile / Santiago,(GMT-04:00) Venezuela / Caracas,(GMT-03:30) Canada / St. John's,(GMT-03:00) Argentina / Buenos Aires,(GMT-03:00) Brazil / Recife,(GMT-03:00) Brazil / Sao Paulo,(GMT-03:00) Greenland / Nuuk,(GMT-03:00) Uruguay / Montevideo,(GMT-02:00) South Georgia & South Sandwich Islands / South Georgia,(GMT-01:00) Cape Verde,(GMT-01:00) Portugal / Azores,(GMT) Coordinated Universal Time,(GMT+00:00) United Kingdom / London,(GMT+01:00) Belgium / Brussels,(GMT+01:00) Bosnia & Herzegovina / Sarajevo,(GMT+01:00) Congo - Brazzaville / Brazzaville,(GMT+01:00) Morocco / Casablanca,(GMT+01:00) Netherlands / Amsterdam,(GMT+01:00) Serbia / Belgrade,(GMT+01:00) Spain / Madrid,(GMT+02:00) Egypt / Cairo,(GMT+02:00) Finland / Helsinki,(GMT+02:00) Greece / Athens,(GMT+02:00) Israel / Jerusalem,(GMT+02:00) Jordan / Amman,(GMT+02:00) Lebanon / Beirut,(GMT+02:00) Namibia / Windhoek,(GMT+02:00) Zimbabwe / Harare,(GMT+03:00) Belarus / Minsk,(GMT+03:00) Iraq / Baghdad,(GMT+03:00) Kenya / Nairobi,(GMT+03:00) Kuwait,(GMT+03:00) Russia / Moscow,(GMT+03:00) Turkey / Istanbul,(GMT+03:30) Iran / Tehran,(GMT+04:00) Armenia / Yerevan,(GMT+04:00) Azerbaijan / Baku,(GMT+04:00) Georgia / Tbilisi,(GMT+04:00) United Arab Emirates / Dubai,(GMT+04:30) Afghanistan / Kabul,(GMT+05:00) Kazakhstan / Oral,(GMT+05:00) Pakistan / Karachi,(GMT+05:00) Russia / Yekaterinburg,(GMT+05:30) India / Kolkata,(GMT+05:30) Sri Lanka / Colombo,(GMT+05:45) Nepal / Kathmandu,(GMT+06:00) Kazakhstan / Almaty,(GMT+06:30) Myanmar (Burma) / Yangon,(GMT+07:00) Indonesia / Jakarta,(GMT+07:00) Russia / Krasnoyarsk,(GMT+07:00) Thailand / Bangkok,(GMT+08:00) Australia / Perth,(GMT+08:00) China / Shanghai,(GMT+08:00) Hong Kong SAR China / Hong Kong,(GMT+08:00) Malaysia / Kuala Lumpur,(GMT+08:00) Russia / Irkutsk,(GMT+08:00) Taiwan / Taipei,(GMT+09:00) Japan / Tokyo,(GMT+09:00) Russia / Yakutsk,(GMT+09:00) South Korea / Seoul,(GMT+09:30) Australia / Adelaide,(GMT+09:30) Australia / Darwin,(GMT+10:00) Australia / Brisbane,(GMT+10:00) Australia / Hobart,(GMT+10:00) Australia / Sydney,(GMT+10:00) Guam,(GMT+10:00) Russia / Vladivostok,(GMT+11:00) New Caledonia / Noumea,(GMT+11:00) Russia / Magadan,(GMT+12:00) Fiji,(GMT+12:00) Marshall Islands / Majuro,(GMT+12:00) New Zealand / Auckland,(GMT+13:00) Tonga / Tongatapu

23.16.	Service: allows selection of the following:		
		Maintenance prompt: none, 3, 6, or 12 months	
23.17.	Auto Test: allows selection of the following:		
		Auto Test time: 00:00, 01:00, 02:00, 03:00, 04:00, 05:00, 06:00, 07:00, 08:00, 09:00, 10:00, 11:00, 12:00, 13:00, 14:00, 15:00, 16:00, 17:00, 18:00, 19:00, 20:00, 21:00, 22:00, 23:00	
23.18.	Passcodes: allows selection of the following:		
		Manual Therapy passcode: 4 digits each selectable from 0 to 9	
		Setup Mode passcode: 4 digits each selectable from 0 to 9	
		Service Mode passcode: 4 digits each selectable from 0 to 9	

24 . Power adapters

24.1.	Power adapters provide operation and battery charging from external AC power
24.2.	Full functionality with or without batteries when connected to external AC
24.3.	Auxiliary power indicator on defibrillator illuminated when connected to auxiliary power
24.4.	Battery charging indicator illuminated when batteries are fully charged and flashing if either battery is being charged.

25. Other

25.1.	Device is designed to help the operator meet U.S. HIPAA (Health Insurance Portability and Accountability Act of 1996) requirements

26. Temperature monitoring

26.1.	The device offers both invasive temperature and surface temperature monitoring via disposable patient sensors. The temperature measurement will automatically populate on screen when the sensor is placed in/on the patient.		
26.2.	Temperature monitoring range is from 24.8° to 45.2°C (76.6° to 113.4°F)		
26.3.	The resolution shall be 0.1°C		
26.4.	The measurement accuracy shall be ±0.32°C, including sensor		
26.5.	The device must have the following accessories:		
	26.5.1	Reusable temperature cable: 6 foot or 10 foot	
	26.5.2.	Disposable sensor types:	
		26.5.2.1.	Surface for reading skin temp
		26.5.2.2.	Esophageal/rectal for core monitoring
		26.5.2.3.	Foley catheter for core monitoring
26.6.	The connection point at the monitor must utilize Molex style connectors.		

27. Continuous waveforms

27.1.	LIFEPAK 35 captures continuous waveforms for all parameters that are connected.
27.2.	In CODE-STAT 9.0 or greater, continuous waveforms can be viewed for post-event review. For example, the waveforms for capnography and SpO2 can be viewed.

28. STEMI recognition

28.1.	Measures the STJ levels and then provides them on the printed or displayed 12/15-lead report
28.2.	The STJ levels are automatically printed/displayed anytime that a 12/15-lead report is printed/displayed.
28.3.	After the first 12-lead acquisition, if a patient's STJ levels have shifted by one millimeter for 2.5 minutes in any lead, the monitor automatically prints another 12/15-lead ECG and notes the new STJ levels on the printout (also available for view on display).

Manufactured by:

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