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SimCPR® Pro User Manual



Read carefully before first use!

1 Intended use and contraindications

SimCPR® Pro support first responders in performing effective chest compressions in accordance with scientific CPR guidelines

Indication of use:

SimCPR® Pro supports first responders performing CPR on patients of 12 years of age and older who are suspected of having a cardiac arrest.

SimCPR® Pro feedback provides extra support for the rescuers doing CPR based on their training and experience.

Contraindications:

SimCPR® Pro may not be used in the following situations:

- The patient is younger than 12 years old.
- The patient reacts when spoken to.
- The patient breathes normally.
- CPR during transport.
- CPR on a soft surface.

2 Description

SimCPR® Pro is a medical device that provides real-time feedback to the rescuer who is performing CPR on a patient in cardiac arrest.

The device is worn as a wristband.

SimCPR® Pro registers the up and down movements of the rescuer's wrist during chest compressions (amplitude). The built-in accelerometer analyses these movements and accurately calculates the traveled distance (depth) and tempo. Through a red and green LED-light the first responder gets feedback if chest compression depth and tempo are correct.

SimCPR® Pro is set according to the scientific CPR-guidelines for patients older than 12 years: chest compressions with a minimum depth of 2 inches (5 cm) and a rate between 100-120 per minute.

SimCPR® Pro can be used multiple times on different patients.

3 Warning

SimCPR® Pro calculates the depth based on the traveled distance during compression/decompression.



Leaning on the chest after recoil, reduces the distance traveled.

When the rescuer compresses the chest for e.g. 2.4 inches (6 cm) but keeps leaning 0.8 inches (2 cm), the measured distance will be only 1.6 inches (4 cm). In this case the red LED-light will keep on flashing.

The moment the rescuer stops leaning, with full chest recoil, the traveled distance will be 2.4 inches (6 cm) and the green LED-light will be activated.

If the rescuer does not keep contact with the patient chest after recoil, the device will measure a larger distance traveled. In this case the green LED-light can be activated while chest compressions are not deep enough.



Releasing hands from the chest increases the distance traveled.

SimCPR® Pro is only intended to be used on patients over 12 years of age. The medical device is not suitable for children under 12 years of age. This age group requires a different compression depth than older children and adults.

4 Complications and safety information

Several medical studies have shown that different types of injuries can be caused by performing chest compressions on patients in cardiac arrest.

In general these injuries are not fatal and the chance of death is more likely without chest compressions.



It is not unusual for ribs to break during chest compressions. Despite breaking ribs, continue with CPR!

For users/patients within the European Union (Medical device regulation EU 2017/745), the following applies: In case of serious harm from the use of this medical device, you need to report this to SimCPR Medical BV and the relevant authority of the Member State where the user/patient is located.

5 Precautions

First check if the patient needs to be resuscitated. Resuscitation is needed when the patient is unresponsive and has no (normal) breathing. Make sure the EMS (Emergency Medical Service) is activated and someone is gone to get an AED (Automated External Defibrillator) to the patient.

It is strongly recommended that first responders using a *SimCPR® Pro*, are trained on a regular basis to keep their skills up-to-date.

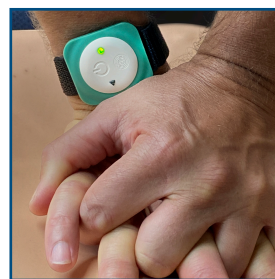
6 Use

Put the *SimCPR® Pro* wristband on the left or right wrist of the upper or lower hand. Ensure that the wristband is tight enough around the wrist to ensure that there is no slackness, so that the wristband exactly follows the movement of the wrist.

First turn on the *SimCPR® Pro* by pressing the ON/OFF symbol on the sensor. You should press the button hard enough to hear it click.



Press the ON/OFF-button to start.



Make sure the LED's are clearly visible.

The SimCPR® Pro is active once the red LED-light starts flashing.

After the device is activated, you continue with placing your hands in the middle of the chest on the nipple-line.

Straighten your back, stretch your arms and place your shoulders perpendicular above the chest. Start chest compressions by pushing the chest down and let it come up again.

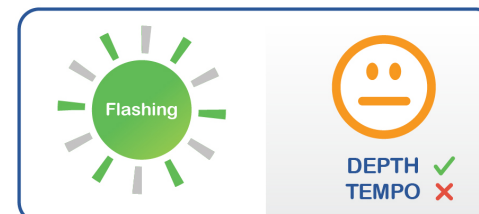


Make sure there is a full chest recoil before you start pushing the chest down again. Do not lean keep leaning on the chest.

As instructed, both hands of the rescuer should always keep in contact with the chest of the patient during compressions. If the *SimCPR® Pro* is worn on the upper hand, this hand should keep in contact with the underlying hand on the chest. This ensures the most accurate measurement of depth.

Note:

First focus on getting a correct depth and then on getting a correct tempo.



As long as the measured chest compression movements are less than 2 inches (5 cm), the red LED keeps flashing. Push harder until the green LED flashes or lights up continuously.

As soon as the measured chest compression movements are equal or above 2 inches (5 cm), the green LED starts flashing or lights up continuously when also tempo is within 100-120/min.



**Allow the patient's chest expand fully before compressing it again.
Do not keep leaning on the patient's chest!**



When the chest of a patient is very stiff, it can be difficult to compress the chest the full 2 inches in order to activate the green LED. Continue CPR anyway and try to push as hard as you can or change places with another first responder.

Continue CPR until EMS-professionals take over or till the patient shows signs of life (= patient responds or has normal breathing).

After use

You can turn off the *SimCPR® Pro* by pushing the ON/OFF-button for 3 seconds.
When the *SimCPR® Pro* is activated and doesn't move for 5 minutes, the device will turn off automatically.
Remark: Check the battery after every use (see section 7).

If necessary the medical device can be disinfected after every use with a 70% isopropyl alcohol solution.
Do not submerge the device in water or hold it under running water. Do not sterilize the device.

7 Periodic monitoring and replacement batteries

The service life of the 3V lithium button cell battery is six years in standby mode or 100 active operating hours.



Check the battery at least every 3 months. In this way you prevent the battery is empty during a rescue event.

Check the battery capacity anytime by switching the *SimCPR® Pro* on and then off again. After you switch it off (by pressing the ON/OFF button for at least 3 seconds), the green or red LED will light up briefly. If the green LED lights up, there is sufficient battery charge available. If the red LED lights up, you need to replace the battery of the device by a new one.

Battery replacement

SimCPR® Pro comes with a replaceable battery (CR2032). Only use Lithium UL-approved batteries from e.g. Varta, Panasonic, Sony, Philips or Duracell.



There is a danger of explosion when batteries are replaced by an incorrect type.

1. Remove the 4 screws at the back of the device (Torx 6).
2. Remove the upper green part of the housing.
3. Remove the white cover (with light guides).
4. Take out the sensor and push the battery out to the metal holder (do not dispose of the battery with household waste but take it to a suitable waste station).
5. Insert a new 3V battery (CR2032) in the same way (+ side up).
6. Place back the sensor (this is only possible in one way) and push the battery down for optimal LED-light effect.
7. Place back the white cover with light guides (also this is only possible in one way).
8. Place back the upper green part (fits one way) and finally put the 4 screws back.

Turn the *SimCPR® Pro* on and check if the red LED flashes and that you can see both LED-lights clearly. The device is now ready for use again.
You can visit the *SimCPR®* Youtube-channel for a video on battery replacement.

The battery and *SimCPR® Pro* should not be disposed off with household waste. Please dispose of the battery separately according to the guidelines for toxic waste through the special collection points.
Dispose of the *SimCPR® Pro* at a specialized electronic collection point.

8 Troubleshooting

Problem	Possible cause	Solution
<i>Red LED does not start to flash.</i>	ON/OFF button has not been pressed hard enough.	Press the ON/OFF button firmly until you hear a 'click'.
	Battery is flat.	Replace the battery or device.
	Device is defective.	Contact your dealer or <i>SimCPR Medical BV</i> .
<i>Green LED does not start to flash.</i>	Your compressions are not deep enough.	Press the patient's chest deeper (≥ 2 inches) and do not lean.
	You are continuing to lean on the patient's chest.	Allow the patient's chest to come all the way up and do not continue to lean on it.
	Device is defective.	Contact your dealer or <i>SimCPR Medical BV</i> .
<i>Green LED will not light up continuously.</i>	Tempo of compressions is too slow or too fast.	Push faster or slower to get a correct tempo of 100-120/min.

9 Technical specifications

Model: *SimCPR® Pro*
Catalog number: 30476
Dimensions: 45x40x20 mm (1.77"x1.57"x0.97")
Weight: 23 g
Transmitter module: 12155A-EMBC22
Batteries: CR2032 (3V Lithium)
Battery lifetime: 6 years/100 hours operational use
Use conditions:
• Temperature: Between 0°C and +40°C
• Relative humidity: 15 to 90% RH
• Atmospheric pressure: 860 hPa to 1060 hPa
Ingress protection: IP54

The device complies with the general safety and performance requirements of (EU) 2017/745 (Class 1) .

This device complies with the European standards EN 61000-4-2 and EN 61000-4-3 and is subject to electromagnetic compatibility safety precautions.

SimCPR®-Feedback

Red LED flashes:
Compression-decompression depth < 2inches/5cm.

Green LED flashes:
Compression-decompression depth ≥ 2 inches/5cm.*

Solid green LED:
Compression-decompression depth ≥ 2 inches/5cm and tempo 100-120/min.

* *When the green LED is activated, the software must first measure a value < 2inches/5cm three times, before the red LED starts flashing. Depth accuracy accelerometer: $\pm 5\%$*

10 Warranty/service

The manufacturer's warranty is 5 years. Please contact your dealer for more information regarding the warranty and conditions.

11 Explanation of symbols



This product complies with the requirements of the European Medical Device Regulation: (EU) 2017/745



Manufacturer



Consult instructions for use or consult electronic instructions for use



Warning: Consult the instructions



Catalogue number



Batch code/Lot number



Medical Device



Unique Device Identifier



Stand-by



Separate collection for waste electrical and electronic equipment recycling: electronic equipment. WEEE Directive 2012/19/EU



Do not use on children under 12



Ingress Protection rating - protected from limited dust ingress and sprays from all direction.



3V lithium button cell battery