

Bid Specifications

Automated External Defibrillator (AED)

LIFEPAK® AED Response System (Connected)

LIFEPAK CR2 defibrillator with LIFELINKcentral™ AED Program Manager

Defibrillator	
In package	<ul style="list-style-type: none"> LIFEPAK CR2 Defibrillator is supplied with pre-connected four-year electrodes, operating instructions, battery, handle, USB cable and a LIFELINKcentral AED Program Manager Basic account at no extra charge. The Basic account includes readiness and use notification, free software updates and basic customer support.
Waveform	<ul style="list-style-type: none"> Biphasic Truncated Exponential waveform with voltage and duration compensation for patient impedance.
Patient impedance range	<ul style="list-style-type: none"> 10 - 300 ohms
Output energy accuracy	<ul style="list-style-type: none"> Output energy from the device is 10% of the energy setting into a 50Ω load, and 15% of the rated energy output into a 25Ω to 175Ω load.
Output limit	<ul style="list-style-type: none"> 360J into a 50Ω load.
Energy settings	<ul style="list-style-type: none"> Four energy levels, user-configurable from 150J to 360J for adults and from 35J to 90J for children. Device can be delivered with customer's preferred energy sequence. Factory default settings are 200J, 300J, 360J for Adult Mode, and 50J, 75J, 90J for Child Mode.
Shock Advisory System™ Technology	<ul style="list-style-type: none"> Analyzes ECG waveform and determines if the rhythm is shockable. Motion detection (which is a setup option) is active during SAS analysis and may delay the analysis up to 10 seconds.
cprINSIGHT™ Analysis Technology	<ul style="list-style-type: none"> Minimises interruptions in CPR by enabling the device to analyse the patient's ECG while CPR is being performed.
Time to shock	<ul style="list-style-type: none"> At 360J after CPR with cprINSIGHT enabled (semi-automatic): < 7 seconds. At 360J after CPR without cprINSIGHT (semi-automatic): < 17 seconds. After CPR with cprINSIGHT enabled (fully automatic): 13 seconds.
Charge time	<ul style="list-style-type: none"> 0 seconds for first shock of either 150J or 200J as the device is pre-charged. Subsequent shocks will be charged during CPR and ready to shock at the end of the CPR period (with cprINSIGHT enabled).
cprCOACH™ Feedback Technology (CPR Coaching)	<ul style="list-style-type: none"> The LIFEPAK CR2 provides CPR coaching on CPR technique and correct depth for adult and pediatric patients at appropriate times during the cardiac arrest response. A metronome provides tones at 104 beats per minute (bpm) to guide the responder; this complies with the 2015 ERC Guidelines to provide 100-120 chest compressions per minute. The LIFEPAK CR2 also detects whether chest compressions are being performed and adjusts the voice prompts, if needed, to help the responder resume CPR and provide the best possible care. An internal study shows that the CPR technology in the LIFEPAK CR2 drove users to achieve guideline-compliant rate and depth of compression. (Physio-Control Internal Semi-Automatic AED Comparison Usability Study, August 2016)
Breathing prompts	<ul style="list-style-type: none"> If configured in the setup options, the LIFEPAK CR2 provides the voice prompt "Check for Breathing" for patient assessment. (On Norwegian devices, this prompt is "Check for Signs of Life".) Note: "Check for Pulse" and "Check for Signs of Circulation" are not in the prompt list.

Energy protocol	<ul style="list-style-type: none"> The LIFEPAK CR2 can be set to Flexible Energy (energy does not increase if first analysis after previous shock resulted in a no shock decision) or Fixed Energy (energy escalates from first to second to third values regardless of the post shock ECG) protocol.
Device setup	<ul style="list-style-type: none"> Configurable at factory at the time of order according to customer preference and medical protocols. Setup options may also be changed by the customer, via LIFENET® System, LIFELINKcentral or USB connection.
Field upgradeable software updates	<ul style="list-style-type: none"> Software updates can be installed directly from LIFELINKcentral AED Program Manager or LIFENET System to the LIFEPAK CR2 in the field; no physical connection is required. Updated Operating Instructions also can be downloaded. When a software update is available, an email notification is sent to the contact designated in LIFELINKcentral or LIFENET.
Warranty	<ul style="list-style-type: none"> The LIFEPAK CR2 is backed by an 8-year warranty.
Guideline recommendations	<ul style="list-style-type: none"> The LIFEPAK CR2 follows the recommendations in the 2015 AED guidelines for the American Heart Association (AHA), the European Resuscitation Council (ERC) and the International Liaison Committee on Resuscitation (ILCOR). The LIFEPAK CR2 is consistent with current guidelines for CPR (energy protocols, CPR protocols, quality assurance).
Operation	
Semi-auto vs. Fully auto	<ul style="list-style-type: none"> The LIFEPAK CR2 can be ordered as semi-automatic device (shock button press needed to deliver a shock) or fully automatic device (delivers a shock automatically, when appropriate).
On/Off	<ul style="list-style-type: none"> The device powers on when the lid is opened or when the ON/OFF button is pressed.
Manual override	<ul style="list-style-type: none"> Manual override is not available on the LIFEPAK CR2.
Intended use	<ul style="list-style-type: none"> The LIFEPAK CR2 is intended for use by lay persons who have been trained in CPR and may have been trained in the use of an AED. The device is also effective for emergency responders wanting to use energy settings up to 360 joules.
Voice prompts	<ul style="list-style-type: none"> The LIFEPAK CR2 guides the operator through operating procedures with a combination of voice prompts, flashing LEDs, and visual prompts.
Electrode placement	<ul style="list-style-type: none"> The LIFEPAK CR2 provides visual prompts (pictures) for placement of the QUIK-STEP™ side-by-side electrodes. The LIFEPAK CR2 has color-coded electrodes which also help with relative pad placement as shown on the pictures. The LIFEPAK CR2 electrodes can be placed on either side of the chest.
CPR prompts	<ul style="list-style-type: none"> The LIFEPAK CR2 prompts the operator to perform CPR for a defined time period, which can be preconfigured to 60, 120 or 180 seconds.
Dual language	<ul style="list-style-type: none"> Optional dual language feature enables the LIFEPAK CR2 to be configured, upon order, for a primary language and a secondary language. If the device is configured for two languages, the device prompts the operator to push the language button to switch between the primary and secondary languages.
Child mode (pediatric button)	<ul style="list-style-type: none"> Upon power on, the LIFEPAK CR2 defaults to the energy delivery and CPR guidance set for an adult patient. When the device operator pushes the Child Mode button, the device will provide the energy delivery and CPR guidance set for a pediatric patient.

Pediatric attenuator	<ul style="list-style-type: none"> • A pediatric attenuator is not required. When the operator pushes the Child Mode button, the device will provide the energy delivery and CPR guidance set for a pediatric patient. The same electrodes are used for both adult and pediatric patients.
Electrodes	<ul style="list-style-type: none"> • Immediately after the lid is opened to turn on the device, an integrated easy-to-open electrode pack is the only item visible (for less operator confusion). After the rapid-release electrode pack is opened by pulling the visible red handle, QUIK-STEP™ side-by-side electrodes will be visible for intuitive placement to patient chest.
Adaptive volume control	<ul style="list-style-type: none"> • Automatically adjusts the volume of the voice prompts in accordance with the background noise for clear instruction.
ClearVoice™ Technology	<ul style="list-style-type: none"> • Processing technology, based on acoustic research, that enables prompts to be heard more clearly in noisy environments.
Real-Time clock	<ul style="list-style-type: none"> • The LIFEPAK CR2 has a real-time clock that reads the time from the battery, which uses Coordinated Universal Time (UTC). • The LIFEPAK CR2 clock is automatically updated to system time at event download (wirelessly during status updates to LIFELINKcentral.)
Readiness indicator	<ul style="list-style-type: none"> • The Readiness indicator is a bright green LED that flashes every six seconds to indicate the LIFEPAK CR2 is ready for use. If the LIFEPAK CR2 has detected an issue affecting readiness, the Readiness indicator will stop flashing and a loud alert tone will sound every 15 minutes. Additionally, the Not Ready condition will be reported to LIFELINKcentral AED Program Manager or LIFENET System via a Wi-Fi or cellular connection and an email is sent to the AED program manager.
Low battery indication	<ul style="list-style-type: none"> • When the battery needs to be replaced, the LIFEPAK CR2 provides an audible alert every 15 minutes and the Readiness Indicator will not flash. In Data Mode, the LIFEPAK CR2 will provide a voice prompt that identifies the specific readiness issue. The LIFEPAK CR2 can still deliver at least six shocks and provide 30 minutes of operating time when this indication is first heard or seen. This process preserves the battery by not having to turn on the device to check the battery.
Self-test (self-check)	<ul style="list-style-type: none"> • LIFEPAK CR2 runs a self-test each time the device is turned on, and daily, weekly and monthly automated self-tests at designated times. If an automatic self-test detects a condition that requires attention, this negative result of the self-test is indicated by visible and audible indicators on the device, and reported in LIFELINKcentral AED Program Manager or LIFENET System with an alert sent to the pre-defined AED program managers. Information on the negative result can be found in the email notification, in LIFELINKcentral or LIFENET, or by opening the lid of the device and pressing the LANGUAGE and CHILD MODE buttons simultaneously. Actions that may need to be performed are provided and can be as follows: <ul style="list-style-type: none"> – Replace electrode tray (if missing or expired) – Replace battery (if low or expired) – Contact qualified service personnel • If automatic self-tests indicate the device is ready, the device checks in to LIFELINKcentral AED Program Manager or LIFENET System once each month and reports that it is READY.

Physical specifications

Handle/case	<ul style="list-style-type: none"> Each device is shipped with a handle. An optional carrying case is available.
Dimensions (with handle, including electrodes and battery)	<ul style="list-style-type: none"> 9.7 cm (3.8 in) depth, 22.6 cm (8.9 in) width, and 27.4 cm (10.8 in) height.
Display	<ul style="list-style-type: none"> Designed for user confidence, the LIFEPAK CR2 uses simple bold graphics, audible instructions and automated features to help users remain focused. A display could be a distraction that takes away the responder's attention from the patient. In addition, for use in loud environments, the voice prompts on the LIFEPAK CR2 are processed with proprietary ClearVoice technology, which uses very specific frequencies to enable the human ear to distinguish between background noises. And the LIFEPAK CR2 has an automated volume adjustment feature that increases or decreases the volume of the prompts based on the noise level of the environment.
Integrated lid	<ul style="list-style-type: none"> Provides protection for the electrode pack and controls.
Weight of device (without case or handle)	<ul style="list-style-type: none"> 2.0 kg (4.5 lbs) including the battery and one set of electrodes.
Port	<ul style="list-style-type: none"> USB
Communications	<ul style="list-style-type: none"> Wi-Fi and cellular wireless communication. USB Wireless 802.11 b/g/n, or Cellular data transfer to LIFELINKcentral AED Program Manager or LIFENET System. The cellular configuration includes a cellular module/antenna and subscriber identification module (SIM), which is dependent upon the device destination.

Shock Advisory System

ECG analysis	<ul style="list-style-type: none"> The LIFEPAK CR2 completes the Shock Advisory System (SAS) analysis cycle in 9 seconds or less. The analysis is performed on both adult and pediatric patients.
Motion detection	<ul style="list-style-type: none"> The LIFEPAK CR2 detects motion during SAS analysis. When motion is detected, the device stops analysis, provides an audible notification to the operator that motion is detected, and resumes analysis after 10 seconds or when the motion subsides. The device identifies ventricular tachycardia based, in part, on the following criteria: <ul style="list-style-type: none"> Minimum heart rate greater than 120 beats per minute No apparent P waves QRS widths with a duration greater than 160 milliseconds No pulse
Overall sensitivity	<ul style="list-style-type: none"> For VF or shockable VT in excess of 95%.
Overall specificity	<ul style="list-style-type: none"> For all non-shockable rhythms in excess of 95%.

Environmental

Operating temperature range	<ul style="list-style-type: none"> 0 to 50°C (32° to +122°F)
Storage temperature range	<ul style="list-style-type: none"> -30° to +60°C (-22° to +140°F) with electrodes and battery installed, maximum exposure is limited to one week.

Long term storage temperature range	<ul style="list-style-type: none"> The defibrillator should be stored within the recommended temperature range of 15° to 35°C (59° to 95°F).
Relative humidity	<ul style="list-style-type: none"> 5 to 95% (non-condensing)
Atmospheric pressure (altitude)	<ul style="list-style-type: none"> -382 to 4,572 meters, (-1,253 to 15,000 feet)
Water resistance	<ul style="list-style-type: none"> Meets IEC 60529/EN 60529 IPX5 with electrodes connected and battery installed.
Dust resistance	<ul style="list-style-type: none"> Meets IEC 60529/EN 60529 IP5X with electrodes connected, and battery installed.
Shock	<ul style="list-style-type: none"> Meets MIL-STD-810F, Method 516.4, Procedure 1, (40g, 6-9 ms pulse, 1/2 sine each axis).
Vibration	<ul style="list-style-type: none"> Meets or exceeds MIL-STD-810F, Method 514.4, Helicopter - category 6 (3.75 Grms) and Ground Mobile - category 8 (2.85 Grms).
Drop test	<ul style="list-style-type: none"> 1 meter/3.3 feet with case

Event documentation

Memory type	<ul style="list-style-type: none"> Internal digital memory (flash RAM).
ECG storage	<ul style="list-style-type: none"> The LIFEPAK CR2 can store 60 minutes of ECG for two patient episodes in internal memory (i.e. without the use of external storage media). Note: Patient event storage is not affected if power is disconnected from the device.
Data retrieval	<ul style="list-style-type: none"> Transferred via cellular/Wi-Fi wireless or using a USB cable as follows: <ul style="list-style-type: none"> Transfer with USB cable to a PC: The device transfers patient (Event Log data, ECG and impedance waveforms) and test log.
Report software	<ul style="list-style-type: none"> DT EXPRESS™ Data Transfer Software allows for downloading, editing of patients' demographics and printing of event data and Test Log. CODE-STAT™ Data Review Software 9.0 or higher, allows replay of continuous ECG and allows for review of Test Log information and editing/adding comments to the clinical data.
Database	<ul style="list-style-type: none"> Patient treatment timeline and ECG segments from device integrates into the CODE-STAT Suite 9.0 or higher for statistical analysis and report generation.

Batteries

Type	<ul style="list-style-type: none"> Non-rechargeable, removable Lithium Manganese Dioxide (Li/MnO₂) battery.
Amp-hours	<ul style="list-style-type: none"> 12V, 4.7
Capacity	<ul style="list-style-type: none"> A fully charged battery typically provides 166 200 joules shocks (with one minute between shocks) or 103 360 joules shocks (with one minute between shocks) or 800 minutes of operating time.
Standby life (assuming only daily tests)	<ul style="list-style-type: none"> New battery provides device power for four years, including the monthly Wi-Fi check-in. Low Battery Indication: At least 6 shocks and 30 minutes of operating time remain when first indicated.
Weight	<ul style="list-style-type: none"> 0.3 kg (0.7 lb)
Replacement cycle	<ul style="list-style-type: none"> Battery should be replaced every four years if the device has not been used.

Electrodes

Performance	<ul style="list-style-type: none"> • QUIK-STEP™ Pacing/ECG/Defibrillation user intuitive, rapid access electrodes are designed to be quick and easy to open, reducing the amount of time that passes before a defibrillation shock can be provided.
Adult / pediatric	<ul style="list-style-type: none"> • Electrodes can be used on both adult and pediatric patients.
Operation	<ul style="list-style-type: none"> • Electrodes are stored in a protective package that is installed in the device. As soon as the device is opened, the user simply uses one hand to pull the red handle to reveal the electrodes, which are placed side-by-side on a tray. The user then uses the loop on each electrode to easily peel the electrodes from the tray. The picture on each electrode indicates where it should be placed on the patient's chest.
Compatibility	<ul style="list-style-type: none"> • Electrodes are compatible with the QUIK-COMBO™ electrode connection system on LIFEPAK devices, if used by local advanced life support responders, without requiring purchase of a connectivity solution.
Replacement cycle	<ul style="list-style-type: none"> • Electrodes must be replaced every 4 years if not used.
Electrode cable length	<ul style="list-style-type: none"> • 1.1 meters (41.8 inches)

Accessories

Defibrillator accessories	<ul style="list-style-type: none"> • Several accessories are available for day-to-day operation of the LIFEPAK CR2. These accessories include the following: <ul style="list-style-type: none"> – QUIK-STEP pacing/ECG/defibrillation electrodes – LIFEPAK CR2 lithium battery – LIFEPAK CR2 carrying case – Replacement lid – Replacement handle – Replacement USB cable – Ambu® Res-Cue Mask® First Responder kit – Wall bracket – Rotaid™ Plus wall cabinet with alarm – Rotaid Solid Plus wall cabinet with alarm – Rotaid Solid Plus wall cabinet with heat and alarm – LIFEPAK CR2 AED surface mount cabinet with alarm
Trainer/trainer accessories	<ul style="list-style-type: none"> • LIFEPAK CR2 Trainer • LIFEPAK CR2 Trainer carry bag • LIFEPAK CR2 Trainer replacement lid • LIFEPAK CR2 Trainer handle • LIFEPAK CR2 Trainer replacement Bluetooth USB • LIFEPAK CR2 Trainer replacement battery compartment cover • Replacement D-cell batteries

Trainer

Descriptions	<ul style="list-style-type: none"> • The LIFEPAK CR2 AED Training System provides realistic training in the use of the LIFEPAK CR2 Defibrillator without the actual charge and discharge of electrical energy. Designed to simulate the appearance of the LIFEPAK CR2, the LIFEPAK CR2 Trainer simulates its actual operation using the same simple user interface. • The LIFEPAK CR2 Trainer is compatible with any CPR manikin system.
Labeling	<ul style="list-style-type: none"> • Includes clear labeling that it is a training unit, and a different color (gray) carrying bag.
Dimensions (with handle)	<ul style="list-style-type: none"> • 27.2 cm (10.7 in) height, 21.8 cm (8.6 in) width, and 8.6 cm (3.4 in) depth.
Weight (with batteries)	<ul style="list-style-type: none"> • 1.8 kg (3.9 lb)
Buttons	<ul style="list-style-type: none"> • Language, Power, Child Mode, Shock
Simulation	<ul style="list-style-type: none"> • All of the functions of the Trainer are programmable to simulate the full range of scenarios users might encounter during “real life” use of the LIFEPAK CR2 Defibrillator. The Trainer provides two fully configurable scenarios that are completely customized using a setup screen and can be updated on the go for maximum flexibility. • Pre-set demos can be programmed for fully automatic or semi-automatic mode to enable a quick demonstration of the key LIFEPAK CR2 features, as well as the benefits of cprINSIGHT™ analysis technology.
Adaptive volume control/ ClearVoice Technology	<ul style="list-style-type: none"> • Adaptive Volume Control to automatically adjust the volume of the voice prompts in accordance with the background noise for clear instruction, and ClearVoice Technology that enables prompts to be heard more clearly in noisy environments.
Training electrodes	<ul style="list-style-type: none"> • The training electrodes are reusable; capable of at least 50 applications to a CPR manikin system.
Batteries	<ul style="list-style-type: none"> • The Trainer uses four non-chargeable D-cell alkaline batteries, which can be purchased in normal retail outlets. New batteries will provide no less than 100 hours of continuous operation at volume 4.
On-Line training	<ul style="list-style-type: none"> • On-line AED training is available to provide instructions on operating the device.
Trainer demo app	<ul style="list-style-type: none"> • The LIFEPAK CR2 Trainer Demo App can be used to set up automatic email notifications or send manual email notifications via Bluetooth® from any Windows®, Android® or IOS® mobile device. This app simulates the automatic email notifications provided when a LIFEPAK CR2 is managed by LIFELINKcentral AED Program Manager.

AED Program management

LIFELINKcentral™ AED Program Manager	<ul style="list-style-type: none"> • LIFELINKcentral AED Program Manager allows for managing device, disposables, readiness, and continuity of treatment with cellular/Wi-Fi wireless connectivity to the defibrillator.
Accounts	<ul style="list-style-type: none"> • The Basic account, provided with every LIFEPAK CR2 device at no extra charge, allows for the management of software and setup options and for remotely monitoring readiness status and location and providing immediate alerts if the device has been used, moved, or needs maintenance. Smart Desk/Tech Support also is provided with the Basic account. • The Advantage and Premium accounts provide full portal access with expanded view and functionality, with additional and optional services (depending on the account) as follows: <ul style="list-style-type: none"> – Manual tracking of CPR/AED training participants and certifications – Manual tracking of non-Physio-Control devices, including other AEDs, accessories and disposables, and other safety devices – Post event report download (wireless) – Supply replenishment for Physio-Control AEDs (replaced free after event) – Post event device readiness verification – Dedicated Physio-Control Account Support Representative (ASR) for Premium accounts
Location tracking	<ul style="list-style-type: none"> • LIFELINKcentral and LIFENET provide automatic tracking of the LIFEPAK CR2 location via the cellular network.
Device in use notification	<ul style="list-style-type: none"> • Wi-Fi-enabled LIFEPAK CR2 provides via LIFELINKcentral email notifications of device in use, including location and time.
Event data to emergency responders	<ul style="list-style-type: none"> • Wi-Fi-enabled LIFEPAK CR2 transmits via LIFELINKcentral event data to arriving emergency responders.
Wireless distribution of event report	<ul style="list-style-type: none"> • Wi-Fi- or cellular-enabled LIFEPAK CR2 is able to transmit AED event reports to professional caregivers.

Physio-Control is now part of Stryker.