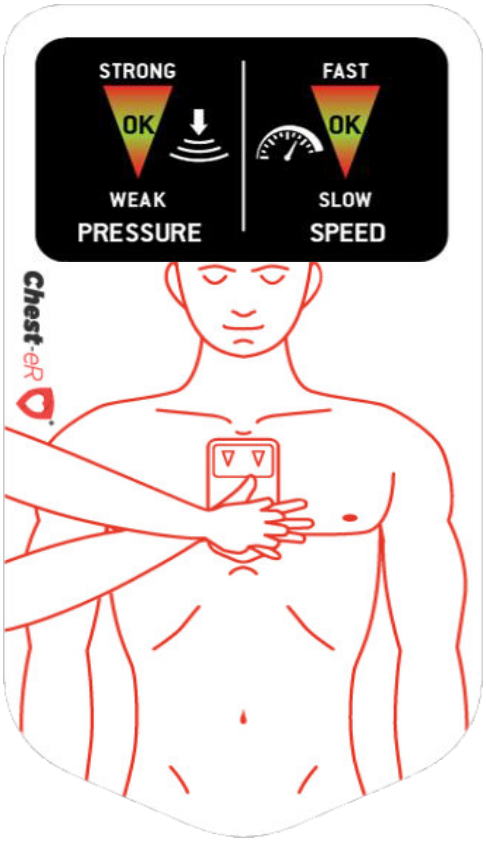
INSTRUCTIONS FOR USE

CPR DEVICE

Chester-eR®

TD2.2-ENG-ChesteR Rev.1.0-2023-06

ENG



EUROPEAN RESUSCITATION COUNCIL
GUIDELINES 2021

CE

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

Rev. 1.0
2023/06

Thank you for chosing *Chest-eR*®.

***Chest-eR*®** is a medical device external cardiac compression, conceived to improve the quality of cardiac massage and designed to reduce the incidence of internal injuries.

It is an intuitive device that is small, easy-to-use, compact and light.

Before using ***Chest-eR*®**, please read these instructions for use carefully because they contain the instructions, procedures, and maintenance information for the safe use of ***Chest-eR*®**.

⚠ **IMPORTANT NOTICE**

ONLY PERSONNEL AUTHORISED BY PROGETTI® CAN PERFORM EXTRAORDINARY MAINTENANCE ON THE DEVICE.

***Chest-eR*® SHOULD BE USED ACCORDING TO THE INSTRUCTIONS SPECIFIED IN THESE INSTRUCTIONS FOR USE.**

To ensure the device safety and reliability, use only the accessories recommended by PROGETTI®.

For further information, please contact PROGETTI S.r.l. Service Dept. by sending an email to **service@progettimedical.com** or by calling the phone number **+39 011 644 738**.

Disclaimer

PROGETTI S.r.l., as manufacturer of the Chest-eR medical device, is responsible for its safety and performance during the expected life of the product. If the customer is unable to demonstrate compliance with the use, maintenance and conservation provisions contained in this manual, PROGETTI S.r.l. will not be held responsible for the safety and performance of Chest-eR.

PROJECTS S.r.l. declines all responsibility for any accidental damage caused to the device during transport to the customer's site or during use of the device. PROGETTI® cannot be held responsible a priori for any errors contained in this document or for accidental damage or consequences related to the use or performance of the device.

PROGETTI S.r.l. is available to the customer for any further information.

Declaration

PROGETTI S.r.l. owns the copyright of this manual and is also authorized to treat this manual as a confidential document. This manual is intended solely for the use, maintenance, and repair of the product; therefore, it cannot be published by others.

The manual contains proprietary information protected by copyright laws; we reserve the copyright. No part of this manual may be photocopied, xerographed or translated into other languages without the written approval of PROGETTI S.r.l.

The information contained in this document may be subject to change without notice.

Limited warranty

The "Limited Warranty" provided with PROGETTI® products is the one and only warranty relating to the product itself.

Useful contacts

- **COMPANY – phone. +39.011.644.738, e-mail info@chest-er.com**
- **SALES DEPT. – sales@progettimedical.com**
- **SERVICE DEPT. – service@progettimedical.com**
- **QUALITY & REGULATORY DEPT. – quality@progettimedical.com**
- **WEBSITE - www.chest-er.com**

For continuous improvement, the Manufacturer welcomes any opinion or suggestion from Customers regarding the device and/or this user manual. In case, contact the Quality & Regulatory Affairs Dept. of PROGETTI S.r.l. by sending an e-mail to quality@progettimedical.com.

Please report any incident that has occurred in relation to the medical device by sending an email to the addresses quality@progettimedical.com and info@progettimedical.com.

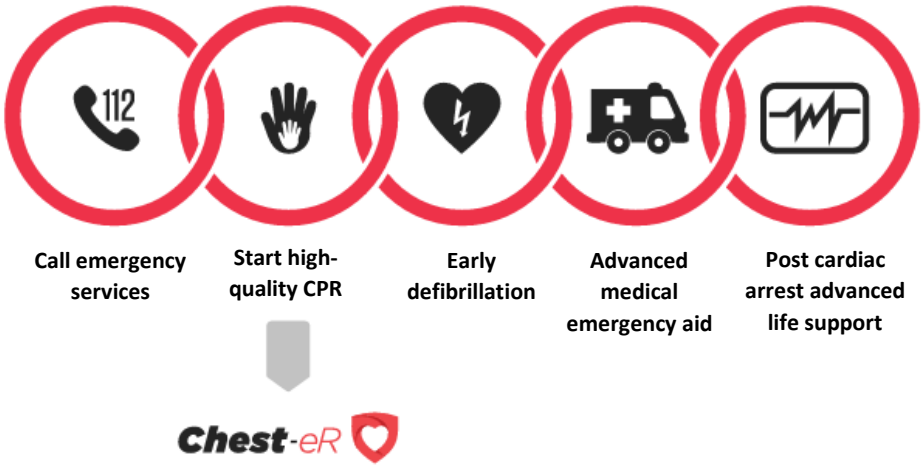
SUMMARY

1. DESCRIPTION OF Chest-eR®

Chest-eR® is a medical device intended for use in the CPR procedure (Cardio-Pulmonary Resuscitation) in order to:

- improve the **quality** of cardiac massage by providing feedback to the rescuer performing CPR;
- improve the **safety** of cardiac massage for both the rescuer and the patient.

With reference to the "survival chain" illustrated below, *Chest-eR®* is intended to be used in the second ring.



The "***European Resuscitation Council Guidelines 2021: Basic Life Support***" recommends that if a bystander recognises **Cardiac Arrest (CA)** in a person, they must intervene by activating the "survival chain" early. In more detail, after the CA has been identified after a rapid assessment of the **state of unconsciousness** (the victim does not respond) and then the **state of non-normal breathing**, the **BLS-D** (*Basic Life Support-Defibrillation*) procedure must be carried out.

The ring in the "survival chain" that concerns the use of *Chest-eR®* is the one related to *Cardio-Pulmonary Resuscitation* (CPR). The latter consists of a cardiac massage characterised by compression-release sequences on the chest of the CA victim, of which ERC 2021 recommends 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) or in a child patient (1÷18 years old).

Chest-eR® is therefore designed on the one hand to **guide the rescuer** to comply with the above recommendation to perform efficient CPR in terms of "depth" and "frequency", and on the other hand to **reduce the incidence of internal injuries in the victim** (particularly in the ribs and sternum) due to the application of excessive or poorly distributed impulsive forces.

Chest-eR® is an innovative system protected by an exclusive patent that combines:

- the use of latest-generation non-Newtonian materials, capable of dissipating the impact energy related to excessively violent chest compressions;
- the special internal triple-layer structure, capable of **reducing dangerous stresses** produced by the incorrect application of force by the rescuer and of redistributing excessive forces over the entire area of the device;
- the use of sophisticated algorithms which, thanks to a luminous **electronic feedback system**, provide indications for correctly performing cardiac massage[1], reducing both the probability of excessive compressions and of ineffective massage;
- a disposable cover, which guarantees hygiene and prevents the risk of infections.

Chest-eR® is an intuitive, easy-to-use, compact, and lightweight device that can be powered by electric batteries of daily use.

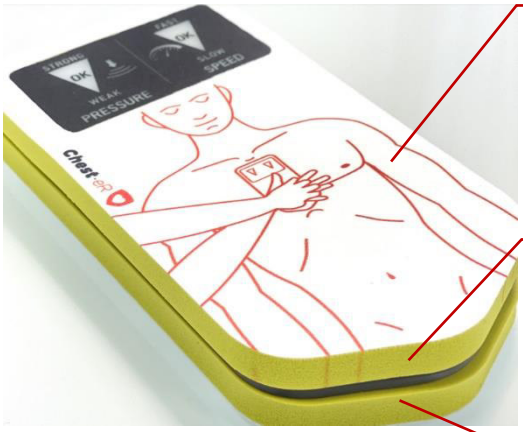
Furthermore, the device is always ready for use:

once *Chest-eR®* is correctly positioned on patient's chest, with the help of its visual indications, it automatically turns on as soon as the compressions start. This is considerably more comfortable for the rescuer, who can focus on the correct rhythm and depth of the massage.

The soft surfaces of *Chest-eR®* dissipate up to 90% of the impact energy when subjected to the application of the impulsive force, thanks to the reorganization of the molecules that constitute the material.

The *Chest-eR®* surface allows the uniform distribution of forces in the lower sternum area and through the combined action of the soft non-Newtonian elastomer coating, capable of adapting to the shape of the chest, avoiding excessive stress concentrated on any protruding bones.

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



Foam layer
(It dissipates impulsive forces and protects the hands of the rescuer)

Rigid central layer
(It distributes forces)

Foam layer
(It dissipates impulsive forces and adapts to the shape of the chest)

Chest-eR® is equipped with a small display as illustrated below, which provides feedback on both the PRESSURE exerted and the FREQUENCY of the compressions. In this way, even an inexperienced rescuer receives the necessary support to perform efficient and effective CPR.

To activate the electronic feedback system, simply place the device on the chest of the patient to be reanimated (or any exercise dummy) and start performing compressions.

Once the cardiac massage is finished, *Chest-eR*® switches off automatically after 30 seconds without use.

Chest-eR® is equipped with sensors to provide feedback to the rescuer, becoming a guide for correct heart massage.

The adequacy of the depth of the message is satisfied **only if** the person to be revived is resting on a rigid support, otherwise incorrect feedback could be provided.

Chest-eR®'s design considers the impact on the operator, opting for the best handle shape, the most comfortable coatings to the touch, and the most intuitive graphics.

The rescuer performing the cardiac massage can suffer injuries to their hands and above all to their skin during the operation, especially if devices of rigid material are interposed between the hand palm and the patient's chest.

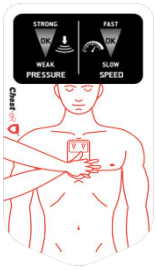
This is a risk factor if the rescuer's hands touch infected blood afterwards, as well as a discomfort that could distract the rescuer from performing CPR correctly.

The structure of *Chest-eR*® device improves the comfort of the rescuer and reduces the risk of injury to the latter.

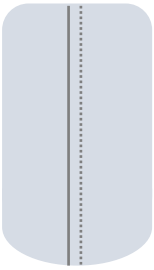
Another characteristic required for the *Chest-eR*® device is the resistance to tearing, to avoid gradual wear as the massage proceeds.

2. DEFINITIONS

- ***Chest-eR®*:** medical device consisting of n.1 MAIN UNIT, n.2 BATTERIES (accessories) e n.1 DISPOSABLE COVER (accessory);



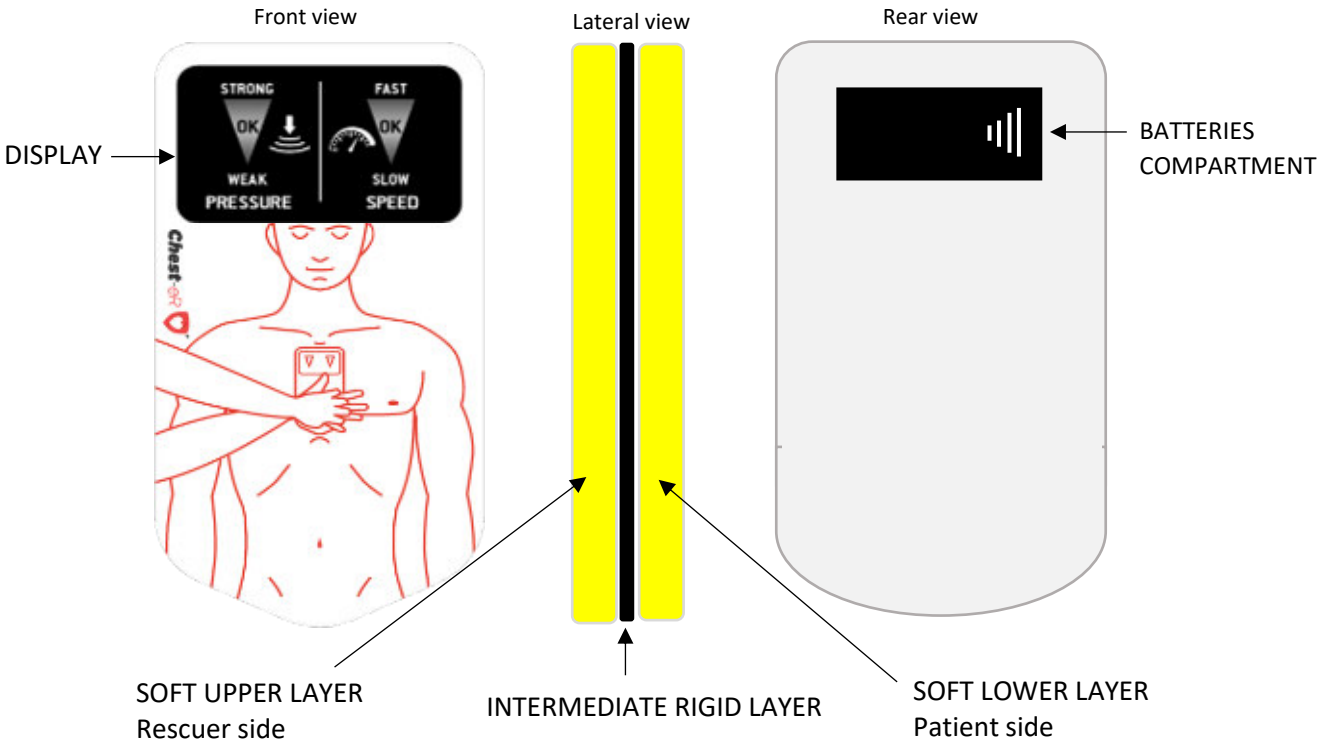
MAIN UNIT



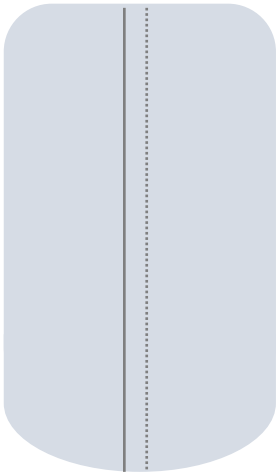
DISPOSABLE COVER

BATTERIES

- **MAIN UNIT:** part of *Chest-eR®* consisting of n.2 soft layers, n.1 rigid layer, n.1 display, n.1 batteries compartment, n.1 label.
  It is intended for "*MULTIPLE-PATIENT, MULTIPLE-USE*" (ref. ISO 20417:2021)



- **DISPOSABLE COVER:** accessory meant to cover the MAIN UNIT**.** It is for "*SINGLE-USE*" (ref. ISO 20417:2021).



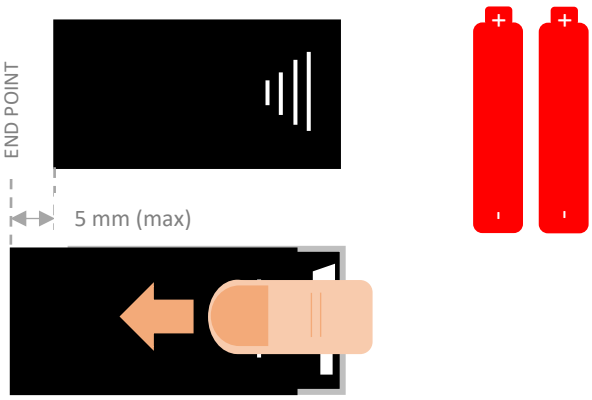
- **CPR**: *Cardio-Pulmonary Resuscitation*
- **BLS-D**: *Basic Life Support-Defibrillation*

3. PREPARATION FOR USE OF Chest-eR®

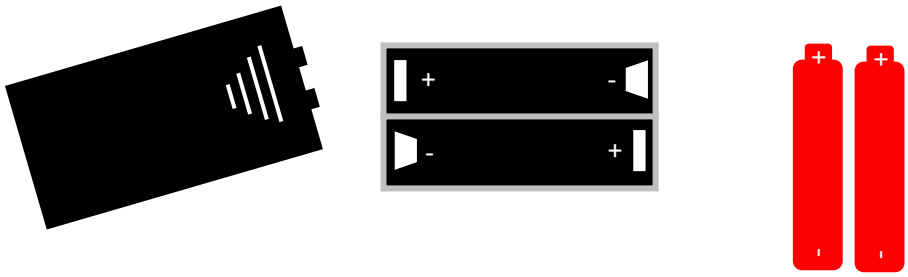
ATTENTION: before preparing Chest-eR® for use, make sure that the device is intact and that its surfaces show no signs of damage or degradation.

3.1 BATTERIES INSERTION

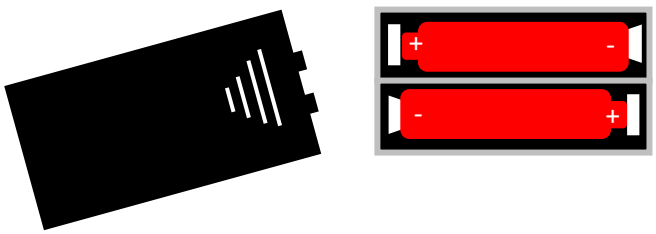
1. **BATTERIES COMPARTMENT OPENING** - move the battery compartment cover to the left, no more than 5 mm (“end point”), as showed in the following figure;



2. **COVER EXTRACTION** - lift the battery compartment cover (using the fingers of the other hand) and remove it;

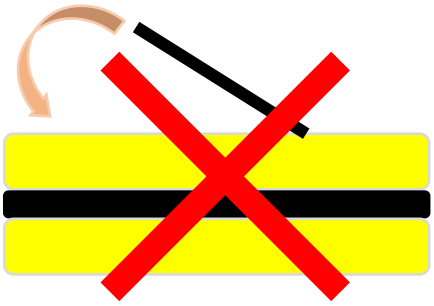


3. **BATTERIES INSERTION** - insert the batteries according to the polarities indicated in each section of the battery compartment;

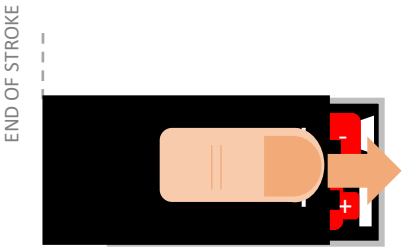


4. **BATTERIES COMPARTMENT COVER RE-INSERTION** - reposition the cover starting from the “end point” (referred to in point 1);

ATTENTION: DO NOT try to reposition the cover as shown below.

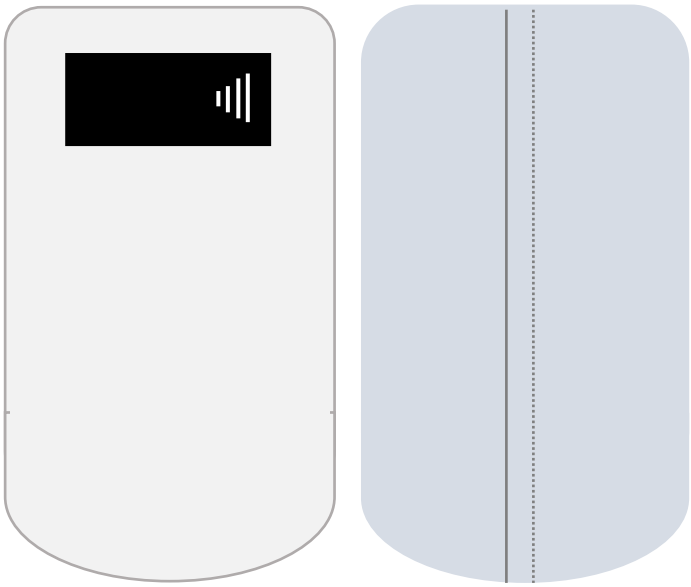


5. **BATTERIES COMPARTMENT CLOSING** - move the battery compartment cover to the right (horizontally) as shown in the following picture, making sure the battery compartment has been closed correctly (if closed correctly a “click” is heard).

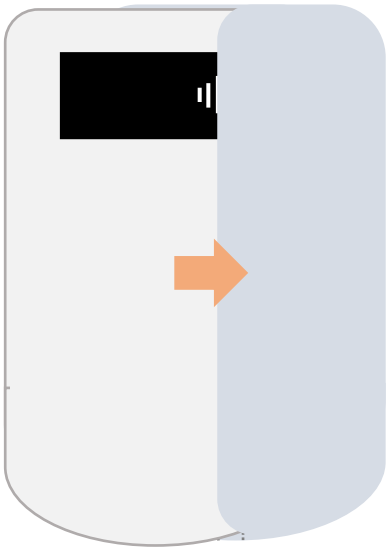


3.2 DISPOSABLE COVER APPLICATION

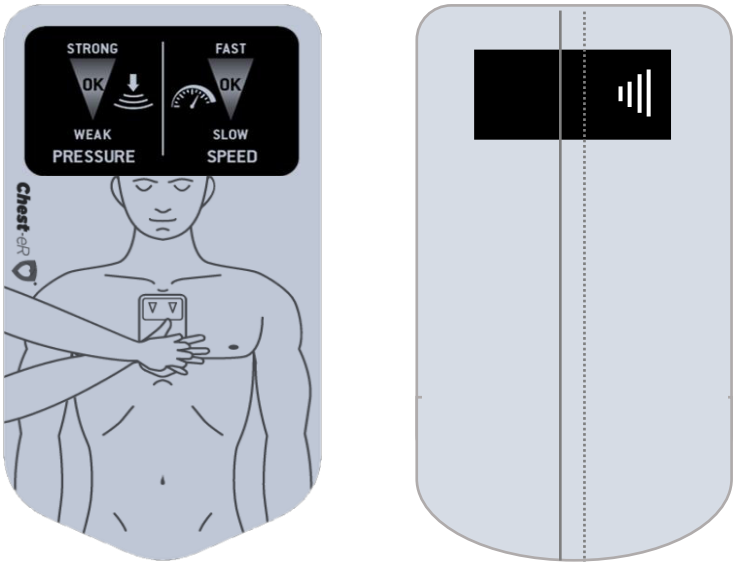
1. After making sure of the integrity of the DISPOSABLE COVER, face upwards the back of the MAIN UNIT and the opening of the DISPOSABLE COVER, as shown in the following picture;



2. Insert the MAIN UNIT in the DISPOSABLE COVER, gently keeping the right half of the disposable cover raised (be careful to avoid breaking the cover);



3. Adhere each point of the disposable cover to the soft surfaces, covering first one half and then the other half, until the MAIN UNIT is covered. Also make sure that the two parts of the cover opening are well overlapped, to protect the MAIN UNIT from the possible infiltration of liquids or other material.



ATTENTION: The disposable cover used, as such, must be replaced with a new one after each use.

Please, watch the video tutorial at the link below for further information on the operations to be performed to prepare Chest-eR® prior to use (i.e. inserting batteries and applying the disposable cover):

https://youtu.be/idfqZizbzYg

4. DANGERS, WARNINGS AND CAUTIONS

This chapter contains a list of recommendations concerning *Chest-eR®*.

KEY

"DANGER"	**Immediate risks that could lead to reversible or irreversible injury to the user or patient.**
"WARNING"	Unsafe conditions, risks or behaviours that could lead to reversible or irreversible injury to the user or patient.
"CAUTION"	Unsafe conditions, risks or behaviours that could lead to reversible injury, damage to *Chest-eR®* and/or to its accessories or loss of information.

4.1 BATTERIES

WARNING

It is recommended to check the batteries charge before each use of Chest-eR®. Lower brightness of the LEDs (relating to the indicators on the display) compared to the normally perceived one is an indicator that the batteries are close to exhaustion. Remove the batteries when they run out and replace them with a new pair.

CAUTION

DO NOT insert the batteries after their expiration date.

CAUTION

DO NOT force the opening or closing of the battery compartment cover more than necessary, to avoid breaking the internal locking elements. Follow the instructions for correct opening or closing.

CAUTION

DO NOT attempt to recharge, short-circuit, pierce, or deform the supplied batteries.

CAUTION

DO NOT expose batteries to heat sources.

CAUTION

The batteries supplied with *Chest-eR®* **are not** rechargeable. Any attempt to recharge them could lead to dangers.

CAUTION

When the user purchases new batteries, it's recommended to check the operating temperature range of the batteries and comparing them with expected environmental temperature range when using *Chest-eR®*.

4.2 DISPOSABLE COVER

WARNING

DO NOT reuse the disposable cover if already used or if there is any reason to believe that it has already been used or stored incorrectly.
DO NOT use the disposable cover if It shows any sign of damage.

CAUTION

Check that the disposable cover is in good condition (e.g. intact and not yellowed) before use.

CAUTION

DO NOT clean or sterilize the disposable cover trying to reuse it, but rather replace it in case *Chest-eR®* must be prepared for a new use.

CAUTION

Use only the dedicated disposable cover for *Chest-eR®,* recommended and supplied by PROGETTI®.

4.3 MAIN UNIT

STORING

WARNING

At the end of each use of Chest-eR®, make sure that the **display** is intact and clean, otherwise it will be difficult to read the visual feedback easily and correctly

WARNING

At the end of each use of Chest-eR®, make sure that the **batteries compartment** is closed correctly, otherwise the batteries could shift and damage the correct functioning of Chest-eR® for subsequent use.

WARNING

At the end of each use of Chest-eR®, make sure that the soft layers are properly **anchored** to the intermediate rigid layer.

CAUTION

DO NOT expose the soft surfaces of the main unit to **sunlight** and **environmental temperatures** above 50°C when Chest-eR® is in stand-by out of its packaging and without disposable covers, otherwise the ageing of the material would be accelerated.
Check that the **soft and hard surfaces** are in good conditions (e.g. intact and not dirty) before use.
DO NOT use or reuse of Chest-eR® if there is any sign of surface degradation.
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 electronics.

CAUTION

CAUTION

CAUTION

Avoid placing weight on the top and bottom surfaces of the device for long periods of time when *Chest-eR®* is not in use.

CLEANING

CAUTION

It's recommended using a mixture of **water and alcohol** to wash the soft surfaces of the main unit, when deemed necessary.

CAUTION

DO NOT substances such as **acetone and white spirits** to wash the soft surfaces of the main unit, otherwise the material would deteriorate.

4.4 Chest-eR® IN USE

DANGER

Chest-eR® **MUST NOT** be used in presence of **flammable substances**.

DANGER

If the user encounters faults relating to the 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 device defect or malfunctioning, please contact the manufacturer.

WARNING

Use *Chest-eR®* only as indicated in this User Manual.

WARNING

DO NOT perform corrective maintenance on *Chest-eR®* without the intervention of qualified personnel from PROGETTI®, except in cases where it corresponds to duly indicated operations, described among the procedures of this User Manual.

WARNING

Adhere the **disposable cover to** *Chest-eR®* as much as possible before use, to protect the lower soft surface of *Chest-eR®* from any infiltration of liquids or other material.
However, **do not** delay CPR manoeuvres to adhere the disposable cover to *Chest-eR®* properly.

WARNING

Stop using *Chest-eR®* when it begins the ECG analysis, after the defibrillator has been placed and positioned on the patient.

WARNING

The correct functioning of *Chest-eR®* cannot be guaranteed when the patient is not on a sufficiently rigid surface for an effective cardiac massage.

CAUTION

DO NOT immerse any part of *Chest-eR®* in **water or other liquids**. Avoid possible spillage of fluids into the device.
Pouring liquids or fluids on *Chest-eR®* could compromise its functionality.

CAUTION

Reduce as much as possible the contact between *Chest-eR®* and the patient's **injured skin**;
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

Chest-eR® should only be used within the environmental condition limits specified in this section.

CAUTION

Handle *Chest-eR®* with care*:* treating it roughly could damage it.

CAUTION

In the event that *Chest-eR®* is used in CPR training activities (eg BLS-D training), it is recommended to use it on Laerdal or Brayden mannequins.

4.5 DEVICE STORAGE

When batteries are inserted, store *Chest-eR*® in an environment that complies with the following condition ranges:

- **Temperature**: **+4°C ÷ + 50°C**
- **Humidity**: **40 ÷ 70%**

Otherwise, the ageing process of the material would be accelerated.

The manufacturer estimates a service life of **5 years** for the MAIN UNIT and **18 months** for each COVER (if new), as long as the device is handled according to the instructions of this user manual.

CAUTION

It is recommended not to use the device if it shows signs of deterioration or damage or if it is not intact.

4.6 CLEANING AND MAINTENANCE

The possible maintenance activities on Chest-eR® are the following:

- **Cleaning of the main unit** (by the user), before every use of the device and if necessary, when dirt or residues are detected on its surface;
- **Batteries replacement** (by the user), when the display brightness is low;
- **Replacement of the disposable cover** (by the user), when it has already been used or it shows anomalies before use.

CAUTION

It is strictly forbidden to wash the device with acetone and white spirits, which could lead to deterioration of the material that constitutes the device.

CAUTION

DO NOT use hydrogen peroxide or alcohol-based substances with an alcohol concentration greater than 5% to clean the device.

It is recommended using water and a mild detergent (with less than 5% alcohol concentration) to wash the device if necessary and limit the rubbing of the upper part as much as possible.

5. INTENDED USE

5.1 INTENDED USERS

Chest-eR® is intended to be used by both **"healthcare"** personnel **(not-lay)** and **"not-healthcare" (lay)** personnel, and in particular by:

- rescuers;
- hospital staff;
- ordinary people;
- trainers.

CAUTION

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

5.2 INTENDED CLASS PATIENTS AND ADDRESSED PATHOLOGICAL CONDITIONS

Chest-eR® is intended to be used on **adult patients** (> 18 years – ref. *ERC Guidelines 2021*) and **child patients** (from 1 to 18 years – ref. *ERC Guidelines 2021*) if the patient shows the typical signs of **cardiac arrest**, that are:

- **non-response to stimuli (unconsciousness)**;
- **not breathing or breathing abnormally[2].**

WARNING

Chest-eR® is **NOT** intended to be used on **newborns** (< 1 years - ref. *ERC Guidelines 2021*).

5.3 INTENDED USE ENVIRONMENT

Chest-eR® can be safely used in any environment as long as its conditions respect the recommendations issued by the Manufacturer in this User Manual.

In addition, *Chest-eR®* can be safely used when exposed to drops of water thanks to the water-repellent property of the material that constitutes its DISPOSABLE COVER.

5.4 RE-CYCLING

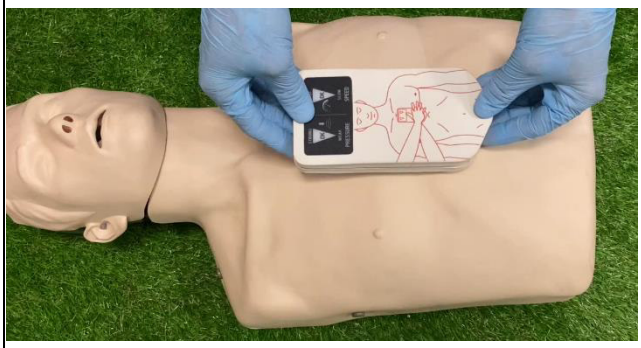
At the end of their service life, it is recommended to properly dispose of Chest-eR® and its dedicated accessories according to the national laws in force on WEEE (Waste Electrical Electronic Equipment). For any questions regarding the device disposal, please contact the Manufacturer.

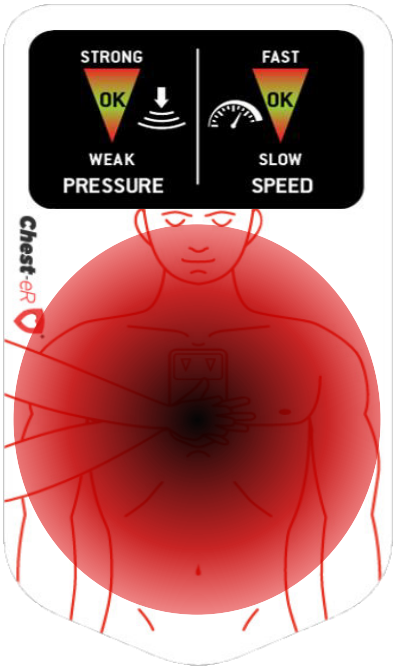
[2] *European Resuscitation Council Guidelines 2021: Basic Life Support. Resuscitation.*

6. TECHNICAL SPECIFICATIONS

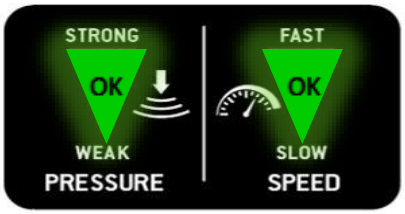
CLASSIFICATION	Class I (ref. MDR 2017/745 and subsequent amendments, annex VIII, rule 13)
SOFTWARE VERSION	4.2
TYPE OF APPLIED PART	BF
MAX LENGTH	16.3 cm
MAX WIDTH	8.4 cm
MAX DEPTH	2.5 cm
POWER SUPPLY	Internal power supply N.2 batteries: type AAA 1.5V
RAW MATERIALS	• Foam (SOFT UPPER AND LOWER LAYERS) • Acetal Resin (RIGID INTERMEDIATE LAYER)
WEIGHT	152 g (batteries included)
STORAGE TEMPERATURE RANGE	+4°C ÷ +50°C (if the storage temperature limits indicated in the battery instructions are more strict, refer to that range).
STORAGE HUMIDITY RANGE	40% ÷ 70%
OPERATING TEMPERATURE	+4°C ÷ +50°C (if the operating temperature limits indicated in the battery instructions are more strict, refer to that range).

7. APPLICATION AND INTERPRETATION

1°		After covering the MAIN UNIT with its DISPOSABLE COVER, place it on its SOFT UPPER SURFACE in the middle of the patient's chest, as shown in the picture on the left.
2°		Place one hand on *Chest-eR®* as shown in the picture, so that the palm is completely adherent to the SOFT UPPER SURFACE (to favor the homogenous distribution of the compression force).
3°		Place the other hand on *Chest-eR®* as shown in the picture, so that the palm is above the back of the underlying hand and the fingers are intertwined (to allow the application of the compression force). Make sure to keep your arms straight and position yourself vertically over the patient's chest.

4°		Start the compression and release cycles on the patient's chest. Hold firmly the contact between *hand-Chest-eR®-chest* during the entire duration of the manoeuvre. Observe the feedback from *Chest-eR®*, i.e. monitor the colours of the "PRESSURE" and "SPEED" indicators of the display. **It is recommended to apply and maintain the pressure force in the middle as much as possible (**see the red area in the picture below**) to avoid the onset of lateral components of the pressure force that could cause interference on the sensor or incorrect pressure detection.** 

CPR is performed in the right way if the "**PRESSURE**" **(DEPTH)** value and the "**SPEED**" **(FREQUENCY)** value are within the recommended ranges set in the ERC 2021 guidelines. So, *Chest-eR®* provides feedback about **PRESSURE** and **SPEED** compressions performed by the user. See the case shown in the following table.

CASE	DISPLAY	"PRESSURE"	"SPEED"	ACHIEVED DEPTH [cm]	ACHIEVED FREQUENCY [compressions/min]	MEANING
1		GREEN	GREEN	4.8 – 6.3 5-6 nominal	99 – 121 100-120 nominal	**CORRECT CPR**

On the other hand, if one of the two variables "**PRESSURE**" **(DEPTH)** or "**SPEED**" **(FREQUENCY)** is not within the limits recommended by the ERC 2021 guidelines, the CPR in progress is considered incorrect. Please, take a look at the cases listed in the following table.

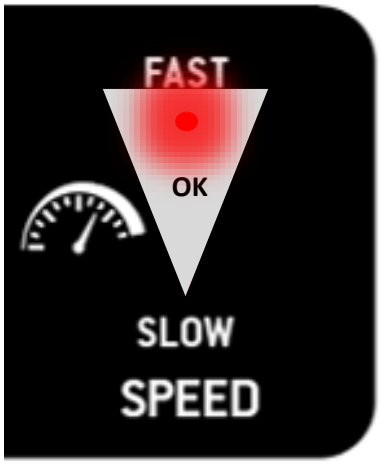
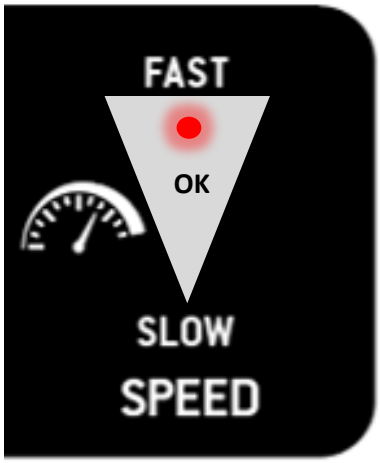
OTHER POSSIBLE "DEPTH" RESULTS

CASE	DISPLAY	DEPTH "PRESSURE"	DEPTH ACHIEVED [cm]	MEANING
2		RED at the top	> 7	CPR **DEFINITELY NOT CORRECT** The depth of the massage is **much higher than 6 cm**: <u>the user must decrease the pressure exerted</u>.

CASE	DISPLAY	DEPTH "PRESSURE"	DEPTH ACHIEVED [cm]	MEANING
3		RED at "STRONG" level Lower light intensity than case (2)	6.3 – 7.0	CPR **NOT CORRECT** The depth of the massage is **just 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 depth of the massage is **slightly less than 5 cm**: <u>the user must increase the pressure exerted</u>.

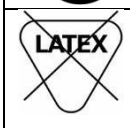
CASE	DISPLAY	DEPTH "PRESSURE"	DEPTH ACHIEVED [cm]	MEANING
5		GREEN Lower light intensity than case (4)	4.0 – 4.5	CPR **CORRECT BUT CAN BE IMPROVED** The depth of the massage is **slightly less than 5 cm**: the user must increase the pressure exerted.
6		RED at the bottom	0 – 4 cm	CPR **NOT CORRECT** The depth of the massage is **much less than 5 cm**: the user must increase the pressure exerted.

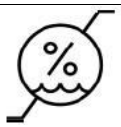
OTHER POSSIBLE "FREQUENCY" RESULTS

CASE	DISPLAY	FREQUENCY "SPEED"	FREQUENCY ACHIEVED [compressions/min]	MEANING
7		RED at the top	>151	CPR **DEFINITELY NOT CORRECT** The frequency of the massage is **much greater than 120 compressions/min**: the user must decrease the speed exerted.
8		RED at the top Lower light intensity than case (7)	121 - 151	CPR **NOT CORRECT** The frequency of the massage is **just over 120 compressions/min**: the user must decrease the speed exerted.
9		RED at the bottom	20 - 99	CPR **NOT CORRECT** The frequency of the massage is **much less than 100 compressions/min**: the user must increase the speed exerted.

CASE	DISPLAY	FREQUENCY "SPEED"	FREQUENCY ACHIEVED [compressions/min]	MEANING
10		TURNED OFF	< 20	CPR **NOT CORRECT** The frequency of the massage is **much less than 100 compressions/min**: the user must increase the speed exerted.

8. USED SYMBOLS

SYMBOL	MEANING
	Device Identification
	Lot Number
	Manufacturer Identification
	Manufacturing Date and code of the Manufacturing COuntry
	Type BF applied part
	Obligation of reading the Instructions for Use prior use
	Follow local regulations regarding disposal or recycling of the device (including batteries)
	Warning
	CE mark
Cover is 	Cover is disposable (not reusable)
	The device does not contain latex
	The device is not sterile

SYMBOL	MEANING
	Direct current
	AAA batteries required
	Temperature range for correct storage (on the packaging)
	Humidity range for correct storage (on the packaging)
	Do not use if the packaging is damaged and consult the instructions for use (on the packaging)

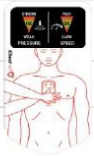
9. EU DECLARATION OF CONFORMITY

progetti® Medical Equipment Solutions

DoC-ITAENG-ChesteR Rev.0.0-2023-06

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 cardiocircolatorio* 
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 (ref. art.31, Reg. 2017/745) ***SRN DEL FABBRICANTE*** *(rif. art. 31, Reg. 2017/745)*	**IT-MF-000008116**
EC MARKING (ref. Reg. 2017/745) ***MARCATURA CE*** (rif. *Reg. 2017/745*)	CE
FIRST ISSUE DATE OF DECLARATION OF EU CONFORMITY ***DATA DI 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**, amended by Regulation (EU) 2020/561 of 23/04/2020 and Regulation (EU) 2023/607 of 15/03/2023.

*Si dichiara che il dispositivo medico sopra descritto è conforme al **Regolamento (UE) 2017/745**, modificato dal Regolamento (UE) 2020/561 del 23/04/2020 e dal Regolamento (UE) 2023/607 del 15/03/2023.*

PLACE AND DATE OF ISSUE ***LUOGO E DATA DI EMISSIONE***	TROFARELLO (TO), **04/06/2023**
SIGNATURE ***FIRMA***	Dr. CESARE MANGONE PRESIDENT & PRRC

Chest-eR®

EUROPEAN RESUSCITATION COUNCIL GUIDELINES 2021

PROGETTI S.r.l.
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ITALY

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www.chest-er.com

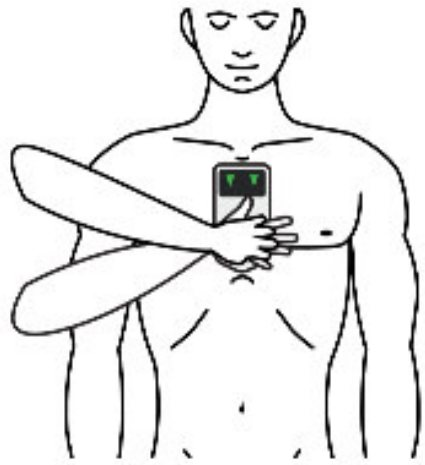
0. **BOX CONTENT**	N.1 Main Unit of Chest-eR®; N.2 Disposable covers; N.2 1.5V batteries; N.1 Quickstart guide (this document)  **Chest-eR® USER IS RECOMMENDED TO READ CAREFULLY THE INSTRUCTIONS FOR USE AVAILABLE ON THE WEBSITE** **www.chest-er.com**
1. **INTENDED USE**	**ADULT PATIENTS** (age > 18 years old[1]), including **pregnant women,** and **PEDIATRIC PATIENTS** (aged between 1 and 18 years old[1]) if the typical signs of cardiac arrest are detectable, i.e. - **non-response to stimuli**; - **no breathing or irregular breathing.** **NOT** intended for use on **NEWBORNS** (age < 1 year old[1]). *1. ref. ERC Guidelines 2021*

2. PREPARATION FOR USE	**a. BATTERIES INSERTION**: Slide the batteries compartment cover to the left and remove it; insert the batteries in the correct direction and replace the cover by sliding it to the right, making sure that the batteries compartment is properly closed (if closed correctly you can hear a "click"); **b. DISPOSABLE COVER APPLICATION:** Face upwards the cover opening side and insert Chest-eR® with its batteries compartment facing upwards. Gently, try to make adhere each point of the cover to the device soft surface, covering first one half and then the other. Be careful to avoid breaking the cover with sudden movements. Also, make sure that the two opening sides of the cover overlap well, to protect Chest-eR® from any possible infiltration of liquids or other materials. **ATTENTION:** The disposable cover must be replaced with a new one after each use.

3.

USE

HOW TO POSITION *Chest-eR®*:



After covering Chest-eR® with the dedicated disposable cover, place it on the patient's chest as shown in the figure and as illustrated on the device upper soft surface.

Place one hand on Chest-eR®, making the palm adhere completely to the upper soft surface to allow the distribution of the compression force.

Place the other hand on the back of the other and intertwine the fingers to allow the application of the compression force.

Make sure to keep arms straight and upright on the patient and begin the compression cycles.

4. **FEEDBACK**	**CORRECT CARDIAC MASSAGE:** Both the "PRESSURE" and "SPEED" LEDs are GREEN.
	INCORRECT MASSAGE: a. Both the "PRESSURE" (DEPTH) and "SPEED" (FREQUENCY) LEDs are RED on the minimum level if pressure and frequency are lower than expected, respectively. The color RED lights up on the maximum level if pressure and frequency are higher than expected, respectively. b. Both the "PRESSURE" (DEPTH) and "SPEED" (FREQUENCY) LEDs are RED on the minimum and maximum levels if compression and release are incomplete. c. *Chest-eR®* does not turn on if the cardiac massage frequency is way below 100 compressions/min.
5. **CONTACTS**	Manufactured by: PROGETTI S.r.l. strada del Rondello, 5 10028, Trofarello (TO) - Italy ph. +39.011.644.738 e-mail. info@chest-er.com