progetti®
Medical Equipment Solutions

INSTRUCTIONS FOR USE

Cardiopulmonary Resuscitation (CPR) Device

Chest-eR®

ENG

TD2.2-ENG-ChesteR Rev.2.0-2024-11

EUROPEAN RESUSCITATION COUNCIL
GUIDELINES 2021

CE

PROGETTI S.r.l.
Strada del Rondello, 5
10028 - Trofarello (TO)
ITALY

Rev. 2.0
2024/11

THANK YOU FOR CHOOSING CHEST-ER®!

Chest-eR® is an intuitive, compact medical device intended for external cardiac compressions according to the *European Resuscitation Council* (ERC) guidelines, "*Basic Life Support - Defibrillation*" (BLS-D). It was designed to support the user during the cardiac massage to improve its quality and reduce the incidence of internal injuries in the patient.

Customers should be trained on the correct use according to such protocol.

Please read this User Manual carefully and thoroughly before using Chest-eR®. It contains instructions on how to operate, maintain, and store the device correctly.

It is crucial that you fully understand all the necessary instructions included in this manual so that you can act quickly during an emergency.

PROGETTI S.r.l. designs and manufactures all products following applicable standards, such as the Medical Device Regulation 2017/745. This ensures that PROGETTI S.r.l. provides high-quality reliable products.

Use only components and accessories recommended by the manufacturer to maintain safety and performance throughout your device life.

Only technicians trained and authorized by the manufacturer shall perform any operation on Chest-eR® and its dedicated accessories. The device does NOT contain user-reparable parts.

For further information, please contact PROGETTI's technical assistance department at the email address **service@progettimedical.com** or by phone at **+39.011.644.738.**

Disclaimer

PROGETTI S.r.l., as Manufacturer of *Chest-eR®*, is responsible for its safety and performance during its entire expected service life unless the customer cannot prove that they have complied with the requirements of use, maintenance, and storage included in this User Manual.

PROGETTI S.r.l. shall not be held liable for any accidental damage caused to the device and its accessories during transport to the customer or during use.

Please contact PROGETTI S.r.l. for any further information.

Declaration

PROGETTI S.r.l. reserves the right to make changes to device specifications and/or information contained in this manual at any time, where necessary, and without notice or obligation to the Customer.

Limited Warranty

The Limited Warranty supplied by PROGETTI is the sole warranty regarding the product.

Information about this User Manual

This manual contains the instructions necessary to use the product safely, according to its function and intended use. Compliance with this manual is a prerequisite for the correct performance of the product and its proper functioning, ensuring patient's and operator's safety.

The manual refers to the complete (full optional) configuration of the medical device; therefore, some contents may not apply to the product in use. If you have any questions, please contact us by e-mail at info@progettimedical.com.

This manual is an integral part of the product and, as such, should be kept close to the medical device so that it can be easily consulted when needed.

All pictures in this manual are for illustrative purposes only and, as such, may not reflect the configuration of the product in use.

Useful contacts

- GENERAL INFORMATION - **info@progettimedical.com**
- SALES DEPT. - **sales@progettimedical.com**
- TECHNICAL ASSISTANCE DEPT. - **service@progettimedical.com**
- QUALITY & REGULATORY AFFAIRS DEPT. - **quality@progettimedical.com**

For continuous improvement, the Manufacturer is pleased to welcome any customer's opinion and suggestions on the device and/or this user manual. Therefore, please contact PROGETTI's Quality & Regulatory Affairs department at quality@progettimedical.com.

Please report any incidents[1] occurring in connection with the medical device to the Manufacturer by sending an e-mail to quality@progettimedical.com and info@progettimedical.com.

Any serious incident[2] related to the device shall be reported not only to the manufacturer but also to the relevant Competent Authority.

1 'Incident' means any malfunction or deterioration in the characteristics or performance of a device made available
on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect (MDR 2017/745, Art.2, §64).

2 'Serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat (MDR 2017/745, Art.2, §65).

SUMMARY

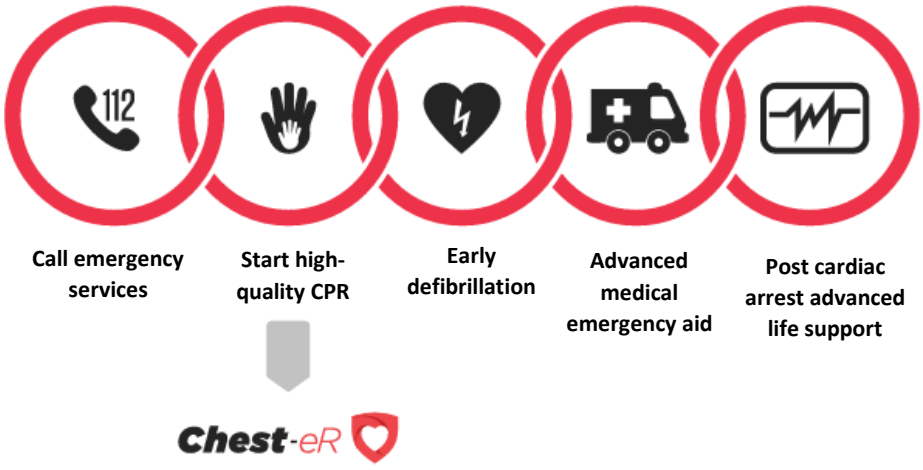
1. INTRODUCTION

This User Manual provides information for the safe and proper use of the Cardiopulmonary Resuscitation (CPR) Device, model *Chest-eR®,* and its accessories.

The device is designed to be user-friendly thanks to its visual indicators, which provide simple guidance to the operator. Also, it is practical, light and intuitive so it can be helpful during an emergency.

When placed on the chest of a person who is neither conscious nor breathing, *Chest-eR®* improves the quality of cardiac massage by providing feedback to the rescuer who is performing CPR and increases the cardiac massage safety for both the rescuer and the patient.

Chest-eR® is intended to be used during the 2nd step of the "survival chain" illustrated in the following picture.



The "*European Resuscitation Council Guidelines 2021: Basic Life Support - Defibrillation*" recommends that if a bystander recognises Cardiac Arrest (CA) in a person, they must intervene straightaway by activating the "survival chain". A CA victim is unconscious, unresponsive and non-breathing. If a bystander rapidly assesses that the person is a CA victim, the BLS-D (*Basic Life Support - Defibrillation*) procedure must be activated immediately.

At first, the rescuer shall call professional emergency services right away. Then, it is recommended to start a high-quality *Cardio-Pulmonary Resuscitation* (CPR), namely a cardiac massage characterised by compression-release sequences on the chest of the CA victim.

2021 ERC Guidelines recommend that the cardiac massage have the following characteristics:

- compression depth between 5 and 6 cm;
- compression frequency between 100 and 120 compressions per minute;

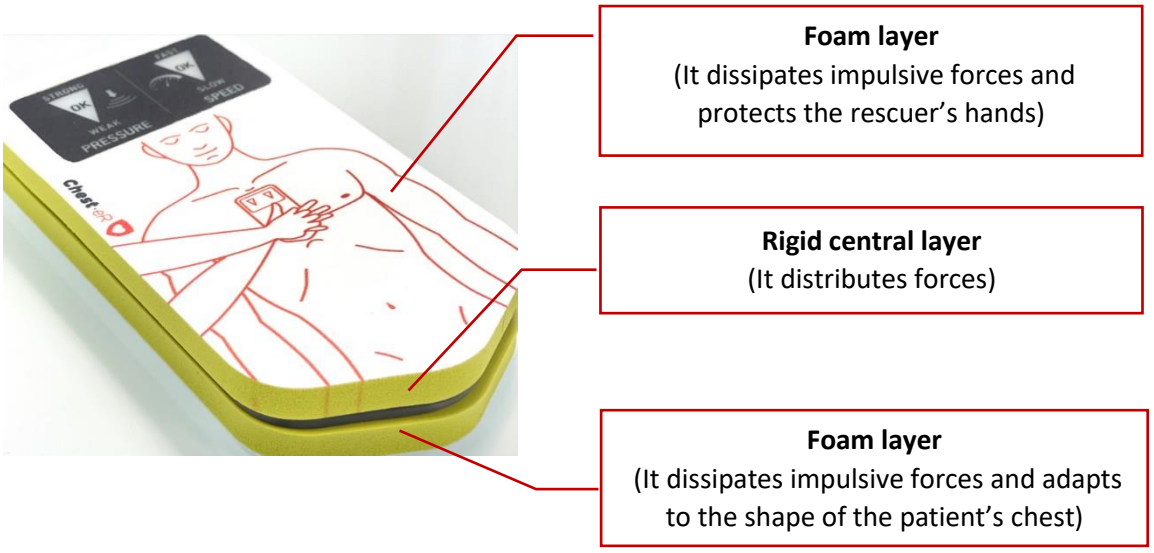
in an adult patient (> 18 years old) and in a pediatric patient (1÷18 years old).

Chest-eR® can be extremely helpful during the cardiac massage because it was designed to guide the rescuer to comply with the recommendation above, resulting in efficient CPR in terms of "depth" and "frequency". Besides, it helps to reduce the incidence of internal injuries and traumas in the victim (particularly in the ribs and the sternum) due to the application of excessive or poorly distributed impulsive forces.

Chest-eR® structure also improves the rescuer's comfort and reduces the risk that they suffer from injuries to their hands. This risk is especially high if devices made of rigid materials are located between the operator's hand palm and the patient's chest during the cardiac massage. Skin irritation, abrasion and/or lesions may be consequences of performing CPR, which pose the risk of operator's infection and/or contamination if they touch infected blood or other biological material afterwards. Also, they cause discomfort and/or pain that could distract the rescuer from performing the CPR correctly and effectively.

For these reasons, the impact of CPR on the patient and the operator's effort were highly considered while designing and developing *Chest-eR®*. The result is a device which relies on an innovative system protected by an exclusive patent that combines:

- Latest-generation non-Newtonian materials, capable of dissipating the impact energy coming from excessively powerful or violent chest compressions;
- a special internal triple-layer structure that reduces dangerous stresses produced by the incorrect force application by the rescuer and redistributes excessive forces over the entire device area and the patient's chest;
- sensors and sophisticated algorithms providing real-time feedback on how the rescuer is performing the cardiac massage[3], increasing the probability of effective CPR;
- a disposable cover, which guarantees hygiene and prevents the risk of infections and cross-contamination.



Overall, the soft surfaces of *Chest-eR®* dissipate up to 90% of the impact energy when impulsive force is applied, thanks to the reorganization of the molecules composing the material.

Besides, the *Chest-eR®* surface allows the uniform distribution of forces on the patient's lower sternum area through the soft non-Newtonian elastomer coating which avoids the concentration of excessive stress on any protruding bones by adapting to the shape of the patient's chest.

Chest-eR® is also resistant to tearing, avoiding gradual wear as the massage proceeds.

[3] *European Resuscitation Council (ERC) Guidelines 2021: Basic Life Support*

Another huge advantage is that *Chest-eR®* is always ready for use: the operator has only to place the device on the patient's chest and start the cardiac massage to get feedback.

If *Chest-eR®* is correctly positioned on the patient's chest (or any exercise dummy), it automatically turns on as soon as the compressions start and provides feedback on the quality of the cardiac massage through visual indicators. The system is straightforward, allowing the rescuer to focus on the correct rhythm and depth of the massage, resulting in effective CPR.

1.1 INTENDED USE

1.1.1 INTENDED CLINICAL CONDITIONS AND CLINICAL BENEFIT

Chest-eR® is intended to be used to help the operator performing CPR on a victim of Cardiac Arrest (CA), i.e. a person who is unconscious, unresponsive and not breathing. In this case, *Chest-eR®* will provide feedback to the user aimed at ensuring a correct and effective cardiac massage.

1.1.2 INTENDED PATIENTS' POPULATION

Chest-eR® is intended to be used for the following patients' classes:

- **Adult patients**, that is age ≥ 18 years old and weight ≥ 25 kg (including pregnant women);
- **paediatric patients,** that is age 1 to 18 years old and weight < 25 kg.

Chest-eR® is **NOT** intended to be used on **infants/neonates** (age < 1 year old).

Do **NOT** delay CPR to determine the exact patient's age or weight.

Chest-eR® is a reusable medical device intended to be used for multiple patients over its expected service life of 5 years. The device cannot be placed on more than one patient at a time.

1.1.3 INTENDED USERS

Chest-eR® is intended to be used by either laypeople or healthcare professionals. For instance, the device may be used by doctors/nurses, common people, trainers, etc.

In any case, the user should meet the following requirements:

- be qualified by a competent organization to operate according to the applicable BLS-D protocols (e.g., ERC or AHA guidelines);
- be trained in using *Chest-eR®* correctly;
- be informed of the hazards due to using *Chest-eR®*;
- be aware of the information contained in this User Manual.

In case of emergency, the lay person shall call professional emergency services right away.

CAUTION: Consult an available healthcare professional for any clarification about the proper use of Chest-eR® during an emergency. In any case, do not delay CPR on the patient.

1.1.4 INTENDED USE ENVIRONMENT

Chest-eR® can be used safely in all environments whose conditions respect those recommended by this User Manual.

The device is intended to be used indoors or outdoors. However, it shall NOT be used in the following environmental conditions:

- in the presence of flammable substances;
- underwater.

However, *Chest-eR®* can be used safely when exposed to drops of water thanks to the water-repellent property of the disposable cover material.

The device has not been evaluated or approved for use in locations considered hazardous according to National Electric Code standards.

For further details on the storage and operating conditions, please refer to section 7.2 *"Environmental conditions".*

Please note that the massage can be performed with an adequate depth only if the person to be resuscitated is lying on a rigid support. Otherwise, incorrect feedback could be provided.

1.2 LIMITATIONS OF USE

Chest-eR® **MUST NOT** be used if the patient shows at least one of the following conditions:

- consciousness;
- breathing;
- pulse.

The device can be used on exercise dummies for training purposes.

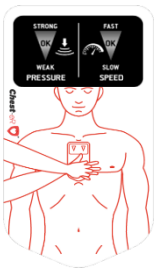
1.3 CONTRAINDICATIONS AND SIDE EFFECTS

Based on the results of the clinical evaluation, there are no substantial contraindications or side effects due to *Chest-eR®* use, provided that it is used according to the Manufacturer's recommendations included in this User Manual.

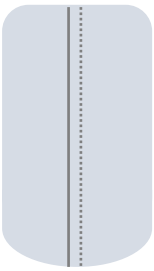
2. DESCRIPTION OF THE MEDICAL DEVICE AND ITS ACCESSORIES

Chest-eR® consists of n.1 MAIN UNIT, n.2 BATTERIES and n.2 DISPOSABLE COVERS.

Before getting started, please identify each component and ensure that your package is complete.



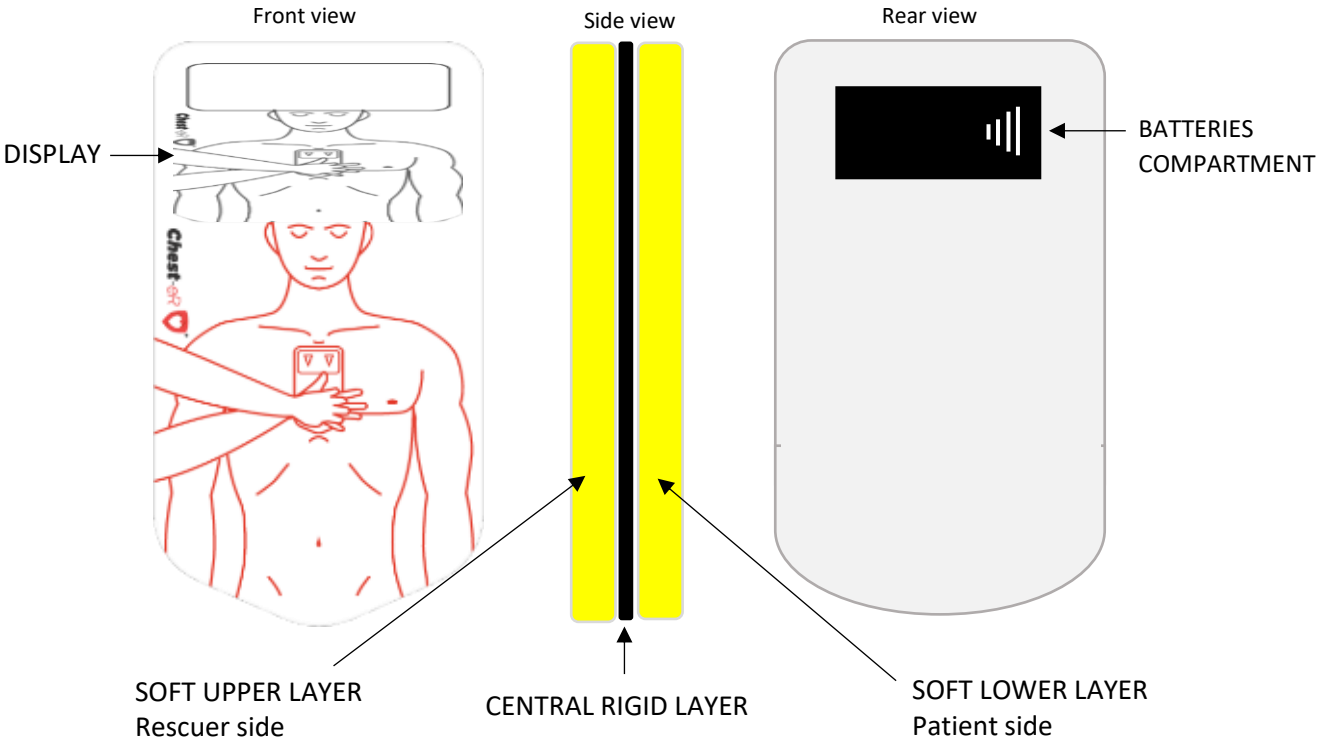
MAIN UNIT



DISPOSABLE COVER

BATTERIES

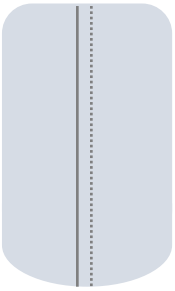
The main unit is composed of n.2 soft layers, n.1 rigid layer, n.1 display, n.1 batteries compartment.



Chest-eR® is equipped with a small display shown on the right, which provides feedback on both the PRESSURE exerted and the FREQUENCY of the compressions.

This way, even an inexperienced rescuer receives the necessary support to perform efficient and effective CPR. Please refer to section 5.1 "*Feedback interpretation*" for more information on the display.

Chest-eR® is powered by n.2 AAA BATTERIES intended for general use.



The device is provided with n.2 DISPOSABLE COVERS where the main unit should be inserted. The cover is for single use and it is intended to reduce the risk of cross-contamination as well as enhance hygiene.

PROGETTI recommends using *Chest-eR®* only in combination with covers provided by the manufacturer.

The use of accessories not recommended by PROGETTI may damage the device and affect its performance. Besides, *Chest-eR®* is not intended to be used in combination with other equipment or medical devices.

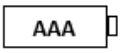
Also, please note that:

- Disposable accessories should be used once and on one patient only. Reuse may pose contamination/infection risks.
- Check accessories for damage before using them. If the accessory is damaged or worn do not use it on the patient and contact the Manufacturer or its local authorized distributor for replacement.

For any further information or request, please contact PROGETTI's technical assistance dept by sending an e-mail to service@progettimedical.com.

2.1 SYMBOLS

The following table explains the meaning of each symbol included on the device's label and its outer carton box.

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Catalogue number		CE marking
	Lot number		Non-sterile
	Manufacturing date and manufacturing country code		Manufacturer
	Type BF applied part		Waste from Electrical and Electronic Equipment - WEEE
	Alternating current		Refer to instructions for use/user manual
	AAA batteries		Keep away from sunlight
	Humidity range		Temperature range
	Keep dry		Fragile, handle with care
	Do NOT use if the package is damaged and consult the instructions for use/user manual		General warning sign
	Latex free		Unique device identifier
	Single-use: do not reuse (referred to the cover)		Medical device

3. SAFETY INFORMATION

This chapter includes a list of hazards, warnings, and caution messages related to *Chest-eR®* and its accessories. Many of these messages may be repeated elsewhere within this User Manual and/or on the equipment. For your convenience, the full list is presented below.

Our customers shall ensure that the person(s) in charge within their organization have access to information about the device, including the general safety information listed below.

3.1 GENERAL INFORMATION

Before and after using *Chest-eR®*, please ensure that the main unit is safe and in good condition (integrity of the surfaces, battery condition).

3.2 KEY

	**DANGER**	Immediate risks that could lead to serious personal injury or death of the patient and/or the user.
	**WARNING**	Unsafe conditions, risks, or behaviour that could lead to serious personal injury or death of the patient and/or the user.
	**CAUTION**	Unsafe conditions, risks or behaviour that could lead to minor personal injury, damage to *Chest-eR®* and/or loss of information.

3.3 MESSAGES

 **DANGER**	**MAIN UNIT**	*Chest-eR®* MUST NOT be used in the presence of flammable substances. The device has not been evaluated or approved for use in locations considered hazardous according to National Electric Code standards. According to the EN classification, the device shall NOT be used with flammable substances and/or air mixtures.
 **DANGER**	**MAIN UNIT**	If the user notices inaccurate feedback on the device display during use, DO NOT delay the CPR trying to reset the device: continue the CPR according to the recommended resuscitation protocol. In case of a damaged or malfunctioning device, please contact the manufacturer or its local authorized distributor.
 **WARNING**	**MAIN UNIT**	Ensure to follow all instructions and recommendations included in this User Manual.
 **WARNING**	**MAIN UNIT**	Ensure that the disposable cover adheres to *Chest-eR®* as much as possible before use to protect the device's lower layer from any infiltration of liquids or other material. DO NOT delay CPR to make the disposable cover adhere to *Chest-eR®* properly.

WARNING	**MAIN UNIT**	If a defibrillator has been connected to the patient and has started the ECG analysis, STOP using *Chest-eR®*.
WARNING	**MAIN UNIT**	The correct functioning of *Chest-eR®* cannot be guaranteed when the patient is not on a sufficiently rigid surface. The patient should lie on a rigid surface to allow adequate feedback and an effective cardiac massage.
WARNING	**COVER**	The disposable cover should be used only once and should be disposed of after use. Reuse could result in cross-contamination or infection, device performance alteration and/or patient's or operator's injury.
WARNING	**BATTERY**	It is recommended to check the battery charge before each use of Chest-eR®. The lower brightness of the LED indicators on the display compared to the normally perceived one indicates that the batteries are almost empty. Remove the batteries when they are depleted and replace them with a new pair.
WARNING	**BATTERY**	Batteries are not rechargeable. Any attempt to recharge them may result in fire or explosion.
WARNING	**BATTERY**	Do not immerse the batteries in water or any other liquid because immersion could lead to fire or explosion.
WARNING	**BATTERY**	To avoid the risk of fire and explosion, do not burn or incinerate the battery. Do not attempt to open or disassemble the battery. Do not try to short-circuit, pierce or deform the battery.
WARNING	**BATTERY**	Do not expose the battery to heat sources.
WARNING	**ENVIRONMENT (USE)**	Use of this equipment adjacent to other equipment should be avoided as it may cause improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are functioning normally.
WARNING	**ENVIRONMENT (STORAGE)**	After using *Chest-eR®,* ensure that the display is intact and clean, otherwise it will be difficult to read the visual feedback easily and correctly afterwards.
WARNING	**ENVIRONMENT (STORAGE)**	After using *Chest-eR®,* ensure that the battery compartment is closed correctly, otherwise, the batteries could shift or come out accidentally, preventing *Chest-eR®* future correct functioning.
WARNING	**ENVIRONMENT (STORAGE)**	After using *Chest-eR®,* ensure that the soft layers are properly anchored to the intermediate rigid layer. If they show signs of wear or damage, please contact the manufacturer or its local authorized distributor.

WARNING	**MAINTENANCE**	Do not remove the soft layers. Do not try to open the unit or repair/modify it without the Manufacturer's authorization. The device does NOT contain any user-repairable parts. If replacement and/or repair of *Chest-eR®* or any of its accessories is necessary, please contact the manufacturer or an authorized service centre.
WARNING	**MAINTENANCE**	Using a damaged/worn device (or accessories) may cause it to function incorrectly and may result in injury to the patient and/or the operator.
CAUTION	**CPR**	Consult an available healthcare professional for any clarification about the proper use of Chest-eR® during an emergency situation. In any case, do not delay CPR on the patient.
CAUTION	**CPR**	Aggressive or prolonged CPR may damage *Chest-eR®*. Please check that the soft and hard surfaces are in good condition (e.g. intact and not dirty) before use. DO NOT use or reuse Chest-eR® in case of visible signs of surface degradation.
CAUTION	**MAIN UNIT**	Please place *Chest-eR®* on the intact patient's skin only. If this is not possible, please reduce as much as possible the contact between *Chest-eR®* and the patient's injured skin.
CAUTION	**MAIN UNIT**	Please use the disposable cover to reduce as much as possible the contact between *Chest-eR®* and conductive fluids such as water, gel, blood or other fluids that could compromise the safety, correct functionality and/or integrity of the device.
CAUTION	**MAIN UNIT**	*Chest-eR®* should only be stored and used within the environmental condition limits specified in this User Manual.
CAUTION	**MAIN UNIT**	If *Chest-eR®* is used for CPR training activities (e.g. BLS-D training), please opt for Laerdal or Brayden mannequins.
CAUTION	**BATTERY**	DO NOT force the opening or closing of the battery compartment lid to avoid breaking the internal locking elements. Follow the instructions in section 4.2 *"Batteries insertion"* to open/close the compartment correctly.
CAUTION	**BATTERY**	Recycle or dispose of the batteries following the applicable regulations.
CAUTION	**BATTERY**	Follow all the instructions on the battery label/package.
CAUTION	**BATTERY**	Check the operating and storage conditions (temperature and humidity ranges) of newly purchased batteries and compare them to those in section 7.2 *"Environmental conditions"*. Please follow the strictest ranges.

CAUTION	**COVER**	Check that the disposable cover is in good condition (e.g. intact and not yellowed) before use.
CAUTION	**COVER**	DO NOT clean or sterilize the disposable cover trying to reuse it, but rather replace it.
CAUTION	**COVER**	Use only the cover dedicated to *Chest-eR®* or those purchased from authorized distributors. Unapproved accessories may affect the device's performance.
CAUTION	**ENVIRONMENT (STORAGE)**	DO NOT expose the soft surfaces of the main unit to sunlight. DO NOT expose Chest-eR® to temperatures above 50°C when it is on standby, out of its box, and without its disposable cover, otherwise, the material ageing would be accelerated.
CAUTION	**ENVIRONMENT (STORAGE)**	In the absence of the DISPOSABLE COVER, DO NOT expose the surfaces of the main unit to water or other liquids and substances that may penetrate and damage the material as well as the internal electronic circuit. Do not immerse any part of this product (including the battery) in water or any other liquid. Do not allow any fluids to get inside the device. Avoid spilling fluids onto the device or its accessories. Immersion or spilling onto the device may damage it, cause fire or pose risks of electric shock.
CAUTION	**ENVIRONMENT (STORAGE)**	Avoid placing weight on the top and bottom surfaces of the device for long periods when *Chest-eR®* is not used to avoid damage to the surface material.
CAUTION	**ENVIRONMENT (STORAGE)**	Although the device is designed for a wide range of usage conditions, treating the device roughly could damage it.
CAUTION	**ENVIRONMENT (STORAGE)**	The device should only be stored and used in the environmental conditions stated in this User Manual.
CAUTION	**CLEANING**	Clean and sanitize the soft surfaces of the device's main unit after each use with a soft cloth.
CAUTION	**CLEANING**	Do not use abrasive materials or strong solvents such as acetone, white spirit and/or their derivatives to clean the device.
CAUTION	**CLEANING**	Do not autoclave or sterilize the device and/or its accessories.

4. SET-UP PROCEDURE

Before using *Chest-eR®*, please ensure that the main unit is intact, with no signs of damage or deterioration.

Chest-eR® is designed to be stored in a "ready-to-use" condition. It does NOT need to be assembled or calibrated by the user.

This section describes how to prepare the device, so that if and when you need it, few steps are required to begin using the device.

Chest-eR® should be stored with batteries inserted into the main unit and a cover applied to it to ease the setting up procedure and the device operations during an emergency.

When setting up *Chest-eR®*, follow the steps described in the next paragraphs.

4.1 UNPACKING

Before unpacking, carefully inspect the packaging for signs of damage. If the package is damaged or opened prematurely, contact the carrier, the manufacturer or its authorised local distributor. If the package is intact, proceed to open it.

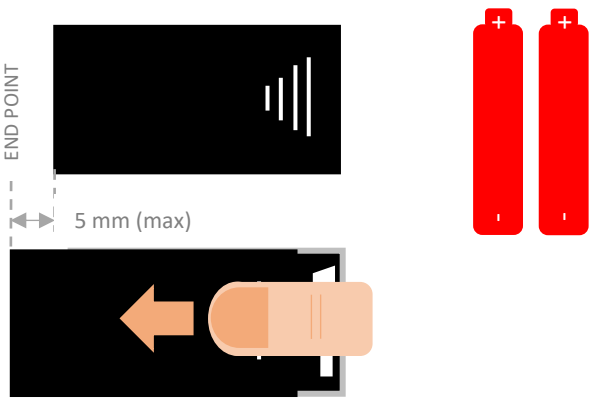
Remove *Chest-eR®* and its accessories from the carton box.

When removing the device from the box, verify that all required parts and accessories are present. Inspect *Chest-eR®* and its accessories for transport damage. If the device or any of its accessories is damaged, do not use it on the patient and contact the manufacturer or its authorized local distributor for assistance.

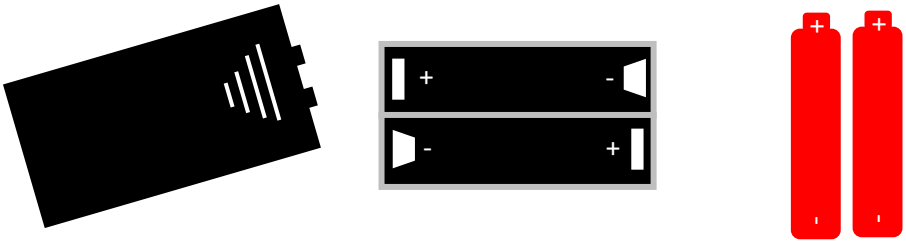
4.2 BATTERIES INSERTION

Insert the batteries into their dedicated compartment located on the rear side of the device, as explained below:

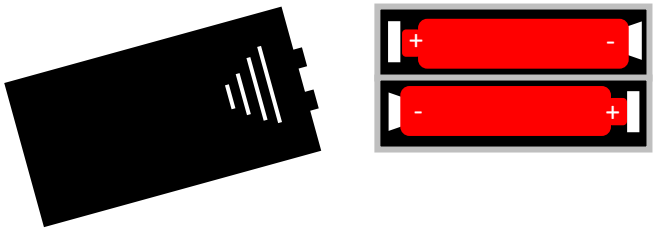
1. **BATTERY COMPARTMENT OPENING:** move the battery compartment lid to the left for no more than 5 mm ("endpoint"), as shown in the following picture;



2. **LID REMOVAL:** lift the battery compartment lid and remove it; ensure that the compartment is clean and clear from any foreign objects. If the compartment already contains a pair of batteries that should be replaced (e.g. empty), please remove them.

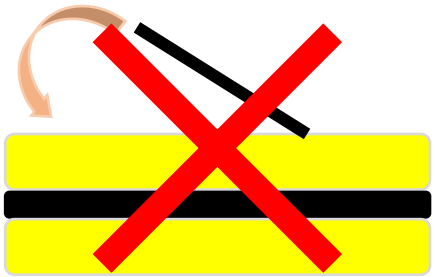


3. **BATTERIES INSERTION:** insert the batteries according to the polarity indicated in each section of the battery compartment;

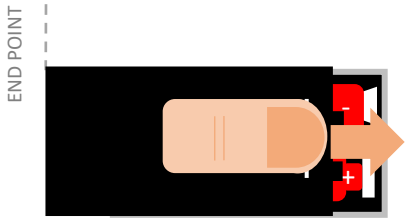


4. **LID REPOSITIONING:** place the lid starting from the “endpoint” (see point 1);

WARNING: DO NOT try to place the lid as shown below.



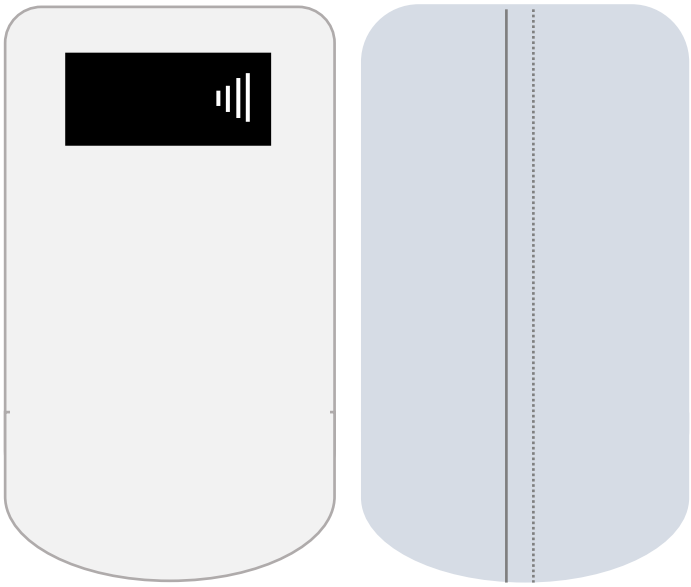
5. **BATTERY COMPARTMENT CLOSING**: slide the battery compartment lid to the right as shown in the following picture, until it clicks.



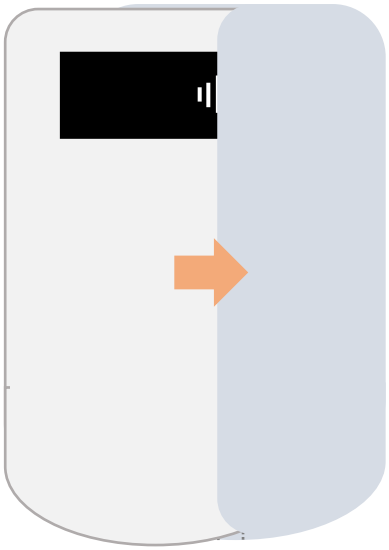
WARNING: do NOT install the battery after the expiration date printed on its label (if present). The battery is NOT rechargeable.

4.3 DISPOSABLE COVER APPLICATION

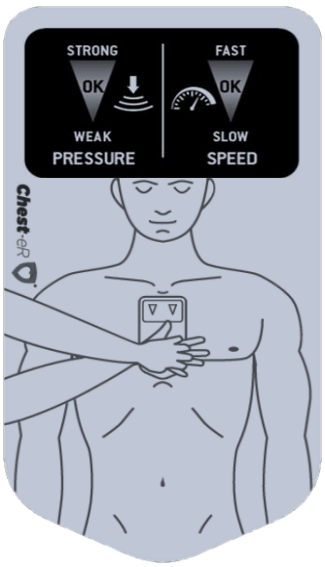
1. Make sure that the disposable cover is intact and not yellowed. Also, please ensure that it has not expired yet (expected service life of 18 months). If the cover shows deterioration or degradation signs, please do not use it and replace it with a new one.
2. Turn the disposable cover upside down because the opening is on the rear side.
   Turn the device main unit upside down so that the back faces upwards. Please refer to the following pictures.

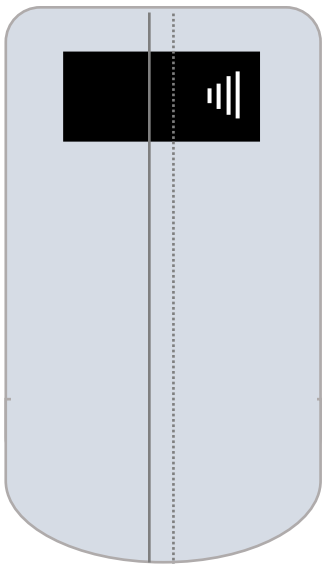


3. Insert the main unit in the disposable cover by gently keeping the right half of the cover raised (be careful to avoid breaking it);



4. The disposable cover should adhere completely to the soft surfaces of the device's main unit, covering one half at first and then the other half.
5. Lastly, please ensure that the two parts at the cover opening are well overlapped to protect the MAIN UNIT from the possible infiltration of liquids or other materials.





WARNING: do NOT use the cover twice. It is for single use ONLY and should be discarded and replaced after use.

6. The device is now ready for use.

Please, watch the video tutorial at the link below for further details on the device set-up procedure (i.e. battery insertion and disposable cover application):

https://youtu.be/idfqZizbzYg

5. CPR PROCEDURE

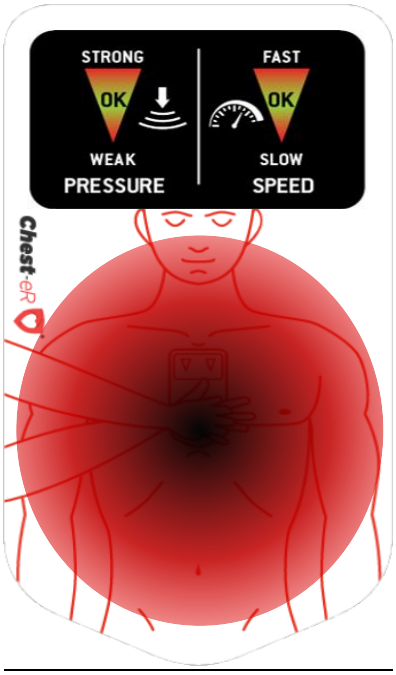
The device is designed for simple operation, allowing the operator to focus on performing an effective cardiac massage on the patient.

Intuitive visual indicators on the display guide the operator during the CPR.

The device does NOT record any data on how the cardiac massage is performed, namely compression pressure and rate.

Please follow the instructions below to use the device correctly:

1°		Once the device is ready for use, place it on its SOFT UPPER SURFACE in the middle of the patient's chest, as shown in the picture on the left. **WARNING: Do NOT use Chest-eR® on infants or neonates (patients aged < 1 year old).**
2°		Place one hand on *Chest-eR®* so that the palm is completely adherent to the SOFT UPPER SURFACE. This is meant to favour the homogenous distribution of compression forces.
3°		Place the other hand on *Chest-eR®* so that the palm is above the back of the underlying hand and the fingers are intertwined to allow the compression forces application. Make sure to keep your arms straight and position yourself vertically over the patient's chest.

4°		Start the compression-release cycles on the patient's chest. Hold firmly the contact *hand-Chest-eR®-patient's chest* during the entire procedure. Get feedback: the "PRESSURE" and "SPEED" indicators on the display change colours according to how the CPR is performed. **It is recommended to apply and maintain the pressure forces in the middle area of Chest-eR® as much as possible** (see the red area in the picture below) **to avoid the onset of lateral components of pressure forces that could interfere with the sensor or lead to incorrect pressure detection.**  Once the cardiac massage is finished, *Chest-eR®* switches off automatically after 30 seconds of inactivity.

5.1 FEEDBACK INTERPRETATION

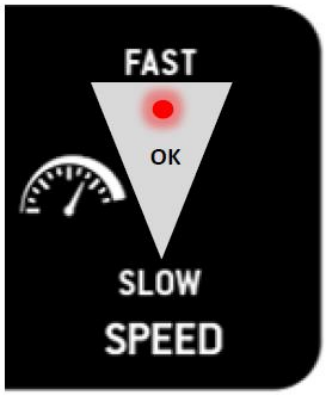
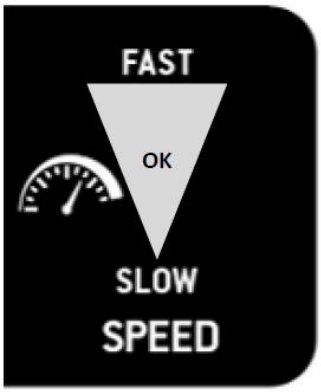
If the "PRESSURE" (DEPTH) and the "SPEED" (FREQUENCY) values are within the ranges recommended by the 2021 ERC guidelines, CPR is performed correctly and effectively. On the other hand, if either the "PRESSURE" (DEPTH) or "SPEED" (FREQUENCY) value is not within the limits recommended by the 2021 ERC guidelines, the ongoing CPR is considered incorrect and likely ineffective.

Chest-eR® provides feedback about the PRESSURE and SPEED of compressions so that the rescuer can adjust its activity in real-time, making the cardiac massage correct and effective.

The following table lists the possible feedback that *Chest-eR®* can provide during CPR.

#	DISPLAY	PRESSURE	SPEED	ACHIEVED DEPTH RANGE [cm]	ACHIEVED FREQUENCY RANGE [compressions /min]	MEANING
1		GREEN	GREEN	4.8 – 6.3 5-6 nominal	99 – 121 100-120 nominal	**CORRECT CPR**
OTHER POSSIBLE "DEPTH" RESULTS						
#	**DISPLAY**	**PRESSURE**		**ACHIEVED DEPTH RANGE [cm]**		**MEANING**
2		RED at the top		> 7		CPR **DEFINITELY NOT CORRECT** The massage depth is **much higher than 6 cm**: <u>the user must decrease the pressure exerted</u>.
3		RED at "STRONG" level Lower light intensity than case (2)		6.3 – 7.0		CPR **NOT CORRECT** The massage depth is **slightly over 6 cm**: <u>the user must decrease the pressure exerted.</u>

4		GREEN Lower light intensity than case (1)	4.5 - 4.8	CPR **CORRECT BUT CAN BE IMPROVED** The massage depth is **slightly less than 5 cm**: the user must increase the pressure exerted.
5		GREEN Lower light intensity than case (4)	4.0 – 4.5	CPR **CORRECT BUT CAN BE IMPROVED** The massage depth is **less than 5 cm**: the user must increase the pressure exerted.
6		RED at the bottom	0 – 4 cm	CPR **NOT CORRECT** The massage depth is **much less than 5 cm**: the user must increase the pressure exerted.
OTHER POSSIBLE "FREQUENCY" RESULTS				
#	**DISPLAY**	**SPEED**	**ACHIEVED FREQUENCY RANGE [compressions /min]**	**MEANING**
7		RED at the top	>151	CPR **DEFINITELY NOT CORRECT** The massage frequency is **much higher than 120 compressions/min**: the user must decrease the compression speed.

8		RED at “STRONG” level Lower light intensity than case (7)	121 - 151	CPR **NOT CORRECT** The massage frequency is **slightly over 120 compressions/min**: the user must decrease the compression speed.
9		RED at the bottom	20 - 99	CPR **NOT CORRECT** The massage frequency is **much less than 100 compressions/min**: the user must increase the compression speed.
10		TURNED OFF	<20	CPR **NOT CORRECT** The massage frequency is **way less than 100 compressions/min**: the user must increase the compression speed.

6. STORAGE AND MAINTENANCE

6.1 STORAGE

Chest-eR® should be stored in an easy-to-access place so that the user can easily find it if needed.

In general, *Chest-eR®* should be stored in a clean, dry environment at moderate temperature. It should be kept away from sunlight and handled with care.

Ensure that the environmental conditions of the storage location comply with those specified in section 7.2 *"Environmental conditions"*.

WARNING: Avoid placing weight on the top and bottom surfaces of the device for long periods when *Chest-eR®* is not used to avoid damage to the surface material.

6.2 CLEANING

The manufacturer recommends cleaning *Chest-eR®* periodically and after each use. The user should remove any dirt, contaminants or other debris.

Please follow these instructions to clean the device properly and effectively:

- The batteries should be installed while cleaning the device.
- Do NOT immerse *Chest-eR®* or any of its parts and accessories in any liquid. Do NOT allow liquids to get into the unit. Use a soft cloth to clean the main unit surfaces to avoid abrasion and damage.
- Do NOT use abrasive materials or strong solvents such as acetone or acetone-based products. Also, do NOT use hydrogen peroxide, white spirit or alcohol-based products/solutions with >5% alcohol concentration.
- Clean *Chest-eR®* main unit with a mild detergent diluted in water (5% alcohol max);

WARNING: Do NOT reuse the device and/or its accessories if they are damaged, lost integrity, or show signs of wear. Use of damaged or deteriorated devices and/or accessories may cause malfunction of the device itself and/or result in injury to the patient or operator.

CAUTION: The device and its accessories are NOT sterile. They are NOT intended to be sterilized before use. Do NOT sterilize the device and its accessories.

CAUTION: It is strictly forbidden to clean the device with acetone or white spirit which could lead to deterioration of the material composing the device surfaces.

CAUTION: DO NOT use hydrogen peroxide or alcohol-based substances/solutions with an alcohol concentration higher than 5% to clean the device. It is recommended to use water and a mild detergent (with less than 5% alcohol concentration) to clean the device if

necessary. Please limit the rubbing of the upper part as much as possible to avoid damaging the device.

6.3 MAINTENANCE

The manufacturer recommends inspecting the device periodically to ensure it is intact and ready to use for future emergencies or training purposes. The user/organization operating the device is responsible for performing the verification and the frequency such controls are carried out.

***WARNING: Chest-eR®* does NOT contain any user-repairable parts. Only technicians authorized by the manufacturer can maintain/repair it.**

Please, contact the manufacturer's technical assistance department for technical support at service@progettimedical.com.

Although *Chest-eR®* is designed to require little maintenance, some simple routine maintenance activities shall be performed regularly by a designated person to ensure the expected safety and performance of the device when needed.

The table below lists a sequence of actions that the manufacturer recommends together with their frequency as part of the maintenance routine of *Chest-eR®* to ensure its reliability.

EVERY MONTH	AFTER EACH USE	ACTION
✓	✓	Check the integrity of the device and its batteries.
✓		Check the integrity of the disposable covers.
✓		Check the expiry date of the batteries (if available).
✓		Check that the disposable cover does not exceed 18 months (i.e. its expected service life).
✓		Ensure that the battery charge is sufficient by assessing the display brightness while performing compressions. If the brightness is lower than usual, please replace the batteries.
✓	✓	Check the legibility of the *Chest-eR®* rear label.
	✓	Replace the disposable cover.
✓	✓	Clean the main unit if dirty or residues/contaminants/other particles are present on the upper and lower surfaces.

6.4 CHECKLIST

The following checklist may be used as a starting point for an Operator's Checklist aimed at documenting the periodic checks carried out on the device and recording the results of each check. The table should NOT be intended as an exhaustive list: new checks can be added according to the user's needs.

The table should be copied and filled out as recommended by the schedule in the par. 6.3 *"Maintenance"*. As each item is completed, it should be checked off.

CPR DEVICE CHECKLIST **REF: CHEST-ER®**				
LOT NUMBER				
Place				
Date	**DD-MM-YYYY**			
MAIN UNIT AND ACCESSORIES ARE CLEAN AND INTACT (NOT DAMAGED)	✔			
SPARE DISPOSABLE COVER AVAILABLE	✔			
SPARE BATTERIES AVAILABLE	✔			
BATTERIES INSERTED IN THE DEVICE'S MAIN UNIT AND STILL CHARGED ENOUGH	✔			
DISPOSABLE COVER IS STILL VALID (NOT EXPIRED)	✔			
Additional check [Please specify]	✔			
NOTES				
VERIFIER'S SIGNATURE				
Inspected by: [Signature]				

6.5 DISPOSAL AND RECYCLING

Each item should be clean and contaminant-free before being disposed of.

At the end of *Chest-eR®* expected service life (5 years), dispose of it according to the local applicable laws.

Chest-eR® is classified as electrical or electronic equipment, according to European Directive 2012/19/EU. Thus, the manufacturer recommends NOT disposing of it in municipal waste, but rather it shall be recycled appropriately as waste from electric and electronic equipment (WEEE).

The batteries must be disposed of at a dedicated collection point; if the battery is not completely discharged, there is a danger of electrical short-circuiting. In this case, insulate the electrical contacts with insulating tape before disposal.

Each new disposable cover is estimated to have an 18-month service life as long as it is handled as per this user manual. When disposing of used disposable covers, follow local clinical procedures to avoid cross-contamination/infections.

7. TECHNICAL SPECIFICATIONS

7.1 GENERAL CHARACTERISTICS

DIMENSIONS	84 x 163 x 25 (L x H x W)
WEIGHT	152 g (with batteries)
CLASSIFICATION	Class I (ref. MDR 2017/745 and subsequent amendments, annex VIII, rule 13)
SOFTWARE VERSION	4.2 The software cannot be selected because it is unique and it is uploaded into the device during its production. The user cannot access or modify the software.
APPLIED PART TYPE	BF
POWER SUPPLY	Internal; N.2 batteries: alkaline batteries, type AAA 1.5 V
BLS PROTOCOL	ERC Guidelines, 2021 edition
EXPECTED SERVICE LIFE	Main unit: 5 years; Disposable cover: 18 months; Batteries: please refer to the battery's package/label

7.2 ENVIRONMENTAL CONDITIONS

OPERATIVE CONDITIONS and STORAGE CONDITIONS (with batteries inserted)	TEMPERATURE	+4°C ÷ +50°C (if batteries have a stricter operating temperature range, please refer to that range).
	HUMIDITY	40% ÷ 70% (if batteries have a stricter operating humidity range, please refer to that range).
	ATMOSPHERIC PRESSURE	80 ÷ 101 kPa (if batteries have a stricter operating pressure range, please refer to that range).
STORAGE CONDITIONS (without batteries inserted)	TEMPERATURE	-40°C ÷ +80°C
	HUMIDITY	40% ÷ 70%
	ATMOSPHERIC PRESSURE	80 ÷ 101 kPa

8. CE MARKING AND APPLIED STANDARDS

The device bears the CE marking and it belongs to the risk class I according to the Medical Device Regulation (MDR) 2017/745.

EN 60601-1:2006+A1:2012+A12:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer

9. CONTACTS

PROGETTI S.r.l. is the manufacturer of *Chest-eR®* and it is responsible for placing it on the market.

The following table lists the manufacturer's contacts the user can refer to for any communication and information/clarification request.

ADDRESS	Strada del Rondello, 5 - 10028 TROFARELLO (TO), ITALY
WEBSITE	**www.progettimedical.com**
PHONE	+39 011 644738
GENERAL INFORMATION	info@progettimedical.com
SALES DEPT.	sales@progettimedical.com
TECHNICAL ASSISTANCE DEPT.	service@progettimedical.com
QUALITY & REGULATORY AFFAIRS DEPT.	quality@progettimedical.com

10. WARRANTY INFORMATION

10.1 COVERAGE

PROGETTI S.r.l. provides a limited warranty that the device and its accessories, whether purchased together or separately, shall be substantially free from defects in material and workmanship. PROGETTI S.r.l. limited warranty refers only to the original consumer who purchased the items from the manufacturer or one of its authorized distributors.

This limited warranty shall not be entrusted or transferred. The terms of the limited warranty in effect as of the date of original purchase shall apply to any warranty claims.

10.2 DURATION

The limited warranty covers the Chest-eR® main unit for at least two (2) years from the purchase date, except in special cases agreed with the customer. The limited warranty also covers the battery, spare parts, and accessories, including consumables. In this case, the warranty is six (6) months from the purchase date. Single-use accessories (disposable covers) shall have a limited warranty up to use or for six (6) months from the purchase date, whichever is earlier. In no event shall the limited warranty period extend past the date printed on the item, be it the battery, a spare part or an accessory, including consumables.

10.3 LIMITATIONS

This limited warranty does not cover damage of any kind resulting from but is not limited to, accidents, improper storage, misuse, alterations, unauthorized service, tampering, abuse, negligence, fire, floods, or wars. In addition, this limited warranty does not cover damage of any kind to the device or its accessories resulting from using Chest-eR® with non-approved accessories or using the accessories with non-approved medical devices. It is not guaranteed that the device and its accessories are compatible with other medical devices.

10.4 VOID WARRANTY

The limited warranty will be cancelled immediately if:

- The device or its accessories are overhauled or repaired by organizations or people not authorized by PROGETTI S.r.l.;
- no specific maintenance is carried out on Chest-eR®;
- the device is used with one or more unauthorized accessories;
- the accessories are used with an unauthorized medical device;
- Chest-eR® or its accessories are not used according to the instructions provided by PROGETTI S.r.l.

10.5 EXCLUSIVE REMEDY

At its sole discretion, PROGETTI S.r.l. shall have the right to repair or replace Chest-eR®. In the event of repair, PROGETTI S.r.l. will have the right, at its sole discretion, to repair the part with a new, repaired, identical or similar part. The choice of such a part will be at the sole discretion of PROGETTI S.r.l. In the event of replacement, the replacement part will under no circumstances have a limited warranty period that goes beyond the limited warranty period of the part being replaced. In the event of replacement, PROGETTI S.r.l. shall also have the right at its sole discretion to replace the item with a new, identical or similar item. Determination of a similar item shall be at the sole discretion of PROGETTI S.r.l. Under no circumstances shall the limited warranty period of a replacement item extend past the limited warranty period of the item it is replacing.

10.6 WARRANTED TECHNICAL SUPPORT

Only PROGETTI S.r.l., its authorized distributors or its authorized service centres can repair the device. If any unauthorized personnel repair the device during the warranty period, the warranty will be cancelled and voided. If the device does not function properly, it must be repaired immediately. If any technical faults or defects are found in the device or if there is a risk of personal injury, the device must be repaired quickly and properly by authorized personnel.

If maintenance is required, please contact PROGETTI S.r.l., its authorized distributors or its authorized service centres immediately. Prepare a summary of the problems and include the device model's name as well as its serial number, purchasing date, dealer's name, and your (customer's) details.

PROGETTI's technical assistance dept.:

PROGETTI S.r.l.

Strada del Rondello, 5
10028, Trofarello (TO)
ITALY

Phone: +39 011 644738
Email: service@progettimedical.com
Website: www.progettimedical.com

10.7 OBLIGATIONS AND WARRANTY LIMITS

The above-mentioned limited warranty expressly supersedes and excludes, to the extent permitted by the applicable state law, any other express or implied warranties, including, but not limited to, warranties of merchantability and fitness for a particular purpose. No one (including any dealer, agent or representative of PROGETTI S.r.l.) is authorized to make any representations or warranties relating to Chest-eR® or its accessories, except by referring to this limited warranty.

The exclusive remedy for any loss or damage arising from any cause shall be as specified above. PROGETTI S.r.l. shall in no event be liable for consequential or incidental damage of any kind, including, but not limited to, exemplary, special, punitive damages, or financial losses of any kind, business interruption, loss of profits or personal injury, even if PROGETTI S.r.l. has been informed of the possibility of such damage, caused in any way, by negligence or other causes, except when the applicable state law precludes such exclusions or limitations.

10.8 WARRANTY CERTIFICATE

PROGETTI S.r.l.	
Chest-eR® - WARRANTY CERTIFICATE	
This medical device is guaranteed against defects in materials and workmanship. The warranty shall not apply if the product has not been used properly, according to the instructions included in this user manual, has been damaged by accident or misuse or has been damaged as a result of modifications or repairs not carried out by PROGETTI S.r.l. This warranty does not cover any accessories. PROGETTI undertakes, at its sole discretion, to replace parts and components free of charge and under warranty in its laboratories.	
CUSTOMER	…….. ……
Chest-eR®	LOT: …….
Validity (warranty starting date)	……. / …….. / ……..
Date of delivery	……. / …….. / ……..
Invoice No.	…….
Invoice date	……. / …….. / ……..

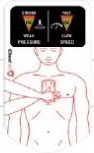
11. EU DECLARATION OF CONFORMITY

progetti® Medical Equipment Solutions

DoC-ITAENG-ChesteR Rev.0.1-2024-11

DECLARATION OF EU CONFORMITY
DICHIARAZIONE DI CONFORMITA' UE

This declaration is issued under exclusive responsibility of the Manufacturer.
Questa dichiarazione è rilasciata sotto la responsabilità esclusiva del Fabbricante.

TYPE OF MEDICAL DEVICE ***TIPO DEL DISPOSITIVO MEDICO***	**Medical device for cardiovascular system** *Dispositivo medico per apparato cardiovascolare* 
NAME OF MEDICAL DEVICE (REF) ***NOME DEL DISPOSITIVO MEDICO***	***Chest-eR®***
INTENDED USE ***DESTINAZIONE D'USO***	Device for Cardiopulmonary Resuscitation (CPR) *Dispositivo per la Rianimazione Cardio-Polmonare (RCP)*
CND CODE (ref.13/03/2018 classification) ***CODICE CND** (rif. classificazione del 13/03/2018)*	C99
BASIC UDI-DI (ref. Ann.VI part C, Reg. 2017/745) ***UDI-DI di BASE** (rif. All.VI parte C, Reg. 2017/745)*	**805414531RCP-CHESTERC6**
CLASS (ref. Ann. VIII, Reg. 2017/745) ***CLASSE** (rif. All. VIII, Reg. 2017/745)*	*I* (according to Rule 13 of Annex VIII) *(ai sensi della Regola 13 dell'Allegato VIII)*
LOT NUMBER ***NUMERO DI LOTTO***	*If you want to receive a dedicated declaration of conformity with the lot number of your device and/or an updated one, please contact Progetti S.r.l. at the email address **info@progettimedical.com**. **Per ricevere la dichiarazione di conformità dedicata contenente il numero di lotto del dispositivo e/o una dichiarazione aggiornata, si prega di contattare Progetti s.r.l. all'indirizzo e-mail **info@progettimedical.com**.*
MANUFACTURER (trademark, name, address) ***FABBRICANTE** (marchio, nome, indirizzo)*	progetti® Medical Equipment Solutions **PROGETTI S.r.l.** Strada del Rondello, 5 10028 Trofarello (TO) - ITALY
MANUFACTURER SRN ***SRN DEL FABBRICANTE***	**IT-MF-000008116**
EC MARKING ***MARCATURA CE***	CE
FIRST ISSUE OF DECLARATION OF EU CONFORMITY ***PRIMA EMISSIONE DELLA DICHIARAZIONE DI CONFORMITA' EU***	17/02/2020

We declare that the above-mentioned medical device is compliant with **Regulation (EU) 2017/745** and subsequent amendments.
Also, the product is manufactured based on **Directive 2011/65/EU** (RoHS) and subsequent amendments.

Si dichiara che il dispositivo medico sopra descritto è conforme al **Regolamento (UE) 2017/745** e ss.mm.ii.
*Inoltre, il dispositivo medico soddisfa i requisiti applicabili della **Direttiva 2011/65/UE** (RoHS) e ss.mm.ii.*

PLACE AND DATE OF ISSUE ***LUOGO E DATA DI EMISSIONE***	TROFARELLO (TO), **26/11/2024**
SIGNATURE ***FIRMA***	Dr. CESARE MANGONE PRESIDENT & PRRC

PROGETTI S.r.l.
Strada del Rondello, 5 - 10028 Trofarello (Torino) - Italy
Tel. +39 011 644 738 - Fax +39 011 645 822
info@progettimedical.com - **www.progettimedical.com**
P.IVA IT06367590012 - C.F. 10213970154 - Capitale Sociale € 100.000,00

Chest-eR

EUROPEAN RESUSCITATION COUNCIL
GUIDELINES 2021

PROGETTI S.r.l.
Strada del Rondello, 5
10028 Trofarello (TO)
ITALY