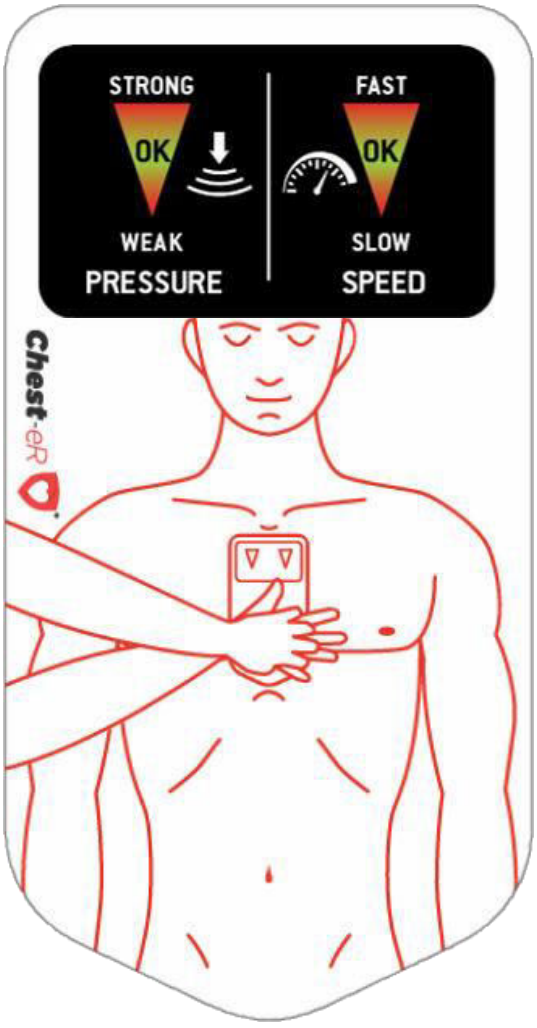
INSTRUCTIONS FOR USE

ENGLISH

Doc. N. TF-Chester-0.0/3.1ITA-0.0



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Thank you for having chosen *Chest-eR®*.

Chest-eR® is a medical device for 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 this user manual carefully, which contains the correct instructions, procedures and maintenance for the safe use of ***Chest-eR®***.

PROGETTI® designs and manufactures its products according to European harmonised standards for compliance with the **Medical Devices Directive 93/42/EEC on European medical devices and subsequent amendments.**

⚠ IMPORTANT NOTICE

For further information, please contact PROGETTI® technical support via email at **info@chest-er.com** or at the telephone number **+39 011 644738**.

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

***Chest-eR®* SHOULD BE USED ACCORDING TO THE INSTRUCTIONS SPECIFIED IN THIS MANUAL.**

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

PROGETTI® cannot be held liable a priori for any errors contained in this document or for accidental damage or consequences related to the use or performance of the device.

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

Limited Warranty

The "Limited Warranty" provided with PROGETTI® products serves as the one and only warranty provided by PROGETTI® with respect to the products contained herein.

INDEX

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 for use in the 2nd link.

1. Call emergency services
2. Begin high-quality CPR
3. Early defibrillation
4. Advanced medical emergency aid
5. Post cardiac-arrest advanced life support

The **ERC** (*European Resuscitation Council)* 2015 Guidelines recommend that if a bystander recognises **Cardiac Arrest** (CA) in a person, he must intervene on the same by activating the "survival chain" early. In more detail, after the CA has been identified and 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 link in the "survival chain" that concerns the use of *Chest-eR®* is that 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 2015 recommends the following characteristics: compression depth between **5** and **6 cm** and compression frequency between **100** and **120 compressions per minute** in a medium-sized adult.

Chest-eR® is therefore designed on the one hand **to guide the bystander** to comply with the above recommendation in order 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) related 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 normal electric batteries.

Furthermore, the device is always ready for use:

once *Chest-eR®* is correctly positioned on the patient's chest with the help of its visual indications, it automatically turns on as soon as the compressions are started. 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 reorganisation of the molecules with which the material is made.

The *Chest-eR®* surface allows for 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] Ref. *European Resuscitation Council* (*ERC*) 2015 Guidelines

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 is given 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 itself off automatically after 30 seconds without use.

Chest-eR® is equipped with sensors to provide feedback to the rescuer, i.e. 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 given. The use of pressure sensors avoids this problem.

The design of *Chest-eR*® takes the impact on the operator into account, applying the best handle shape, the choice of coatings which are most comfortable 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 palm of the hand and the patient's chest.

This is a risk factor if the rescuer's hands then come into contact with infected blood, as well as a discomfort that can distract the rescuer from correctly performing CPR.

The structure of the *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 resistance to tears in order to avoid gradual wear with the progress of the massage.

2. DEFINITIONS

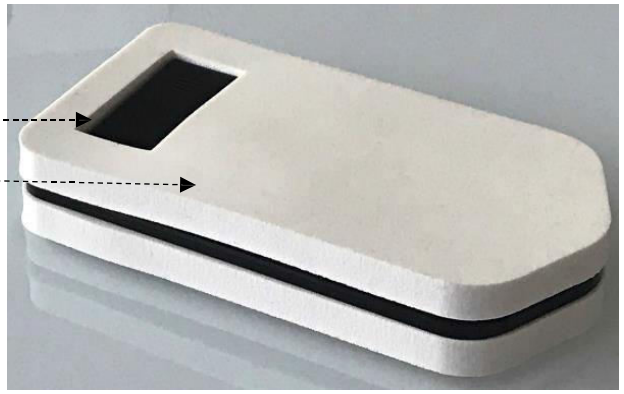
- ***Chest-eR®*:** medical device consisting of 1 MAIN UNIT, 2 BATTERIES (accessories) and 1 DISPOSABLE COVER (accessory);

MAIN UNIT

DISPOSABLE COVER

BATTERIES

- **MAIN UNIT:** part of *Chest-eR®* consisting of 2 soft layers, 1 rigid layer, 1 display, 1 battery compartment, 1 label;



- **DISPOSABLE COVER:** disposable part of *Chest-eR*® for covering the MAIN UNIT**;**

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

3. DANGERS, WARNINGS AND CAUTIONS

This chapter has 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 which could lead to reversible or irreversible injury to the user or patient.
"CAUTION"	Unsafe conditions, risks or behaviours which could lead to reversible injury, damage to *Chest-eR®* and/or its accessories or loss of information.

3.1 BATTERIES

CAUTION

✕ **Do not** insert the batteries after their expiration date.

CAUTION

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

CAUTION

✕ **Do not** attempt to recharge the supplied batteries, short circuit, puncture or deform them.

CAUTION

✕ **Do not** expose batteries to heat sources.

CAUTION

When purchasing batteries, we recommend checking the operating temperature range of the batteries and comparing them with the expected environmental temperature range when using *Chest-eR®*.

WARNING

We recommend checking the charge state of the batteries before each use of *Chest-eR®.* If the LEDs (of the indicators on the display) are less bright than the normally-perceived brightness, this is an indicator that the batteries need to be replaced soon. Remove the batteries when they are finished.

3.2 DISPOSABLE COVER

CAUTION

Check that the packaging of the disposable cover is intact before removing its contents.

CAUTION

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

CAUTION

✕ **Do** not clean or sterilise the disposable cover in an attempt to reuse it, but replace it in case *Chest-eR®* must be prepared for a new use.

CAUTION

Use only disposable covers for *Chest-eR®,* i.e. only those supplied by PROGETTI®.

WARNING

✕ Do not reuse the disposable cover if it has already been used or if there is any reason to deduce that it has already been used or not stored correctly.

3.3 MAIN UNIT

STORAGE

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 outside of its packaging and without disposable covers, otherwise the ageing of the material will be accelerated.

CAUTION

Check that the **soft and hard surfaces** are in good conditions (e.g. intact and not dirty) before use.

CAUTION

✕ Do not expose the surfaces of the main unit to water or other liquids and substances that can penetrate and damage the material as well as the internal electronics.

CAUTION

At the end of each use of *Chest-eR®,* make sure that the **label** applied to the back is intact and properly adhering to the soft surface.

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 easily and correctly read the visual feedback of *Chest-eR®.*

WARNING

At the end of each use *of Chest-eR®,* make sure that the **battery 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

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

CLEANING

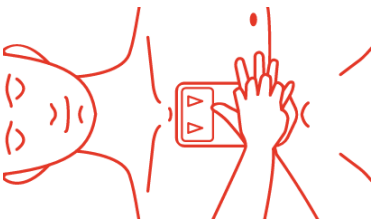
CAUTION

We recommend using a mixture of **water and alcohol** to wash the soft surfaces of the main unit, when deemed necessary.

CAUTION

Do not use substances such as **acetone and white spirits** to wash the soft surfaces of the main unit, otherwise the material will deteriorate.

3.4 *Chest-eR®* IN USE



DANGER

✕ Chest-eR® *must* not be used in the presence of **flammable substances**.

CAUTION

✕ **Do not** immerse any part *of Chest-eR®* in **water** or **other liquids**. Avoid possible spills of fluids into the device. Pouring liquids or fluids onto *Chest-eR®* may impair its operation.

CAUTION

Minimise contact between Chest-eR ® and any **injured skin** of the patient as much as possible;
Minimize the contact between *Chest-eR®* **and conductive fluids** such as water, gel, blood or other as much as possible, which could compromise the safety, correct functionality and integrity of the device.

CAUTION

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

WARNING

Use *Chest-eR®* only as directed 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 interventions in the procedures of this Manual of use.

WARNING

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

WARNING

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

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

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

3.5 Device Storage

We recommend keeping *Chest-eR®* inside its box in environmental conditions that respect the following limits:

- **Temperature**: from **- 40°C** to **+ 80°C**;
- **Humidity**: **40 - 70%.**

If *Chest-eR®* cannot be stored in its box, try to avoid exposing the device to ambient temperatures above 50°C and to solar radiation. Otherwise the ageing process of the material will be accelerated.

The environmental temperature range within which *Chest-eR®* performance and safety are guaranteed, when used, is between **- 20°C** and **+ 50°C (operating temperature**)**.**

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

3.6 Cleaning and Maintenance

✕ It is expressly forbidden to wash the device with acetone and white spirits, which could lead to a deterioration of the material with which the device is made.

We recommend using water and alcohol to wash the device when necessary.

4. INTENDED USE

4.1 INTENDED USERS

Chest-eR® is intended for use by both "healthcare" (non-lay) personnel and "non-healthcare" (lay) personnel and in particular by:

- Rescuers;
- Hospital staff;
- Ordinary people;
- Trainers.

4.2 PATIENT CLASSES ENVISAGED AND TREATABLE PATHOLOGICAL CONDITIONS

Chest-eR® is intended for use on **adult patients** (including **pregnant women**), i.e. over 8 years of age and weighing over 25 kg, if all the following states can be detected:

- **unconsciousness**;
- **absence of breath**;
- **absence of "pulse"**.

✕ *Chest-eR®* is **NOT** intended for use on **paediatric patients** (under 8 years of age and weighing less than 25 kg).

4.3 ENVIRONMENT OF INTENDED USE

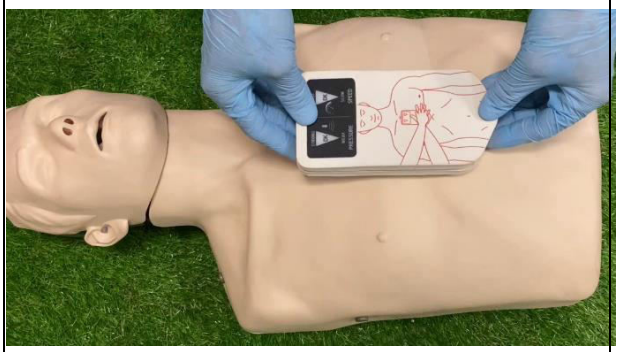
Chest-eR® can be used safely in any environment as long as its conditions respect the recommendations issued by the Manufacturer in this user manual.

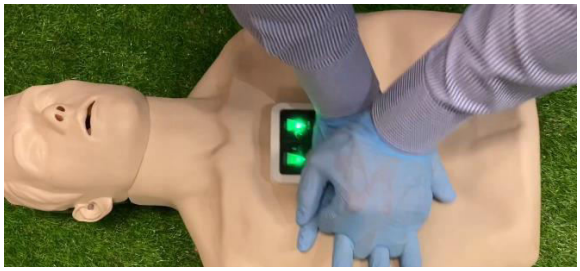
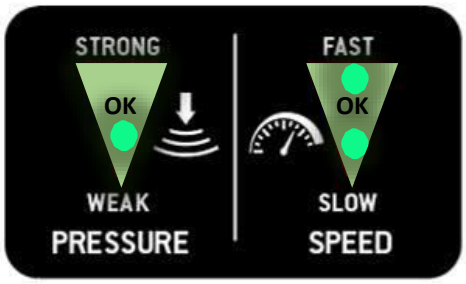
In addition, *Chest-eR®* can be used safely when exposed to drops of water thanks to the water-repellent property of the material with which its DISPOSABLE COVER is made.

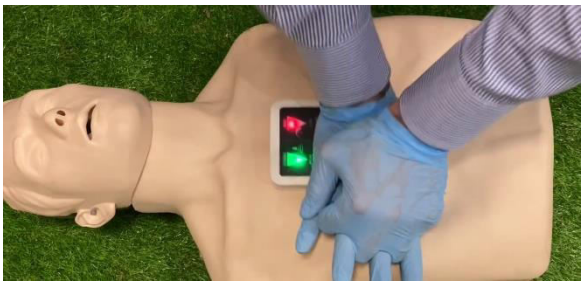
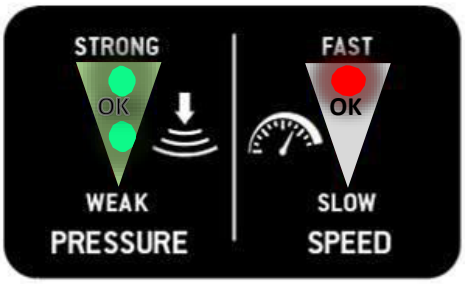
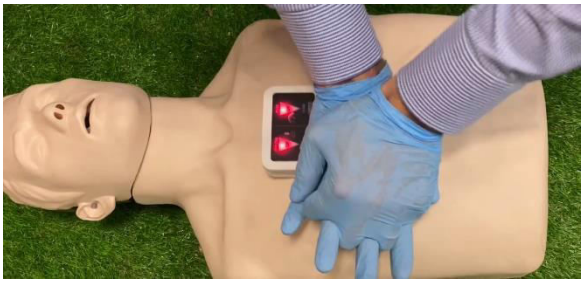
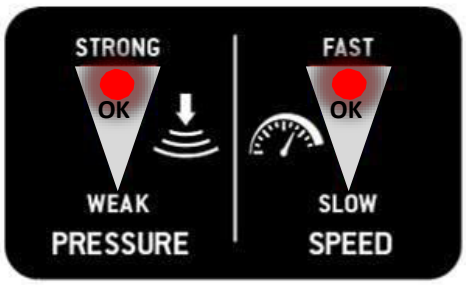
5. TECHNICAL SPECIFICATIONS

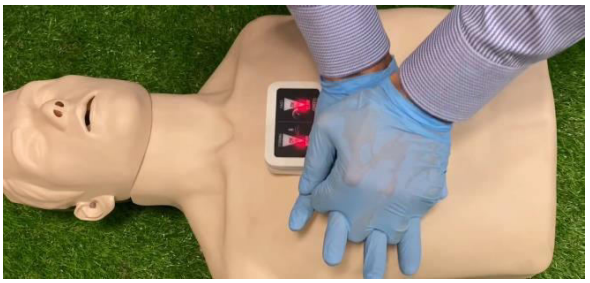
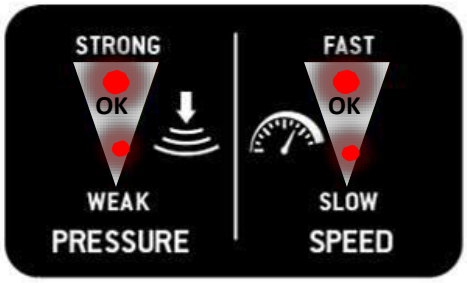
CLASSIFICATION	Class I (ref. MDD 93/42/EEC and subsequent amendments, Annex IX, rule 12)
TYPE OF APPLIED PART	BF
MAX LENGTH	16.3 cm
MAX WIDTH	8.4 cm
MAX DEPTH	2.5 cm
POWER SUPPLY	2 batteries: type AAA 1.5V
SOFT UPPER AND LOWER LAYER	Foam
RIGID INTERMEDIATE LAYER	Acetal Resin
WEIGHT	152 g (batteries included)
STORAGE TEMPERATURE	-40°C - +80°C
RELATIVE STORAGE HUMIDITY	40% - 70%
USE TEMPERATURE	-20°C - +50°C

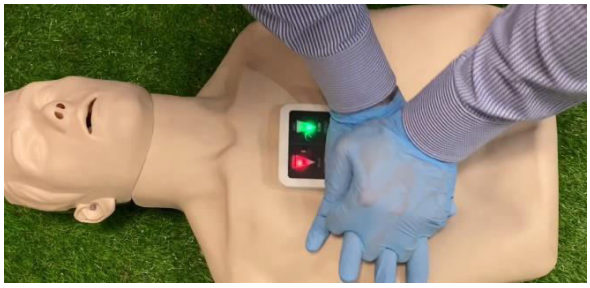
6. APPLICATION AND INTERPRETATION

1		After covering *Chest-eR®* with its DISPOSABLE COVER, position it on the patient's chest as shown in the figure on the side and as illustrated on its SOFT UPPER SURFACE, i.e. in the centre of the patient's chest.
2		Place one hand on *Chest-eR®* as in the figure, that is, so that the palm is completely adherent to the SOFT UPPER SURFACE (in order to favour the distribution of the compression force in a homogeneous way).
3		Place the other hand on *Chest-eR®* as in the figure, i.e. 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). At this point 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, (keeping the hand-*Chest-eR®*-chest contact firm for the entire duration of the manoeuvre), observing the feedback from *Chest-eR®* or monitoring the colours of the “PRESSURE" and "SPEED" indicators of the display. Upon the first half-compression, the "PRESSURE" indicator could illuminate RED up to the "STRONG" level. This state is to be considered transitory while waiting for the manoeuvre to be completed.

FEEDBACK		
A	 Frequency: 100-110 compressions/minute  Frequency: 110-120 compressions/minute  	**Case (A). CARDIAC MASSAGE PERFORMED CORRECTLY - both the "PRESSURE" indicator and the "SPEED" indicator illuminate in GREEN** (as in the figure on the side). In this case, the resuscitation manoeuvre has been performed correctly (ref. *ERC Guidelines - ed. 2015*), i.e. the depth of compression achieved is in the range of 5-6 cm and the frequency of compression achieved is in the range of 100-120 compressions per minute. If only the compression frequency in the range if 100-110 compressions/minute has been achieved, then only a single LED (GREEN) of the "SPEED" indicator will illuminate; if a compression frequency in the range of 110-120 compressions/minute is achieved, then two LEDs (GREEN) of the "SPEED" indicator will illuminate.

B	 	**Case (B). THE COMPRESSION FREQUENCY IS HIGH - the "SPEED" indicator illuminates in RED at the "FAST" level and the "PRESSURE" indicator illuminates in GREEN** (as in the figure on the side). In this case, the resuscitation manoeuvre has NOT been performed correctly (ref. *ERC Guidelines - ed. 2015*) because the compression frequency achieved is NOT in the range 100-120 compressions/ minute, but greater than 120 compressions/minute. Therefore, the *Chest-eR®* user must decrease the compression frequency until it settles in the correct range, i.e. the "SPEED" indicator illuminates in GREEN.
C	 	**Case (C). BOTH THE COMPRESSION FREQUENCY AND PRESSURE ARE TOO HIGH - the "PRESSURE" indicator illuminates in RED at the "STRONG" level and the "SPEED" indicator illuminates in RED at the "FAST" level** (as in the figure on the side). In this case, the resuscitation manoeuvre has NOT been performed correctly (ref. *ERC Guidelines - ed. 2015*) because: • the compression frequency achieved is NOT in the range 100-120 compressions/minute (ref. *ERC Guidelines - ed. 2015*), but above 120 compressions/minute; • the compression depth achieved is NOT in the range 5-6 cm (ref. *ERC Guidelines - ed. 2015*), but greater than 6 cm. Therefore the *Chest-eR®* user must decrease the compression frequency and pressure so that they settle in the correct range, i.e. both indicators illuminate in GREEN.

D	 	**Case (D). BOTH THE COMPRESSION FREQUENCY AND PRESSURE ARE LOW - the "PRESSURE" indicator illuminates in RED at the "WEAK" level and the "SPEED" indicator illuminates in RED at the "SLOW" level** (as in the figure on the side). In this case, the resuscitation manoeuvre has NOT been performed correctly (ref. *ERC Guidelines - ed. 2015*) because: • the compression frequency achieved is NOT in the range 100-120 compressions/minute (ref. *ERC Guidelines - ed. 2015*), but less than 100 compressions/minute; • the compression depth achieved is NOT in the range 5-6 cm (ref. *ERC Guidelines - ed. 2015*), but less than 5 cm. Therefore, the *Chest-eR®* user must increase the compression frequency and pressure so that they settle in the correct range , i.e. both indicators illuminate in GREEN.
E	 	**Case (E). COMPRESSION AND RELEASE INCOMPLETE - the "PRESSURE" indicator illuminates in RED on both levels and the "SPEED" indicator illuminates in RED on both levels** (as in the figure on the side). In this case, the resuscitation manoeuvre has NOT been performed correctly (ref. *ERC Guidelines - ed. 2015*) because: • the compression is incomplete; • the release is incomplete. Therefore the *Chest-eR®* user must modulate the compression frequency and the pressure so that they settle in the correct range , i.e. both indicators illuminate in GREEN.

F	 	**Case (F). THE PRESSURE IS HIGH - the "PRESSURE" indicator illuminates in RED at the "STRONG" level and the "SPEED" indicator illuminates in GREEN** (as in the figure on the side). In this case, the resuscitation manoeuvre has NOT been performed correctly (ref. *ERC Guidelines - ed. 2015*) because the compression depth achieved is NOT in the range 5-6 cm but greater than 6 cm. Therefore, the *Chest-eR®* user must decrease the compression pressure until it settles in the correct range, i.e. the "PRESSURE" indicator illuminates in GREEN.

7. SYMBOLS USED

SYMBOL	SYMBOL DESCRIPTION
	Identification of the Device
	Serial Number
	Manufacturer Identification
	Manufacture Date
	Applied part type BF
	Please read the instructions for use
	Follow local regulations regarding battery disposal or recycling
	Warning
	Warning: electrical hazard
	EC marking
Cover 	The cover is Disposable (not reusable)

8. EUROPEAN DECLARATION OF CONFORMITY

DECLARATION OF EU CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
and subsequent amendments CONCERNING MEDICAL DEVICES

DICHIARAZIONE DI CONFORMITA' CE
ai sensi della Direttiva 93/42/CEE del 14 Giugno 1993
e i suoi successivi emendamenti
riguardo I DISPOSITIVI MEDICI

PRODUCT: *Prodotto:*	**Cardiovascular Medical Device** *Dispositivo Medico per Apparato Cardiocircolatorio*
MODEL (REF): *Modello (REF)*	***Chest-eR***
CND CODE: *Codice CND:*	**C99 "Cardiovascular Medical Device - Other"** *C99 "Dispositivo Medico per Apparato Cardiocircolatorio – Altri"*
CLASS: *Classe:*	**I (ref. Annex IX, Rule 12)** *I (rif. Allegato IX, Regola 12)*
MANUFACTURER : *Fabbricante:*	**PROGETTI S.r.l.** Strada del Rondello, 5 10028 Trofarello (TO) ITALY
SERIAL NUMBER: *Numero di Serie:*	*

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES, ACCORDING TO ESSENTIAL REQUIREMENTS AND SUBSEQUENT AMENDMENTS.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
*IL FABBRICANTE DICHIARA CHE IL PRODOTTO SOPRA MENZIONATO E' CONFORME ALLA REGOLAMENTAZIONE APPLICABILE, QUINDI ALLA **DIRETTIVA DISPOSITIVI MEDICI 93/42/CEE** DEL 14 GIUGNO 1993 E I SUOI SUCCESSIVI EMENDAMENTI, NONCHE' AI REQUISITI ESSENZIALI DA ESSA IMPOSTI.*
TUTTA LA DOCUMENTAZIONE PERTINENTE E' DEBITAMENTE CONSERVATA DAL FABBRICANTE.
*INOLTRE, IL PRODOTTO E' FABBRICATO IN ACCORDO ALLA **DIRETTIVA 2011/65/CEE (ROHS)** E I SUOI SUCCESSIVI EMENDAMENTI.*

FIRST ISSUE: *Prima Emissione:*	17 / 02 / 2020
PLACE, DATE OF ISSUE : *Luogo, Data di Emissione:*	TROFARELLO (TO), 17 / 02 / 2020
SIGNATURE: *Firma:*	Dr. CESARE MANGONE MANAGEMENT REPRESENTATIVE

* IF YOU WANT RECEIVE DEDICATED DECLARATION OF CONFORMITY FOR YOUR DEVICE SERIAL NUMBER AND/OR UPDATED ONE PLEASE CONTACT PROGETTI S.R.L. OFFICE TO THE EMAIL info@progettimedical.com
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