CARDIOLINE

elife700

elife700 is a biphasic Monitor/Defibrillator for advanced monitoring and resuscitation functions.
elife700 incorporates a wide screen displaying ECG signal, monitoring parameters, information and user guide messages.
Monitoring function allows 4.5 seconds visualization (9 in cascaded mode) of the patient's ECG picked up via of 3, 5 and 10 lead patient cable, reusable external paddles or multifunction disposable electrodes.
elife700 has a user-configurable high resolution thermal recorder, for printing waveforms and notes relating to the utilization.
The unit can operate with NiMH rechargeable batteries, connected to a supply AC mains or connected to a car battery.
The remaining battery capacity is displayed in the top part of the screen. When the device is connected to an external power supply (AC mains or car battery) the battery is charged, by means of an internal charger, independently of whether the device is switched on or off.
At start-up and during the utilization, it carries out a number of self-tests for detecting any malfunction or anomalous condition.

elife700 is available in two versions:
- Manual
- Manual/AED

Manual version

elife700 provides a defibrillation shock by means of an truncated exponential type biphasic pulse. The energy of this pulse is transmitted to the patient via external reusable paddles or multifunction disposable electrodes that connect to the device and to the bare chest of the patient.
When operating in Synchronized Cardioversion mode, biphasic defibrillation shock can be synchronized with the R wave of the patient's ECG.
In the Manual version, defibrillation shock can be simply applied by three steps: (1) select the energy, (2) charge, (3) shock.

Manual & AED Version

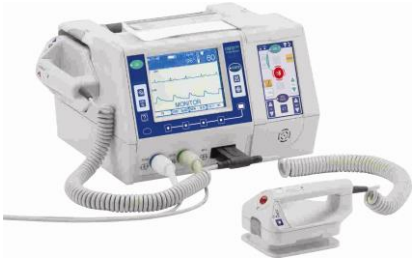
In manual/AED version **elife**700 analyzes ECG of the patient, and determines if the rhythm analyzed can be defibrillated. During the whole process, the device displays on-screen text messages, and provides audible messages by means of a loudspeaker situated in its front part.
In AED mode, all information are automatically stored in a Compact Flash Card, including ECG signal, clinical parameters and alarms; the last 100 events of defibrillation, pacing or printing are also memorised.
All information can be easily downloaded and analysed on PC.

Each version can be equipped with the following options:
- Transcutaneous External Pacemaker option.
- Pulse oximetry (SpO2) option

Pacemaker Option

Integrated pacemaker for external stimulation both fixed or on demand.

elife700



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This option adds to the unit cardiac pacing features, with programmable stimulation rate and current.

Pulse Oximetry Option

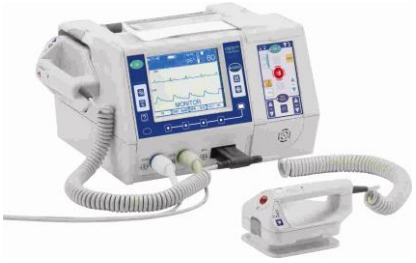
Pulse oximetry with SIMS BCI transducer.
This option offers oxygen saturation monitoring by displaying on the screen the percentage value of SpO2 and the plethysmographic waveform, in combination with HR value and electrocardiographic waveforms.

Indications of use

elife700 is indicated for use in hospital and out-of-hospital environments by medical personnel who have been specially qualified by training in Basic Life Support (BLS), Advanced Life Support (ALS) techniques or in any other type of emergency situations response techniques recognised by the competent authority.

elife700 must be used on a single patient at a time.

elife700



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Technical Specifications

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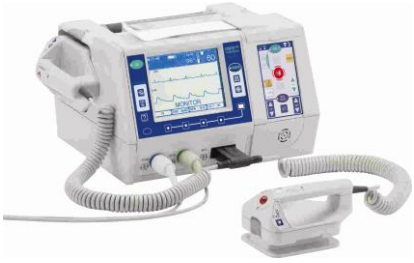
Generals

Electrical Protection	Input protected against high voltage defibrillation pulses (IEC 60601)
Safety Classification	IEC 60601, CF type. Class I, internally powered Continuous operating mode
Indicators	- Battery Status Indicator - Device malfunction indicator - Power supply indicator - Charge indicator - Energy charged indicator - Synchronization indicator
Self-tests	- At start-up - While operating - Manuals on request by user
Weight	- Device with recorder, reusable external paddles and battery: 6.9 Kg - Device with recorder, multifunction disposable electrodes and battery: 6.0 Kg - Device with recorder, SpO2 option, AED, pacemaker, multifunction disposable electrodes and battery: 6.3 Kg - Reusable external paddles: 0.95 Kg - Battery: 0.8 Kg
Dimensions	195 mm high x 249 mm long x 310 mm wide

Monitoring function

ECG	Monitored by means of 4, 5 and 10 lead cable, reusable internal or external paddles and single-use multifunction electrodes
Leads	- 4 Lead cable: PADDLES, I, II, III, aVR, aVL and aVF - 5 Lead cable: PADDLES, I, II, III aVR, aVL, aVF and V - 10 Lead cable: PADDLES, I, II, III, aVR, aVL, aVF and V1 to V6
Lead-Off Indicator	An on-screen icon appears when any lead is off or poorly connected The amplitude of the current applied to the patient to detect a lead-off is less than 0.5 uA.
Size of the ECG	0.5, 1, 2 and 4 cm/mV selectable from the front panel
ECG on-screen speed	25 mm/sec
Frequency response	- AC Filter (50/60 Hz). - Diagnostic: 0.05-150 Hz (only in recorder) - Muscle artifact filter: 0.67-40 Hz (only in recorder) - Screen response: 0.05-25 Hz
Heart Rate	30-300 bpm ± 10 % displayed on the device screen
Accuracy in the heart rate and response to an arrhythmia	Conforms to Safety Standard IEC 60601-2-27:2005 for ventricular bigeminy (HR=40 bpm)
Averaged heart rate	- For heart rates greater than or equal to 50 bpm, the 8 most recent R-R intervals are used for averaging the heart rate. - For heart rates lower than 50 bpm, the 4 most recent R-R intervals are used for averaging the heart rate.
Heart rate response time	- From 80 to 40 bpm: 3 seconds



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- From 80 to 120 bpm: 2 seconds

Alarm response time for tachycardia:
- 206 bpm (1 mV): 2 seconds
- 206 bpm (half amplitude): 3 seconds
- 206 bpm (double amplitude): 3 seconds
- 195 bpm (2 mV): 2 seconds
- 195 bpm (half amplitude): 2 seconds
- 195 bpm (double amplitude): 2 seconds

Capacity to reject T-waves: Rejects T-waves with a maximum amplitude of 0.7 mV

Alarms:
- Maximum and Minimum Heart Rate
- Maximum and Minimum SpO2% (only with pulse oximeter option)
- VT/VF Alarm (only with the Semi-Automatic Defibrillator option)

Common mode rejection: > 100 dBs

Simultaneous use of the Elife700 with other equipment connected to the patient:
- The Elife700 can be utilized simultaneously with an electrosurgical unit. A defect in the neutral electrode of the electrosurgical unit does not represent any safety risk for the patient since the device provides protection against high-frequency burns. This protection resides in the fact that the patient cable is electrically isolated through a ground connection.
  Consult the Instructions for Use for the electrosurgical unit to reduce the risk of burns in case of a defect in this device.
- The simultaneous use of the Elife700 with an external pacemaker and other electrical pacers connected to the patient do not represent any safety risk. The device could detect the internal pacemaker pulses as QRS complexes which results in an indication of an incorrect heart rate.

SpO2 Pulse Oximetry (Optional)

Saturation (% SpO2) range: 1-100%

Saturation (%SpO2) accuracy during no motion conditions:
- Adults/Paediatrics: 70% - 100 % : ± 2 digits; 0% - 69 % : Not specified
- Neonates: 70% - 100 % : ± 3 digits; 0% - 69 % : Not specified

Saturation (%SpO2) accuracy during motion conditions
- Adults/Pediatrics/Neonates: 70% - 100 % : ± 3 digits; 0% - 69 % : Not specified

Saturación (% SpO2) resolution: 1%

Pulse Rate Range (bpm): 25-240 bpm

Pulse rate (ppm) accuracy during no motion conditions: ± 2 bpm

Pulse rate (ppm) accuracy during motion conditions: ± 5 bpm

Pulse rate (ppm) resolution: 1 bpm

Defibrillator

Waveform: Biphasic truncated exponential, with energy compensation according to the patient's impedance

Output Energy Accuracy (over 50 □): ± 15 % or ± 3 J, whichever is greatest in the entire range

Manual Defibrillator

Output energy:

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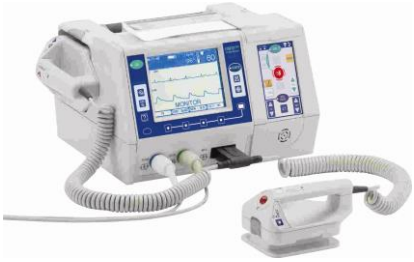

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External paddles	1 - 2 - 3 - 5 - 7 - 9 - 10 - 15 - 20 - 30 - 50 - 70 - 100 - 125 - 150 - 200 Joules.
Internal paddles	1 - 2 - 3 - 5 - 7 - 9 - 10 - 15 - 20 - 30 - 50 Joules
Paddles Options	- Reusable external paddles - Internal paddles - Multifunction single-use cable-electrodes - Permanent single-use multifunction electrode cable
Energy Selection	Front panel button and external paddle buttons
Charge Control	Front panel button and external paddle buttons
Charge Indicator	Charging tone, end of charge tone, LED in charge button and shock button on the front panel blinking for single-use multifunction electrodes and internal paddles
Shock Control	Buttons on the external paddles, front panel button for single-use multifunction electrodes and internal paddles
Charging time	- Less than 5 seconds at 200 J with a new and fully charged NiMH battery pack at 25ºC. - Less than 10 seconds without a battery pack and connected to a power voltage at 90-100 % of the nominal value. - Less than 10 seconds with a new and fully charged NiMH battery pack, depleted with 15 shocks at 200 J at 25ºC.
Maximum time from the initial power supply connection until ready to shock status	- Less than 10 seconds from initial start-up with a new and fully charged NiMH battery pack. - Less than 15 seconds from initial start-up, without a battery pack, and connected to a power voltage at 90-100 % of the nominal value. - Less than 15 seconds with a new and fully charged NiMH battery pack, depleted with 15 shocks at 200 J at 25ºC.
Synchronization	Front panel button. On-screen indication of the synchronization points
Maximum time delay between the synchronization pulse and energy delivery	Energy delivery is carried out within 60 ms following the detection of a QRS peak

Semi-Automatic Defibrillation (Optional)

Output energy	Maximum: 200 J □ 15%
Paddle Options	- Single-use multifunction cable-electrodes - Permanent cable with single-use electrodes
Guide messages	Emission of on-screen and audible voice prompt messages that guide the user during operations
Charge Indicator	Charging tone, end of charge tone and blinking front panel shock button
Shock Control	Front panel button
Configuration of utilization parameters	By means of the corresponding Configuration Mode options
Detection features	- VF Sensitivity: Conforms to AHA Safety Standards - VT Sensitivity: Conforms to AHA Safety Standards - NSR Specificity: Conforms to AHA Safety Standards - Specificity of other signals: Conforms to AHA Safety Standards
Maximum time from the start of the rhythm analysis until ready to	- Less than 20 seconds with a new and fully charged NiMH battery pack.

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shock status	- Less than 20 seconds without a battery pack and connected to a power voltage at 90-100 % of the nominal value. - Less than 20 seconds with a new and fully charged NiMH battery pack, depleted with 15 shocks at 200 J at 25ºC.
Maximum time from the initial power supply connection until ready to shock status	- Less than 26 seconds with a new and fully charged NiMH battery pack. - Less than 26 seconds without a battery pack and connected to a power voltage at 90-100 % of the nominal value. - Less than 26 seconds with a new and fully charged NiMH battery pack, depleted with 15 shocks at 200 J at 25ºC.

Pacemaker (Optional)

Waveform	Rectilinear continuous current
Pulse width	40 msec
Amplitude	From 0 to 150 mA in increments of 5 mA
Rate	From 30 to 180 bpm in increments of 5 bpm
Operating modes	- Fixed - On-Demand
Refractory period	- 240 msec from 30 to 80 bpm - 340 msec from 85 to 180 bpm

Screen

Size	120 x 89 mm (SP14Q001 - Hitachi) 115.2 x 86.4 mm (EL320.240.36 HB -Planar)
Type	LCD with backlight (SP14Q001- Hitachi) High Resolution EL (EL320.240.36 HB–Planar)
Resolution	320 x 240 pixels (1/4 VGA)
Sweep rate	25 mm/sec
Waveform viewing time	4.5 seconds

Recorder (Optional)

Continuous ECG strip	Prints a continuous strip with one ECG channel along with the annotations and events. For devices with pulse oximetry option, 2 channels can be printed: The ECG signal and the pleth waveform (SpO2)
Automatic Printing	It can be configured to automatically print the 8 seconds prior to and after the events that set off alarms and defibrillation shock events.
Reports	- Utilization performance report. - Heart Rate Trends and SpO2% graphs (optional). - Results of the manual tests and the device self-tests. - Configuration parameters. - Events/incidences stored in the memory card along with the corresponding ECG signal.
Paper Width	50 mm
Speed	10, 25 and 50 mm/sec ± 5 %

Data Storage (Optional)

Memory Type	External removable Compact Flash memory card
Capacity	Minimum 16 MB, equivalent to 4 hours of continuous ECG signals plus audio
Data	Continuous ECG plus audio (optional) Significant incidences/events along with the corresponding ECG

Power Supply

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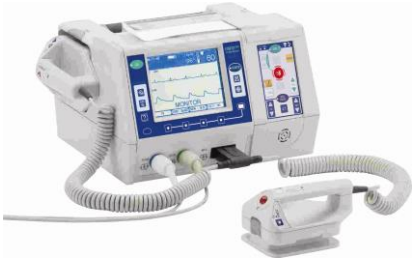

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Battery:

Type	NiMH (rechargeable)
Capacity	- More than 130 shocks at 200 J at 20ºC - More than 150 minutes of monitoring - More than 120 minutes of monitoring plus pacemaker (60 mA and 60 bpm)
Charging time	Approximately 3 hours
Weight	800 grams
AC mains	100-240 V AC and 50-60Hz
Continuous (Car battery)	10-16 V DC
Equipotential Conductor	It provides an additional connection to the ground connection of a building electrical installation. If this ground connection is not available, connect the equipotential conductor to any metal element accessible on the building structure.

Environmental Conditions

Operating temperature	- 0ºC to 50ºC in Monitor mode and Defibrillator mode only, with installed battery pack and without any power supply connection - 0ºC to 40ºC connected to a power supply connection
Storage temperature	-20ºC to 60ºC except for batteries and single-use multifunction electrodes
Relative humidity	10 to 95 %
Atmospheric Pressure (functioning)	Ambient to 525 mmHg (0 to 3,000 m)
Resistance to water	IPX2
Vibration	IEC 60068-2-64
Shock	IEC 60068-2-27

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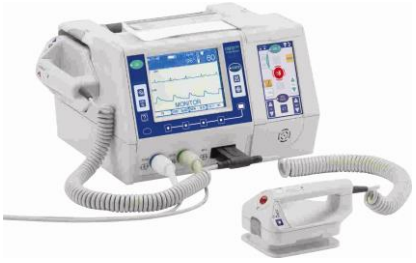

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Standard accessories

Manual Version

Code	*Description*	*Qty*
	Power supply cable	1
63050089	Patient cable – 5 leads	1
69701603	Rechargeable battery	1
63040019	External paddles (adult/paediatric)	1
R8930534	Disposable cable and electrodes for defi.	1
	ECG paper roll, 50mmx30m	1
66030035C	Disposable snap electrodes, 25 pcs	1
66020002	ECG electrode gel, 260ml	1
	User Manual	1

Manual & AED Version

Code	*Description*	*Qty*
	Power supply cable	1
63050089	Patient cable – 5 leads	1
69701603	Rechargeable battery	1
63040019	External paddles (adult/paediatric)	1
R8930534	Disposable cable and electrodes for defi.	1
	ECG paper roll, 50mmx30m	1
63090632	Compact Flash 256Mb	1
66030035C	Disposable snap electrodes, 25 pcs	1
66020002	ECG electrode gel, 260ml	1
	User Manual	1

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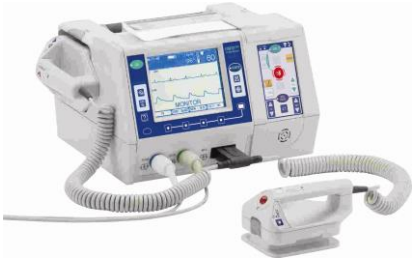
Options

Code	*Description*
63090223	ECG Visor analysis sw (for AED Version only)



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Accessories

Code	*Description*
63010022	Power supply cable for external battery
63040019	External paddles Adult/Pediatric
63040023	SPO2 transducer
63040024	Extension cable for SPO2 transducer
63040046	Set adult internal paddles elife
63040047	Set pediatric internal paddles elife
63050088	DefiECG patient cable, 4 lead
63050089	DefiECG patient cable, 5 lead
63050090	DefiECG patient cable, 10 lead
63090063	Carrying case
63090630	PCMCIA card reader - USB (for AED Version only)
63090632	Compact Flash 256MB (for AED Version only)
63090633	Compact Flash - PCMCIA Adapter (for AED Version only)
66030035C	Disposable snap electrodes, 25 pcs
69701603	Rechargeable battery
8730420	Disposable defib electrode, 2 pcs pack
8743531C	DefiECG 50 mm paper Roll, 10 pcs pack
8950160	Cable for disposable defi electrodes
R8930534	Disposable cable and electrodes for defi

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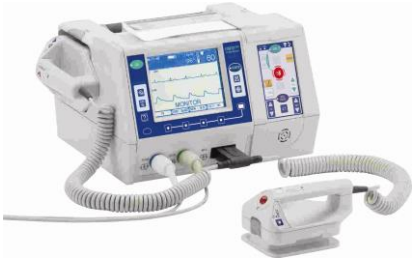

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