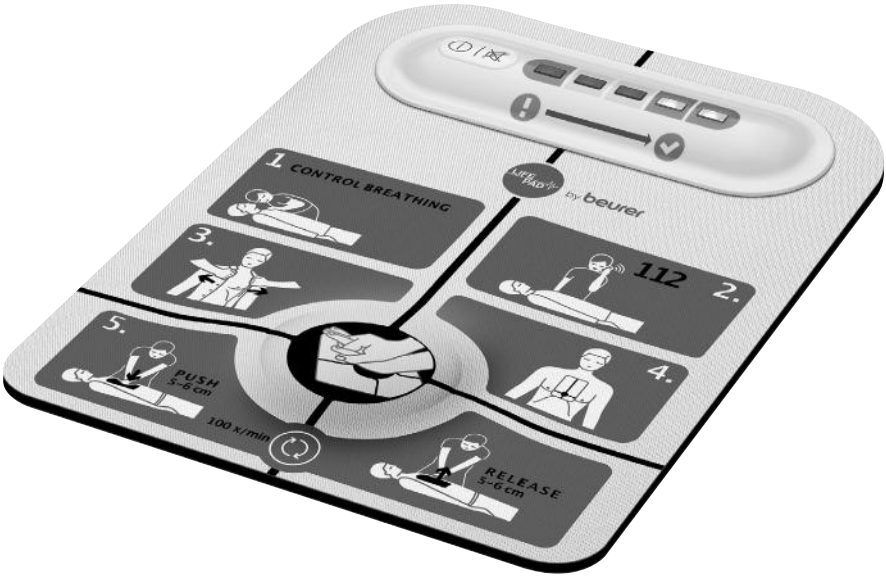
LIFE PAD by beurer

RH 112



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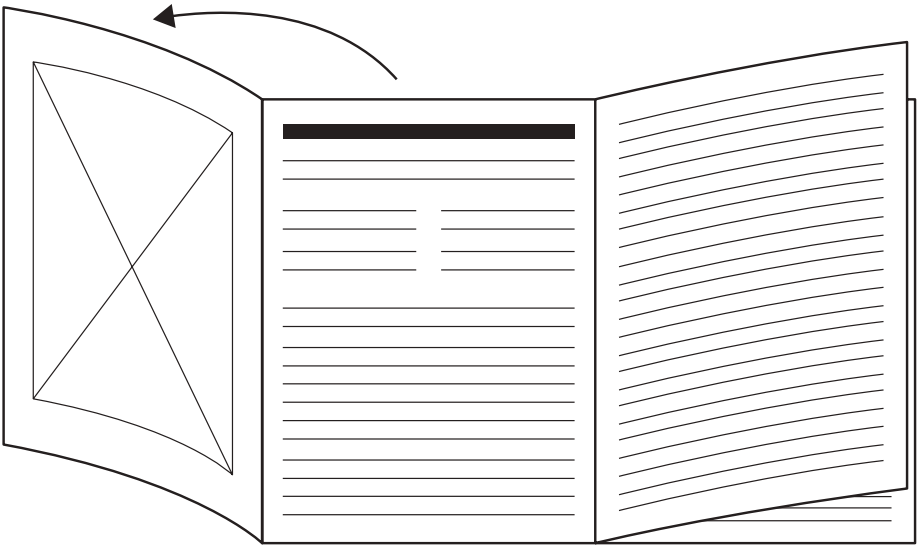
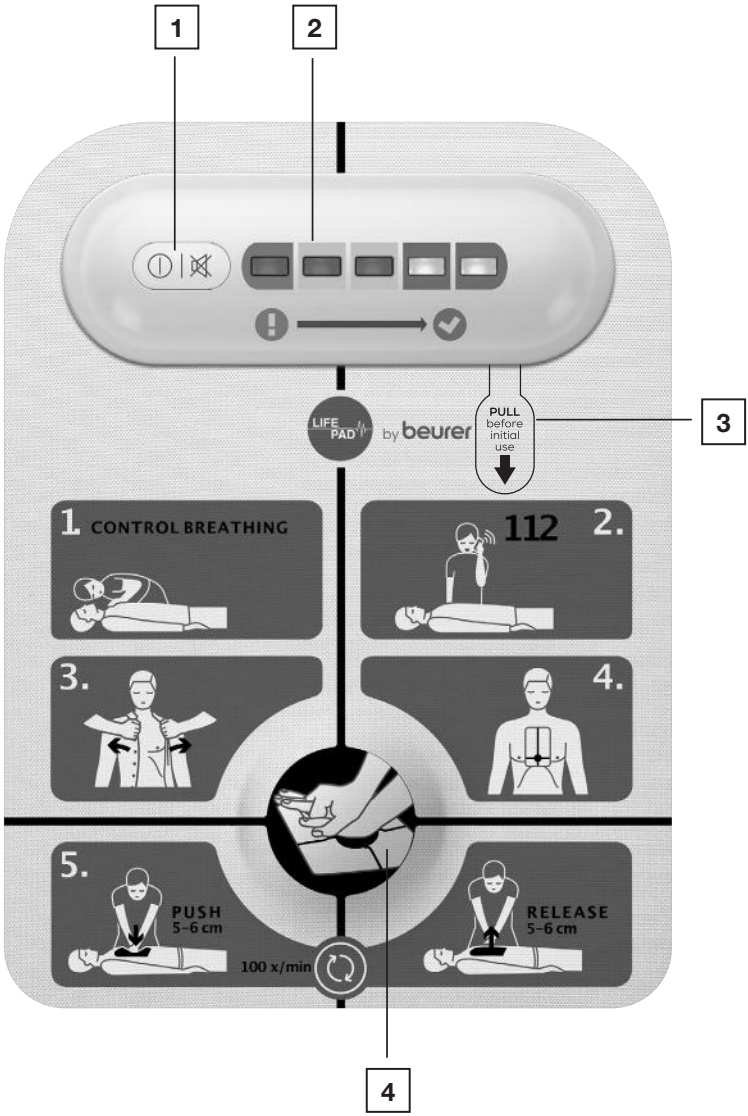
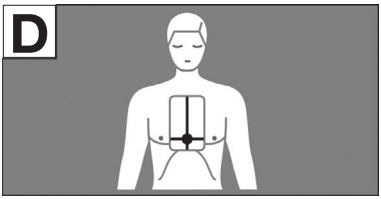
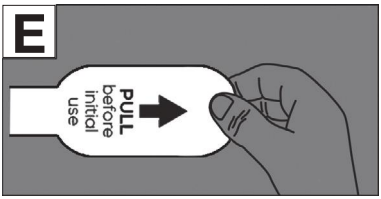
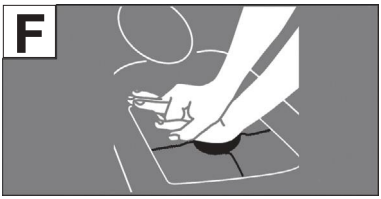


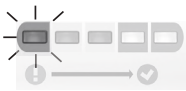
DE Klappen Sie vor dem Lesen der Gebrauchsanweisung die Seite 3 aus.
EN Unfold page 3 before reading the instructions for use.
FR Dépliez la page 3 avant de lire le mode d'emploi.
ES Despliegue la página 3 antes de leer las instrucciones de uso.
IT Prima di leggere le istruzioni per l'uso aprire la pagina 3.
TR Kullanım kılavuzunu okumadan önce 3. sayfayı açın.
RU Перед чтением инструкции по применению разложите страницу 3.
PL Przed przeczytaniem instrukcji obsługi otworzyć stronę 3.
NL Vouw pagina 3 uit voordat u de gebruiksaanwijzing gaat lezen.
DA Fold side 3 ud, før du læser betjeningsvejledningen.
SV Vik ut sid. 3 innan du läser bruksanvisningen.
NO Åpne side 3 før du leser bruksanvisningen.
FI Käännä sivu 3 auki ennen käyttöohjeen lukemista.

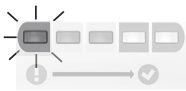

1
2
3
4
LIFE PAD
by beurer
PULL
before
initial
use
1 CONTROL BREATHING
112
2.
3.
4.
5.
PUSH
5–6 cm
100 x/min
RELEASE
5–6 cm

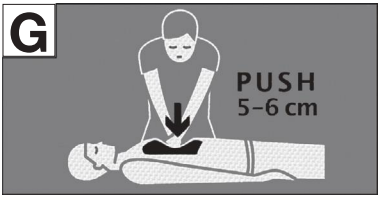


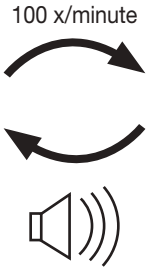


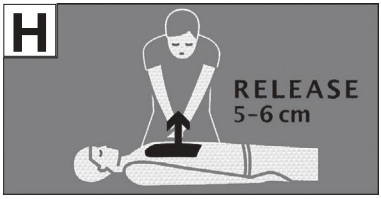


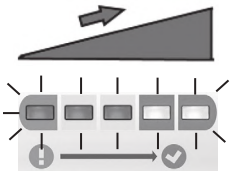


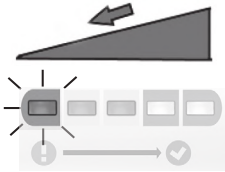












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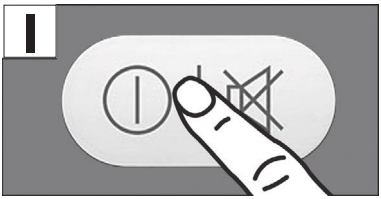

Read these instructions for use carefully. Observe the warnings and safety notes. Keep these instructions for use for future reference. Make the instructions for use accessible to other users. If the device is passed on, provide the instructions for use to the next user as well.

Table of contents

1. INCLUDED IN DELIVERY

Check that the exterior of the cardboard delivery packaging is intact and make sure that all contents are present. Before use, ensure that the device and accessories have no visible damage and all packaging material is removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Services address.

1x LifePad®
1x these instructions for use

2. SIGNS AND SYMBOLS

The following symbols are used on the device, in these instructions for use, on the packaging and on the device's type plate:

	**Warning** Warning notice indicating a risk of injury or damage to health		**Consult instructions for use**
	**Important** Safety note indicating possible damage to the device/accessory		**Product information** Note on important information
	**Single-use** Not suitable for reuse		**Use by**
	**Manufacturer**	MD	**Medical device**
UDI	**Unique device identifier (UDI)** Identifier for unique product identification	REF	**Item number**
SN	**Serial number**	LOT	**Batch designation**

IP44	**Protection class** Protected against solid foreign objects ≥ 1 mm in diameter and against splashing water.		**Defibrillation-proof type CF applied part**
	**Temperature limit** The temperature limit values to which the medical device can safely be exposed are indicated	CE	**CE labelling** This product satisfies the requirements of the applicable European and national directives
	**Humidity, limit** Indicates the humidity range to which the medical device can safely be exposed		**Atmospheric pressure, limit** Indicates the range of atmospheric pressures to which the medical device can be safely exposed
	**Disposal** Disposal in accordance with the Waste Electrical and Electronic Equipment EC Directive – WEEE		**Battery disposal** Do not dispose of batteries containing harmful substances with household waste
	**Direct current** The device is suitable for use with direct current only		Marking to identify the packaging material. A = Material code, B = Material number: 1-6 = Plastics, 20-22 = Paper and cardboard
	**Dispose of packaging in an environmentally friendly manner**		

3. INTENDED USE

Use the LifePad® for the purpose it was developed for only and in the manner specified in these instructions for use.

Intended use

The LifePad® motivates and supports first-aiders in cardiopulmonary resuscitation (CPR) of individuals over 12 years of age after a sudden cardiac arrest (SCA) through an acoustic and visual feedback system to evaluate the compressions performed. The LifePad® is intended for single use only and must not be used multiple times under any circumstances.

Target group

The LifePad® is intended for use by adults and adolescents over the age of 12 and has been specially designed for use by lay persons. Therefore, no specific knowledge or professional ability is required to use the LifePad®.

Indication/clinical benefits

The LifePad® should be used once the first-aider has identified that the patient is experiencing a cardiac arrest. For this reason, the first-aider must check whether the person who has collapsed is conscious and breathing, as described in the section "What to do in an emergency?" before using the LifePad®. If the patient is not responsive and is not breathing, it should be assumed they are experiencing a cardiac arrest. In this case, the first-aider should make an emergency call and start using the product immediately. The LifePad® consists of a flexible and non-slip mat that adapts to every body shape. It is placed on the patient's bare upper body and aligned using reference lines and pictograms.
Once the product has been automatically activated by pulling the battery strip, the feedback system starts. It consists of an acoustic signal that tells the user the correct rhythm for 100 compressions per minute, as well as the colour-coded LEDs that, in combination with the built-in pressure sensor, indicate whether the compressions are being performed correctly. In doing so, the sensor checks whether suf-

ficient pressure is being applied to compress the chest, but also whether the chest has been released again in order to simulate the pumping effect of the heart.
The LifePad® is not only intended to motivate more people to provide first aid, but also to support inexperienced first-aiders in performing cardiopulmonary resuscitation.

4. WARNINGS AND SAFETY NOTES

⚠ Contraindications

- Do not use the LifePad® if the patient has suffered an obviously fatal injury.
- Do not use the LifePad® if you are sure that the patient is breathing normally – even if they are not responding.
- Do not use the LifePad® on people under the age of 12.
- Never delay treatment to find out the exact age of the patient.

⚠ General warnings

- Even if resuscitation is initiated immediately, this does not guarantee that the patient will survive, even if it is performed optimally. In some cases, the underlying problem causing the cardiac arrest means that the patient will not survive, despite the best care.
- Patients with serious injuries should not be moved. Without using the LifePad®, the layperson (user) should also not move the patient on another ground.
- Rib fractures and other injuries are common, but acceptable consequences of resuscitation given that the alternative is death due to cardiac arrest. After resuscitation, all patients should be assessed for injuries caused during resuscitation.
- In addition to the above-mentioned consequences, skin abrasions, bruises and wounds on the chest can often occur during resuscitation. Despite this, do not stop performing the compressions, but continue CPR until professional help arrives.
- Check the LifePad® surface for integrity before starting resuscitation to prevent sharp edges or dangerous areas.
- In the event of a defect, perform the cardiac massage without the assistance of the LifePad®. Do not delay or interrupt the start of first aid measures to rectify the defect. Continue to follow the instructions for carrying out CPR illustrated by the pictograms.
- Even if the device fails, continue cardiac massage at a pressure frequency of at least 100 per minute until clear signs of life are once again perceptible or the emergency doctor takes over.The pressure must be high enough to achieve a pressure depth on the chest of 50 mm to 60 mm.
- The LifePad® is only intended to support the emergency services (which have been alerted) and cannot completely replace them.
- The LifePad® is not intended to replace possible training measures in the field of first aid. Prior knowledge is a benefit, but not absolutely necessary for use.
- Keep packaging material away from children. There is a risk of suffocation.
- The LifePad® is not a toy. Store the LifePad® out of the reach of children.
- To reduce the risks associated with strong electromagnetic fields, such as device failure, do not use the LifePad® near strong high-frequency signals or portable and/or mobile HF devices.
- The use of accessories, converters and cables other than those intended for the LifePad® may result in increased HF emissions or decreased immunity of the LifePad®.
- To avoid unnecessarily shortening the service life of the LifePad®, only switch it on when treating a patient.
- If you pull out the battery strip prematurely, the battery life can no longer be guaranteed.

- If the LifePad® is used in combination with a defibrillator follow the safety instructions of the defibrillator.
- Please report any unexpected operation or events to the manufacturer.
- Device not suitable for use in presence of anaesthetic mixtures inflammable with air, oxygen or nitrogen protoxide.

⚠ General precautions

- The LifePad® is intended for single use only and is therefore not suitable for reuse:
  - After a single use and the associated closing of the circuit through pulling the battery strip, the supplied battery is discharged, meaning that it can no longer be ensured that the product can be used again at a later time.
  - Furthermore, the product cannot be used on different people for hygienic reasons, as it cannot be disinfected or cleaned.
- Protect the LifePad® against impacts, moisture, dust, chemicals, strong temperature fluctuations, direct sunlight, water, sand and sources of heat that are too close to it (ovens or heaters), as faultless functionality of the LifePad ® can no longer be guaranteed thereafter.
- Under no circumstances should you open or repair the LifePad®, as faultless functionality can no longer be guaranteed thereafter and you may receive an electric shock. The LifePad® cannot be maintained and/or calibrated.
- Do not use additional parts that are not recommended by the manufacturer or offered as accessories.
- If you see or suspect damage to the LifePad®, you must replace it with a new LifePad®.
- The LifePad® is protected against splashes. Never submerge the LifePad® in water.

⚠ Notes on handling batteries

- If your skin or eyes come into contact with battery fluid, wash the affected area with water and seek medical assistance.
- ⚠ Choking hazard! Small children may swallow and choke on batteries. Therefore, batteries should be stored out of the reach of small children.
- Observe the plus (+) and minus (-) polarity signs.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- Protect batteries from excessive heat.
- ⚠ Risk of explosion! Do not throw batteries into a fire.
- Do not charge or short-circuit the batteries.
- Do not use rechargeable batteries.
- Do not disassemble, open or crush the batteries.
- Battery must comply with IEC 60086-4.

5. STORAGE

⚠ Possible damage due to incorrect storage

- Store the LifePad® in a dry environment with no external stresses.
- Make sure to store the product in a place that is quick and easy to access in case of an emergency.
- The LifePad® must not be bent or subjected to other external stresses during storage, as this could damage the pressure sensor.

- Regularly check that the printed use-by date has not been exceeded when the LifePad® is in storage. In this case, replace the product immediately with a new one.

6. DEVICE DESCRIPTION

The device is shown on the fold-out page.

1 **ON/OFF** button (with battery strip removed: short press -> ON / long press -> OFF) / **mute** button (short press again after switching on -> muted)

2 LED feedback system

3 Battery strip

4 Pressure sensor

7. WHAT TO DO IN AN EMERGENCY?

The associated drawings are shown on the fold-out page.

A Check for consciousness and breathing

Check if the person that has collapsed is responsive. To do this, shake them lightly by their shoulders and ask loudly: "Is everything OK?" If they respond, try to find out what the problem is with them and get help if necessary. Regularly check their condition.
If they do not respond, check their breathing using sight, hearing and touch. To do this, turn the patient onto their back. Place your hand on their forehead and gently tilt their head backwards using your other hand's fingertips in order to clear the airways. If you are unsure whether breathing is normal, work on the basis that it is not normal and start resuscitation.

B Make an emergency call

If the patient is not responsive and is not breathing normally, immediately alert the emergency services (the number for Europe, for example, is 112).

C Expose the upper body

As far as possible, ensure that the patient is lying on a firm and level surface. Expose the patient's upper body. The LifePad® must be able to rest directly on bare skin.

D Place the LifePad®

Place the LifePad® on the patient's bare upper body as shown. Align the product using the red reference lines. The LifePad® should be positioned on the patient's upper body so that the vertical red line is in the middle of the body and the lower edge of the product is in line with the sternum/breastbone so that the pressure sensor 4 is in the lower half of the sternum.

E Pull out the battery strip

Then pull the battery strip 3 completely out of the housing to activate the LifePad®. An acoustic signal begins to sound on the LifePad®.

F Place your hands on the patient

Kneel next to the patient. Place the ball of one hand on the raised part of the LifePad® pressure sensor 4. Place the ball of your other hand on the first hand and interlace your fingers. Make sure that they do not press on the patient's ribs and do not put any pressure on the upper abdomen.

G Perform the compressions

Place your shoulders vertically over the patient's chest and extend your arms. Now start the cardiac massage in the rhythm of the acoustic signal. Each time the beep sounds, press the sternum down by at least 5 cm, but not more than 6 cm.
The coloured LED feedback system 2 will tell you whether you are applying enough pressure. You are applying sufficient pressure to the chest if you make all of the LEDs light up one after the other in ascending order from orange to green.
If you only light up the orange or the two yellow LEDs, you are not applying enough pressure. Increase the pressure for the subsequent compressions until all LEDs light up.

H Release the chest again

Completely release the chest after each compression you perform without losing contact between your hands and the LifePad®.
Here, too, the LED feedback system 2 helps you to assess this.
After each compression, release the chest until the LEDs go out one after the other in descending order from green to orange until only the orange LED lights up.
If the green and yellow LEDs do not go out completely, the chest has not been released sufficiently. During subsequent compression, release the chest even more until all LEDs except the orange LEDs go out.

Repeat steps G and H in the rhythm of the acoustic signal to ensure a frequency of 100 compressions per minute. Perform cardiac massage until there are clear signs of life again or until the emergency doctor takes over.

If you are trained to do so, you can give 2 rescue breaths after 30 compressions.

I Deactivate acoustic signal (optional)

You can deactivate the acoustic signal at any time when the product is activated by pressing the ON/OFF button 1 again. This can be useful, for example, if a defibrillator is being used at the same time, as it also emits acoustic signals. Please note, however, that in this case you can no longer receive feedback on the frequency required for the compressions to be carried out.

8. DISPOSAL

Disposal of the device

For environmental reasons, do not dispose of the LifePad® with your household waste after a single use. Dispose of the device at a suitable collection point in your country. Dispose of the LifePad® in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal. When disposing of the LifePad®, ensure that the battery has been removed and dispose of it separately.

Disposal of the batteries

- Batteries must not be disposed of in the household waste. They may contain poisonous heavy metals and are subject to special refuse treatment.
- The codes below are printed on batteries containing harmful substances:
  Pb = Battery contains lead,
  Cd = Battery contains cadmium,
  Hg = Battery contains mercury.

9. TECHNICAL SPECIFICATIONS

Model	LifePad®
Type	RH 112
Dimensions	210 x 160 x 20 mm
Weight	Approx. 130 g
Volume	66 dB
Permissible operating conditions	5°C to 40°C, 15 to 93% relative humidity 700–1060 hPa ambient pressure
Permissible storage and transport conditions	5°C to 35°C, 45–85% relative humidity 700–1060 hPa ambient pressure
Protection class	IP44
Power supply	1x CR2032 (3 V) ⎓
Battery life	Approx. 1 hour in continuous operation
Frequency of the acoustic signal	100 bpm
Use-by date	See type plate (5 years after production)
Expected useful life	Single-use product
Classification	Internal supply, continuous operation, application part defibrillation-proof type CF (back side of device is considered as defibrillation-proof type CF applied part)

The technical data is subject to change without notice, as updates are possible.

The serial number is located on the device or in the battery compartment.

- The device complies with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, as well as the respective national provisions.
- This device complies with European standards EN 60601-1 and EN 60601-1-2 (in compliance with CISPR 11, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-8) and is subject to special precautionary measures with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this device. Further information can be obtained from the Customer Services address provided.

10. WARRANTY/SERVICE

Further information on the warranty and warranty conditions can be found in the warranty leaflet supplied.

For users/patients in the European Union and identical regulation systems (EU Medical Device Regulation (MDR) 2017/745), the following applies: If during or through use of the product a major incident occurs, notify the manufacturer and/or their representative of this as well as the respective national authority of the member state in which the user/patient is located.

Subject to errors and changes