EN

NeoBeat

Newborn Heart Rate Meter

User Guide

NeoBeat 532-010xx

NeoBeat Mini 531-010xx

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Contents

Clinical Indications

Device Description

NeoBeat is a heart rate measurement device using dry-electrode technology, with integrated digital display.

Indication for Use

NeoBeat is indicated to measure the heart rate in newborns.

Intended Use

NeoBeat is intended for use on newborns in the following weight groups:

NeoBeat is intended for use on newborns approximately 1.5 – 5 kg.
NeoBeat Mini is intended for use on newborns approximately 0.5 – 2 kg.

Intended Users

NeoBeat is intended to be used by healthcare professionals involved in newborn care.

Clinical Benefits

The intended clinical benefit of NeoBeat is the positive impact on newborn assessment by providing rapid and accurate presentation of the newborn's heart rate in real time.

Clinical Outcome

Desired outcome of NeoBeat is the presentation of the heart rate in real time.

Known Side Effects

None known.

Contraindications

None known.

Limitation of the Device

NeoBeat does not provide any type of alarms.
NeoBeat is not intended to be used unattended.

Important Information

The information in this User Guide applies to both NeoBeat and NeoBeat Mini.

Prior to first use, read the User Guide completely to become familiar with the operation and maintenance of NeoBeat. Read all Cautions and Warnings before using NeoBeat.

Warnings and Cautions

A Warning states a condition, hazard, or unsafe practice that can result in serious personal injury or death.
A Caution states a condition, hazard, or unsafe practice that can result in minor personal injury or damage to the product.

Notes

A Note states important information about the product or its operation.

Warnings

- *Decisions on when to start or end resuscitation efforts should not be made based on the output of this device alone.*
- *If an error has occurred, if the device provides no heart rate or if you do not trust the output, continue therapy without device.*
- *Handling of the newborn may cause false heart rate readings even when the patient has no heart rate (asystole). The device alone should not be used to confirm asystole/stillbirth.*
- *Care should be taken with newborns with exposed internal organs. Ensure placement on area of torso with intact skin.*
- *To avoid potential skin damage and infection, take care when placing NeoBeat Mini on preterms.*

- *Heart rate may not be detected correctly in the case of severe arrhythmia.*

⚠ Cautions

- *Excessive patient handling and movement may cause missing or erroneous heart rate readings.*
- *Do not misuse the device; e.g. using it on adults or children, or exposing the device to hard surface impacts.*
- *Do not use the product if it is damaged or cracked.*
- *Not intended to be sterilized as it may damage the device.*

Notes

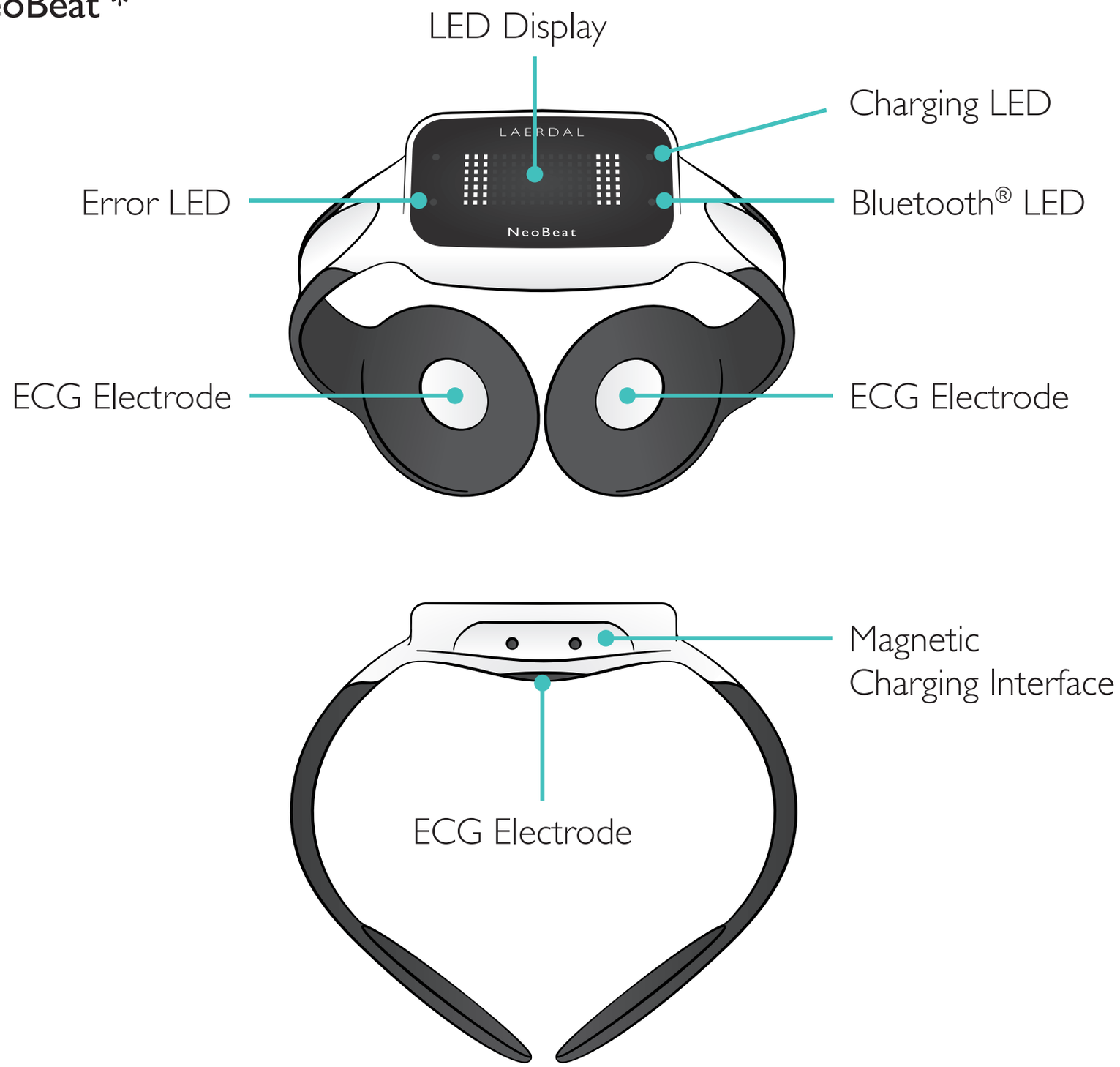
- *The device detects and displays the electrical heart rate, which in some conditions (e.g. pulseless electrical activity), may not reflect presence of circulatory pulse.*
- *Another person touching the electrodes simultaneously with the patient may interfere with the heart rate measurement.*
- *The device may indicate patient contact if one of the charging pins is touched while holding one ECG electrode.*
- *If the device is placed on a conductive surface, e.g. a metal tray or the electrodes are in contact with each other, it may show a number on the display, and may not go to standby, thus draining the battery.*
- *The electrodes are intended for use on moist newborn skin, and may reduce the heart rate accuracy when used with the thicker and drier skin of e.g. an adult's fingers.*

Before Use

Clean and disinfect NeoBeat as described in Reprocessing.
Charge NeoBeat as described in Charging.

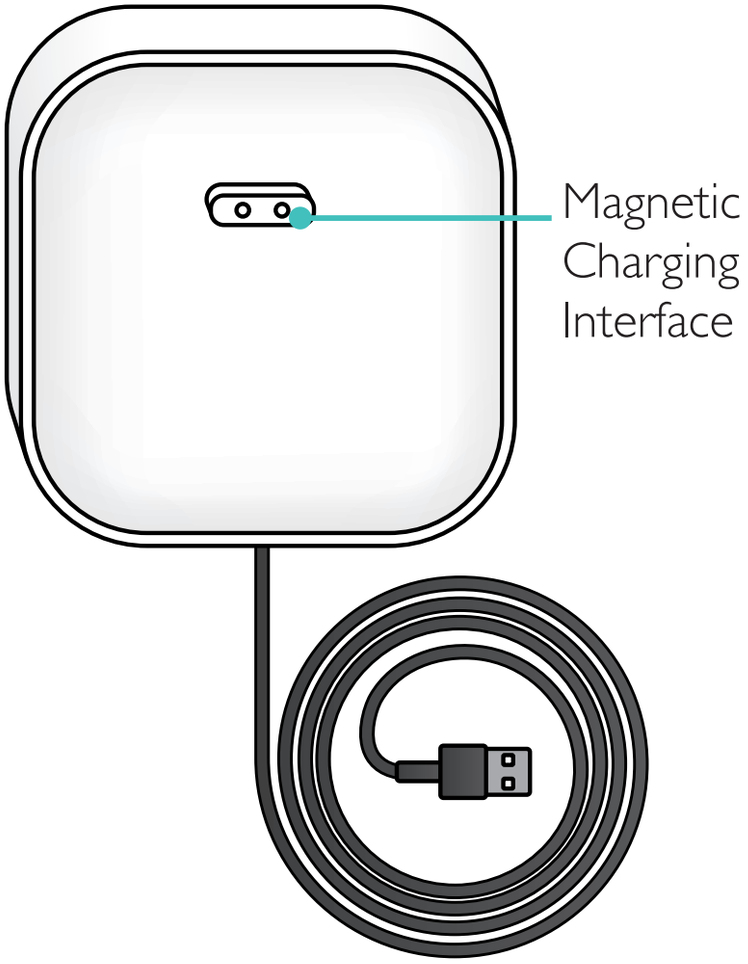
Overview

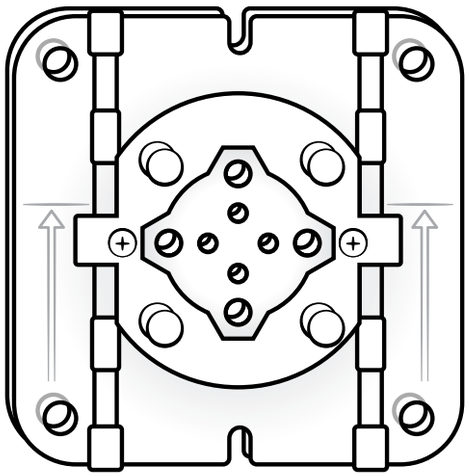
NeoBeat *



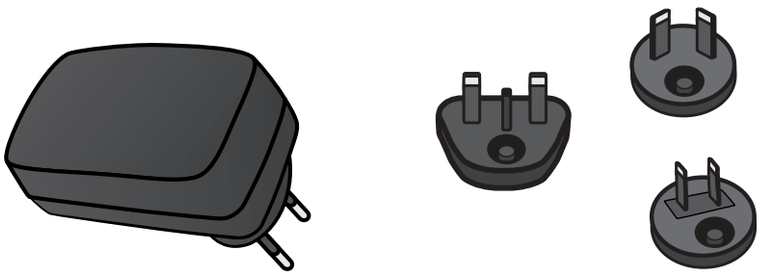
* Patient Applied Part

Charging Stand





Mounting Bracket



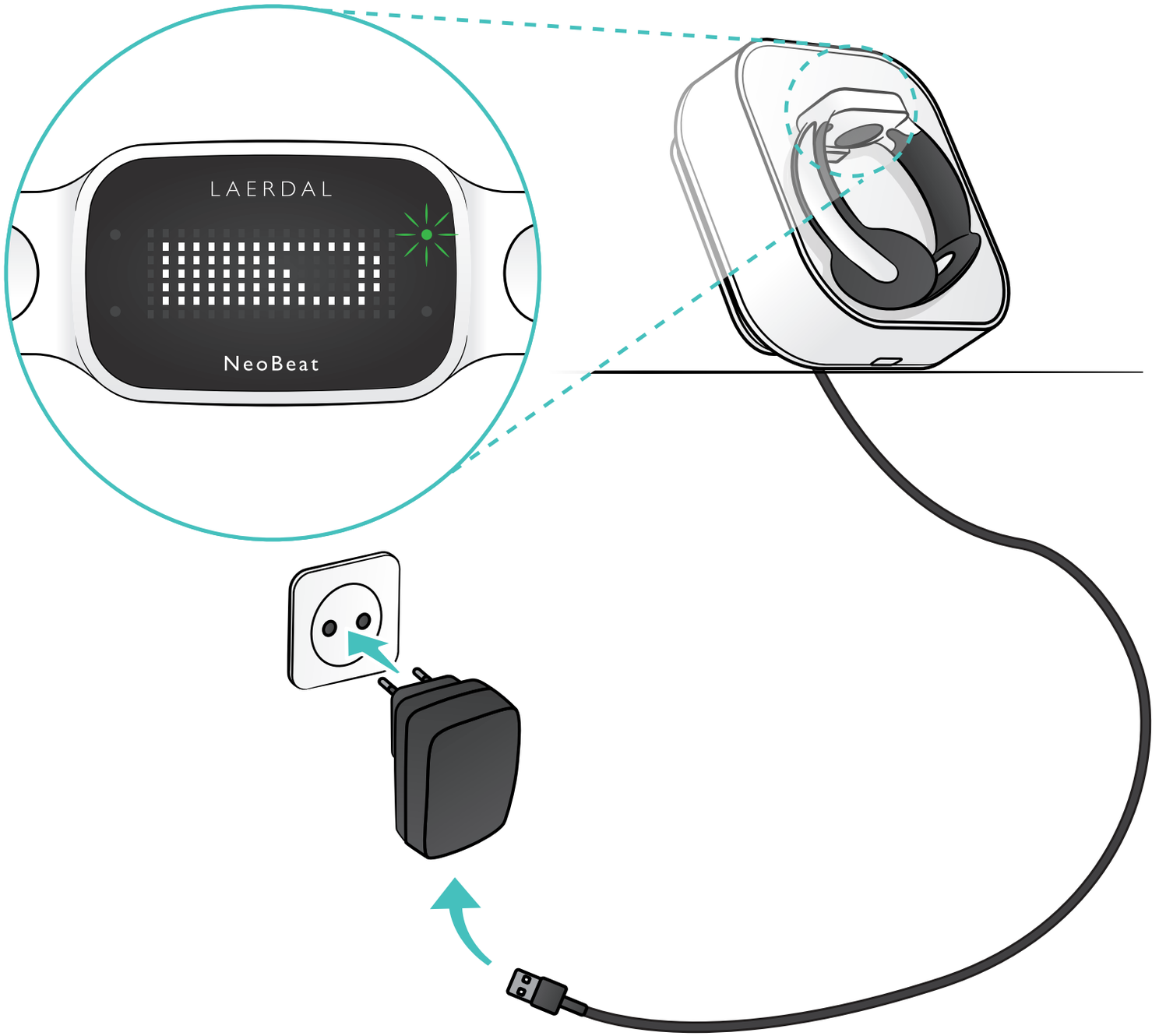
Power Adapter with interchangeable plugs

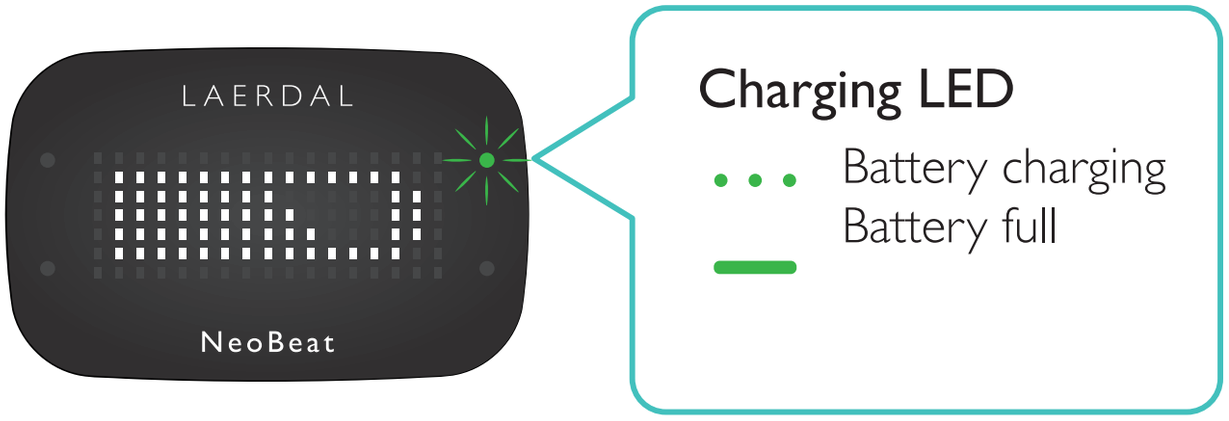
User Guide

Charging

First time use

To initiate the device, NeoBeat must be charged for up to 3 hours before first use. Place it on the Charging Stand to charge the battery.





Notes

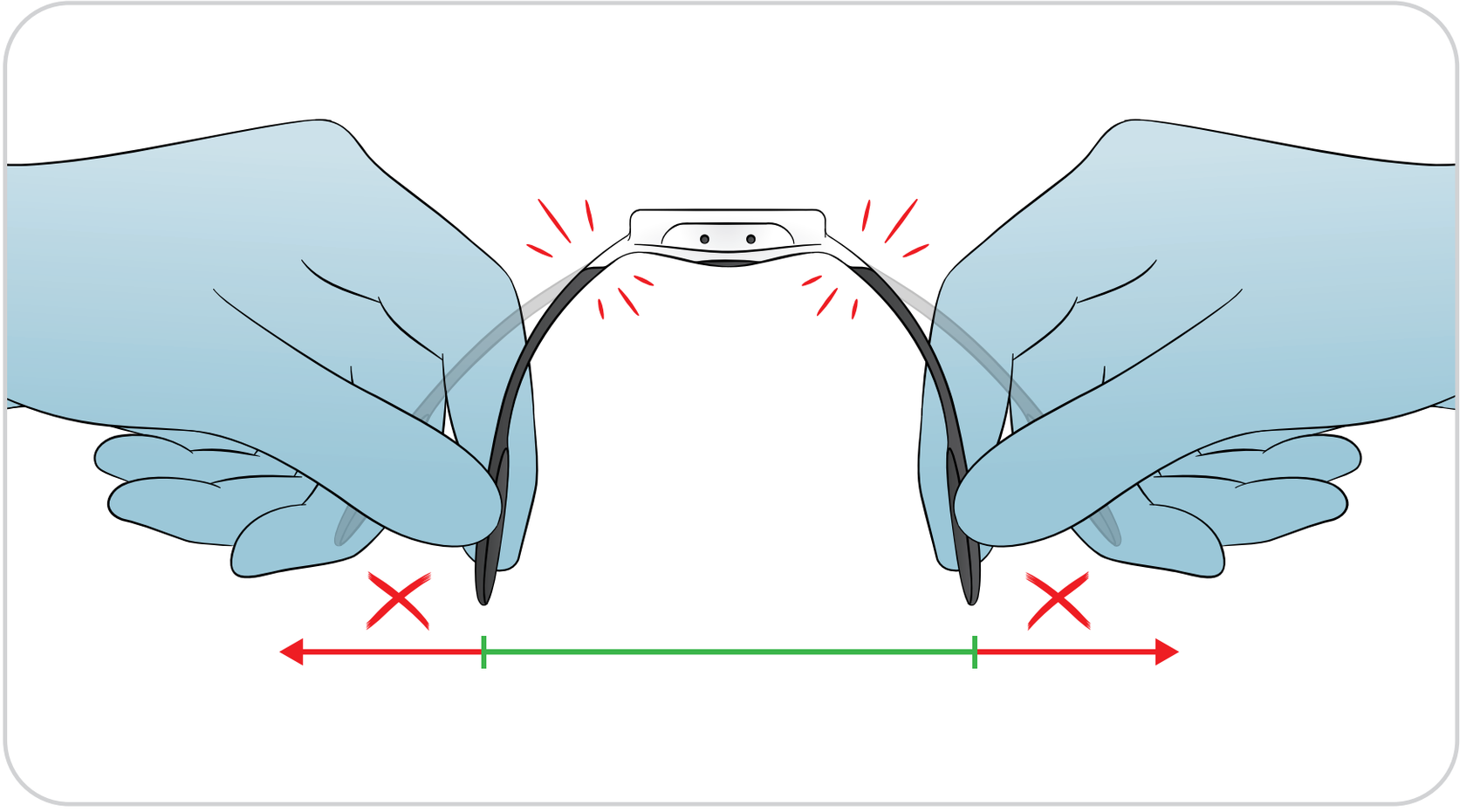
- *Maintenance charging: If NeoBeat is not stored on the Charging Stand, recharge it at least monthly.*
- *The USB port on the Charging Stand can be used to connect one (and only one) additional Charging Stand.*
- *It may take up to 30 minutes before the device indicates charging if the battery is very depleted.*
- *If a device does not start, perform restart procedure (p. 42) and leave it charging for another 30 minutes.*
- *NeoBeat is activated by motion. When not in use, store it on the Charging Stand to avoid unnecessary battery use.*
- *Device cannot be used clinically while charging*

Durability instructions

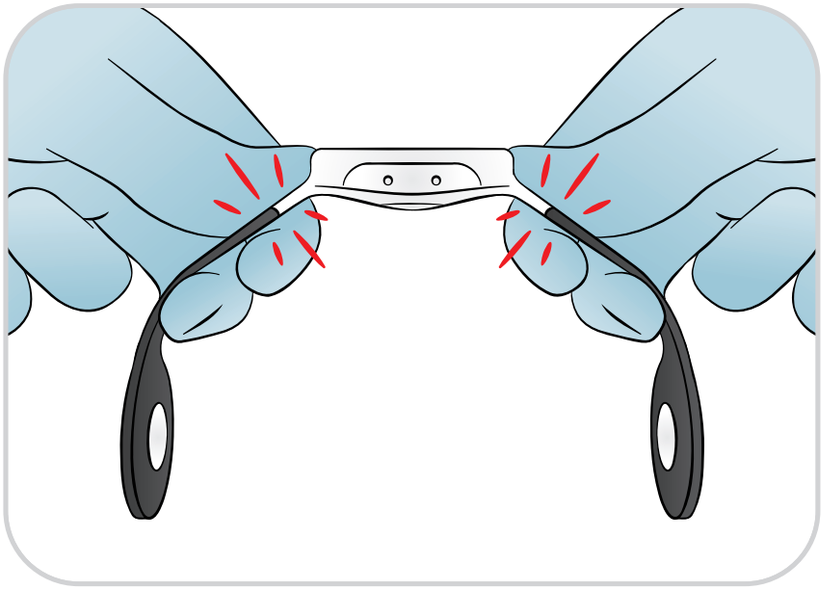
NeoBeat's ECG electrode arms are sensitive to stress from all bending applied during non-clinical or clinical use. Cumulative effects of stress on the arms may lead to them breaking.

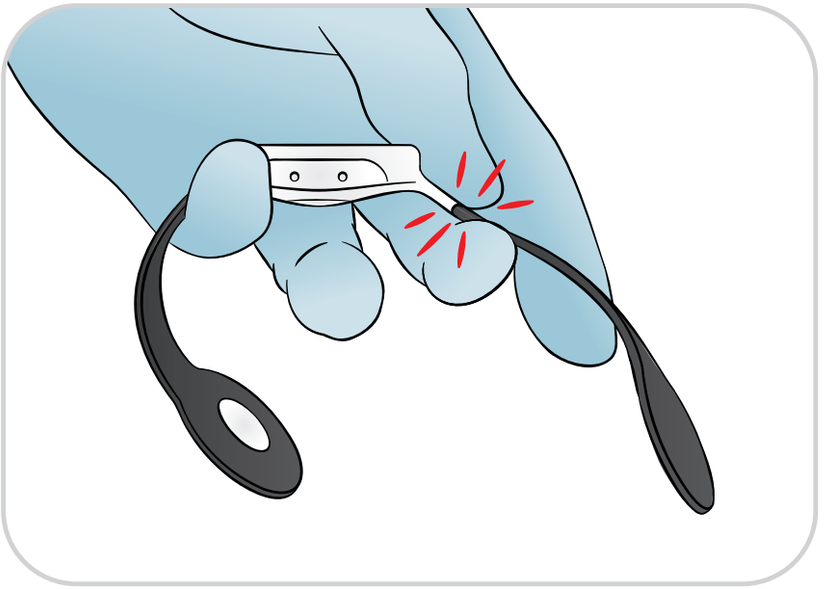
Handling of NeoBeat

The gentlest method of applying or removing NeoBeat is by extending the arms from the ends.



Other methods of extending the device such as pulling the arms outward from the centre or twisting them while holding the frame, can place excessive stress on the arms. This added strain increases the risk of bending or breaking the arms. Always extend the device using the recommended method to avoid damage.



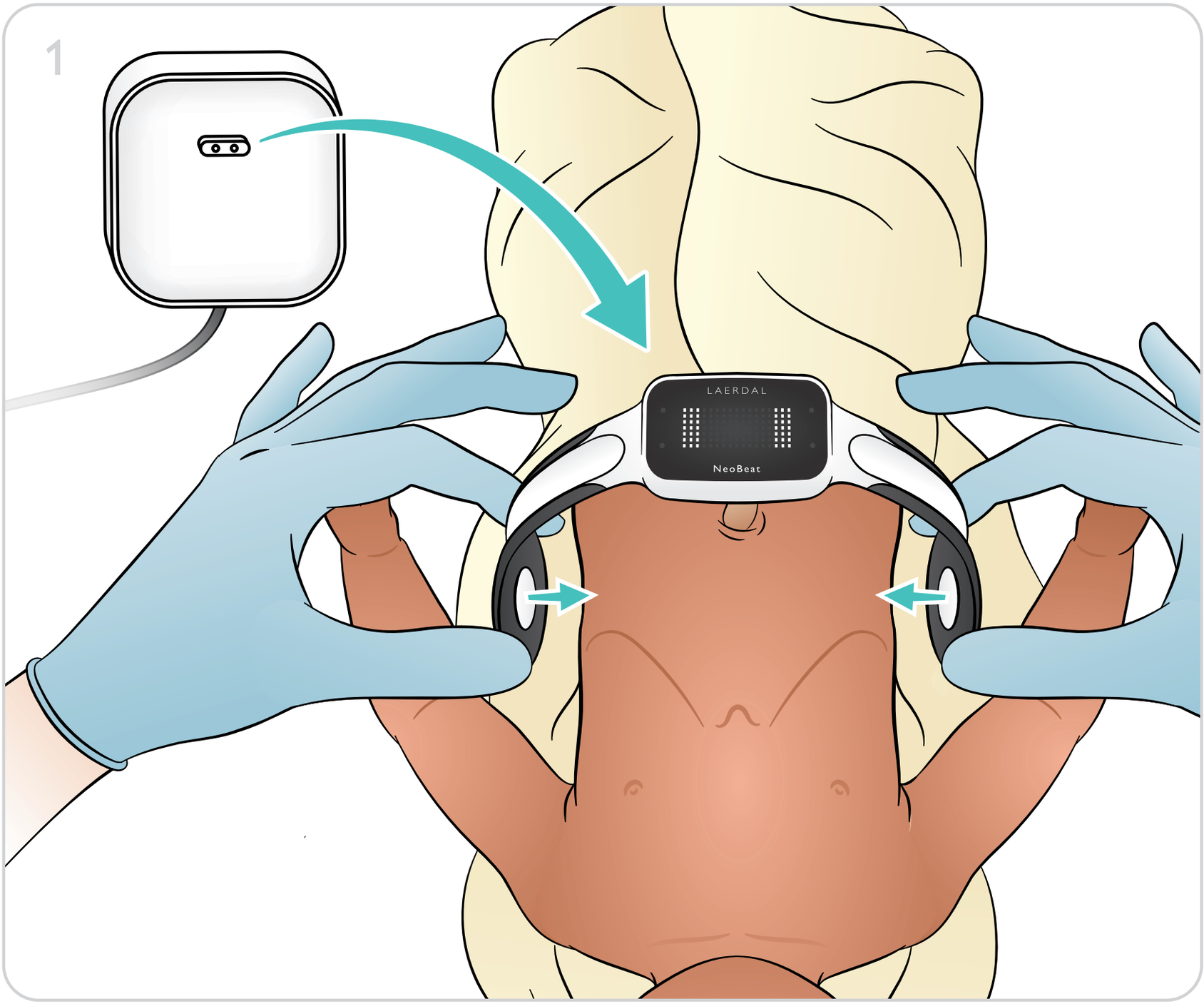


⚠ Caution

Do not extend the arms more than necessary for application to the newborn. Excessive bending may cause breaking of the arms.

Clinical Use

Remove NeoBeat from the Charging Stand and place it around the newborn's torso. NeoBeat automatically turns on when it detects motion.



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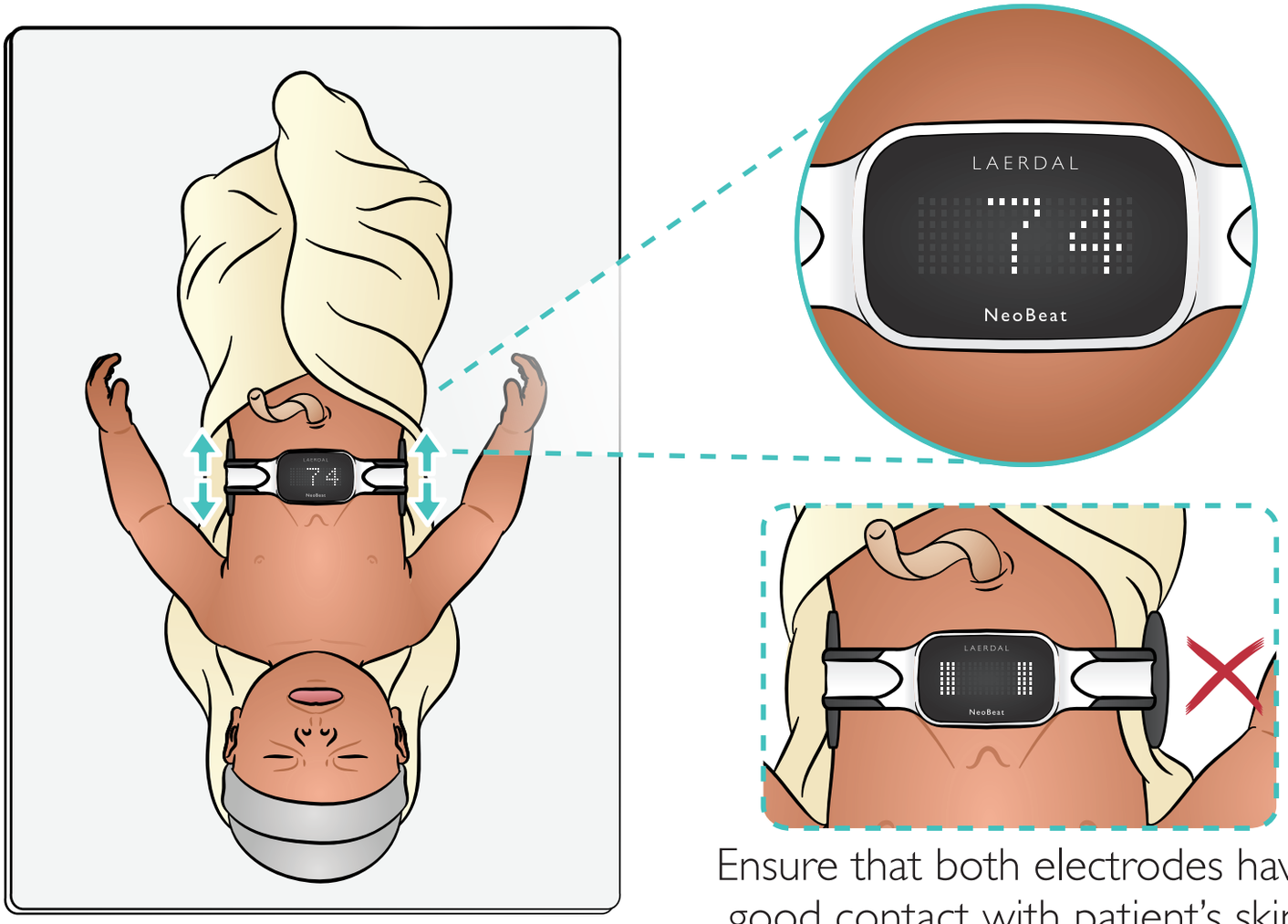


Ensure that both electrodes have good contact with patient's skin.

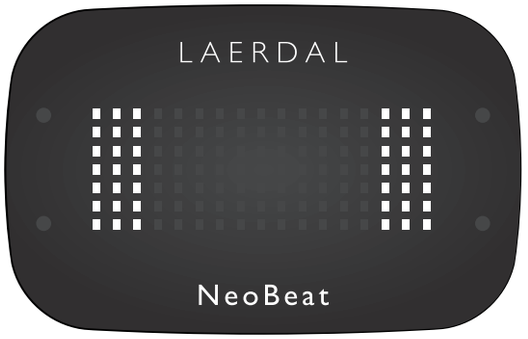
Warning

Stabilization or resuscitation maneuvers performed while the NeoBeat is in place may increase local pressure on the newborn's skin. This may result in temporary skin marks or bruising.

Notes

- *NeoBeat's position on the torso can be shifted so that its placement does not interfere with other therapies, e.g. chest compressions, palpation, auscultation, umbilical access.*
- *NeoBeat's can also be repositioned on the torso to improve signal quality.*

Clinical Use – Display

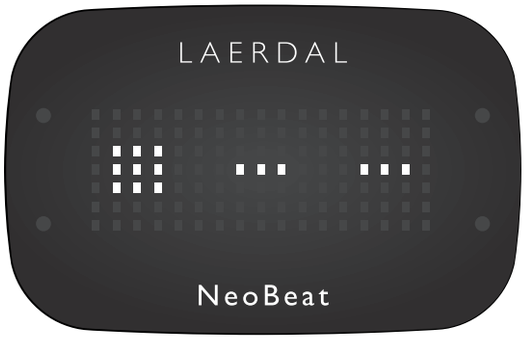


Activated - No contact

NeoBeat is activated, but there is no or inadequate patient contact. If no patient contact, the device will return to standby automatically after 10 seconds.

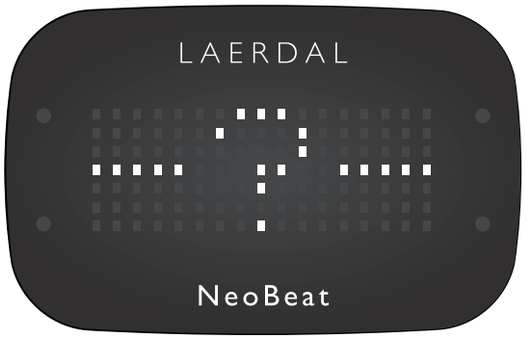
Note

Skin contact is necessary to measure heart rate. If the patient skin is too dry, add a drop of water under the electrodes to achieve contact or improve performance of the device.



Initial calculation

NeoBeat has patient contact and is calculating the heart rate.



Heart rate unknown

Heart rate cannot be detected. This may be due to poor positioning of the ECG electrodes, or lack of detectable heart rate despite having good contact.

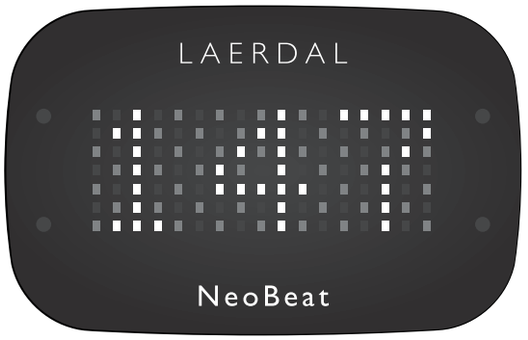
Note

Reposition device if no heart rate can be obtained. Moving the device closer to the heart may give a stronger signal.

Clear detection

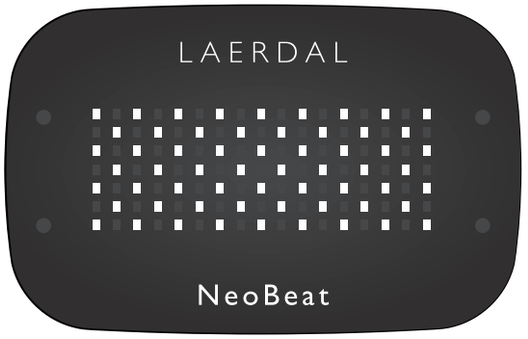
Heart rate is detected and there is good signal quality.

Clinical Use – Display



Weak detection

Heart rate is detected, but the signal quality is not good. This may be due to poor positioning of the device, skin is too dry or motion.



Undetectable due to motion

There is too much motion to detect heart rate.

Note

When excessive movement (e.g. stimulation) is detected, the device will not show a heart rate.

Low battery

From when low battery is first indicated, the device will have approximately 30–60 minutes remaining run time. Recharge NeoBeat after use and reprocessing, by placing it on the Charging Stand.

Error display

NeoBeat has detected an internal technical error. See troubleshooting section for details.

Use other methods for assessing newborn heart rate, e.g. by auscultation or palpation.

Reprocessing

Clean and disinfect NeoBeat after each patient use to minimize the risk of cross-contamination.

⚠ Warning

Do not place a used NeoBeat back onto the charging stand before it has been cleaned and disinfected.

Cleaning

1. Rinse NeoBeat under running lukewarm water for 15 seconds.
2. Clean all surfaces of NeoBeat using a cloth dampened with lukewarm (30 to 40 °C, 86 to 104 °F) tap water and mild dishwashing detergent for 30 seconds. To remove difficult soil, use a bristled brush (e.g. toothbrush) dipped in the cleaning solution. Clean for a minimum of 2 minutes, ensuring that all soil has been removed.
3. Rinse NeoBeat under running lukewarm water, for 15 seconds. Repeat once.
4. Dry NeoBeat using a clean cloth or by air drying.

Disinfection

1. Wipe all surfaces of NeoBeat with a clean cloth soaked with 70% ethanol or 70% isopropanol for a minimum of 2 minutes.
2. Spray 70% ethanol or 70% isopropanol on all surfaces of NeoBeat. Ensure it remains wet for a minimum of 12 minutes. Repeat spraying as necessary to account for evaporation.
3. Allow to air dry.

⚠ Cautions

- *Effective disinfection is not possible without first performing a thorough cleaning.*
- *Care should be taken while handling the product between cleaning and disinfection.*
- *Do not submerge any of the product components in liquid (including ethanol or isopropanol).*
- *Do not use disinfectants other than those specified, as this may damage NeoBeat materials, affect device functionality, and/or leave harmful chemical residues on the device surface.*
- *Do not use chlorine-based disinfectants, including sodium hypochlorite/bleach, or peroxide-based disinfectants*
- *The reprocessing method is designed to ensure NeoBeat is adequately disinfected between uses. Any deviation will increase the risk of cross-contamination especially for newborns that may have compromised immune defense, such as a pre-term baby or in the case of outbreaks of highly transmissible pathogens.*

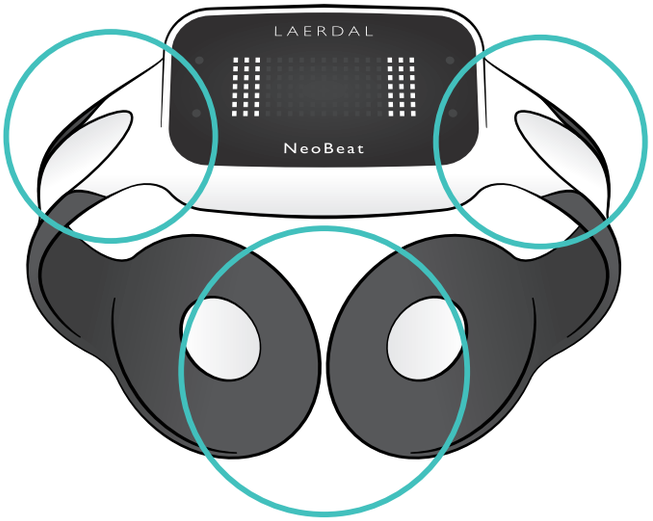
Notes

- *The disinfection procedure has been validated to meet the requirements for intermediate level disinfection in accordance with applicable standards.*
- *The reprocessing procedure uses carefully selected chemicals to ensure material compatibility, biocompatibility, absence of harmful residues, and maintained device functionality.*

Reprocessing

Inspection

After reprocessing, inspect NeoBeat for cracks and damage with particular attention to the highlighted areas.



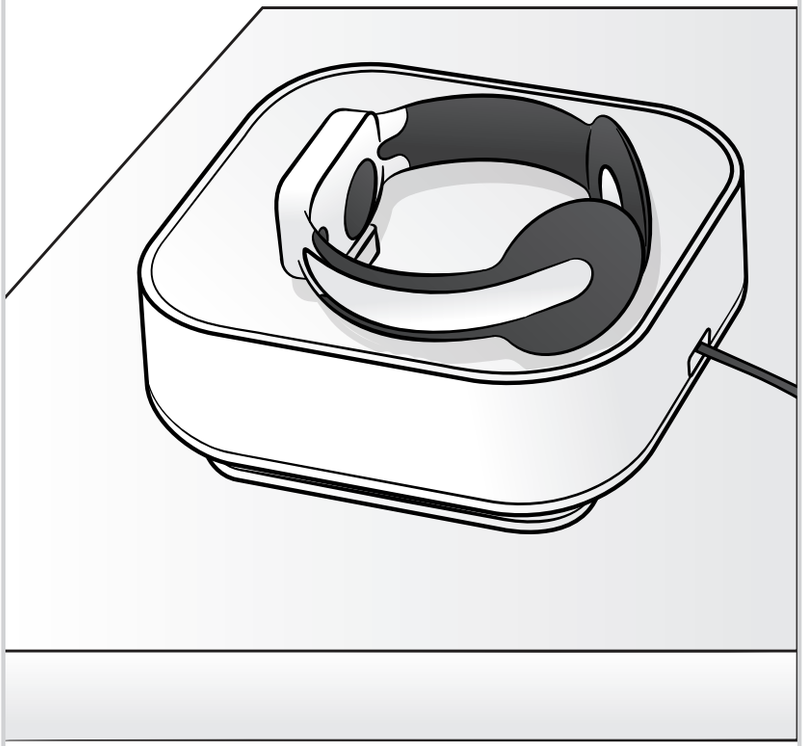
If there is any damage, remove the device from service. Otherwise, put the device back onto the Charging Stand.

Charging Stand

When needed, the Charging Stand can be cleaned and disinfected using the same method as previously described.

NeoBeat Charging Stand can be placed on a tabletop. NeoBeat Charging Stand can optionally be mounted vertically to a wall, rail or post.

Tabletop Use



Vertical Mount

⚠ Caution

Do not mount or place the Charging Stand in close proximity to heat sources (e.g. directly below an infant warmer heat lamp).
Ensure that the mounting of NeoBeat Charging Stand to any surface is safe and is performed by a competent person.

Installation

Vertical Mount

Use double sided foam tape (not included) or screws to mount the Mounting Bracket.

Multiple mounting screw hole patterns:

9 x 9 mm, 21 x 21 mm, 75 x 75 mm.

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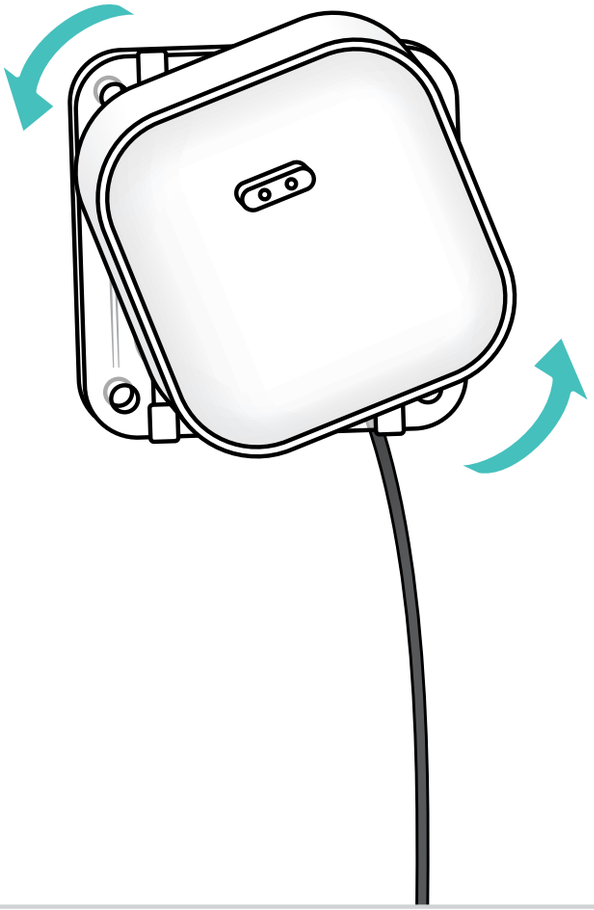

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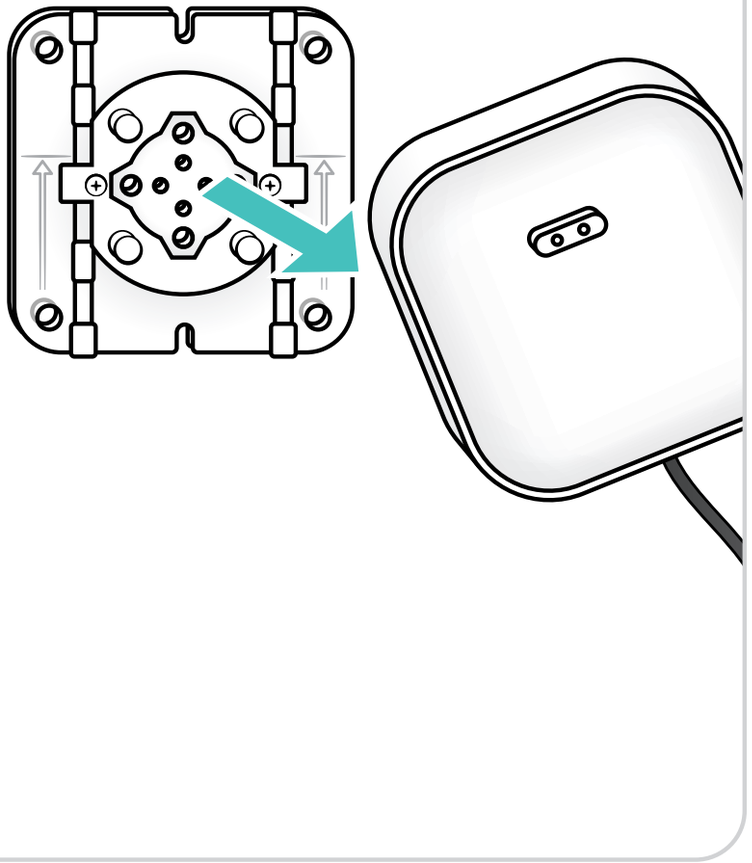

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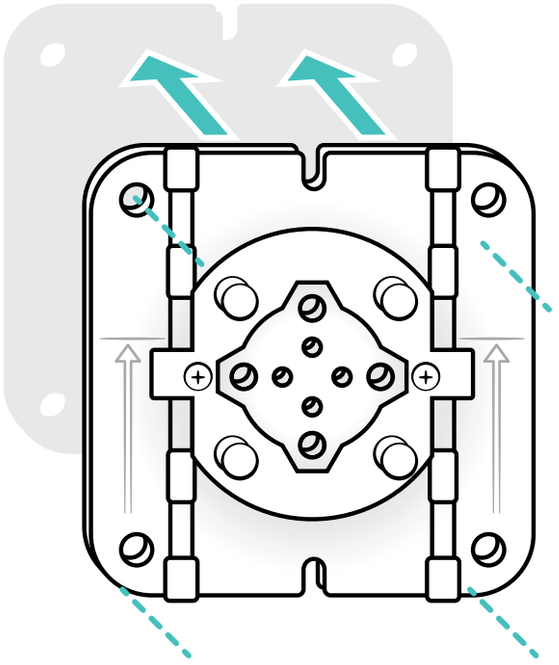

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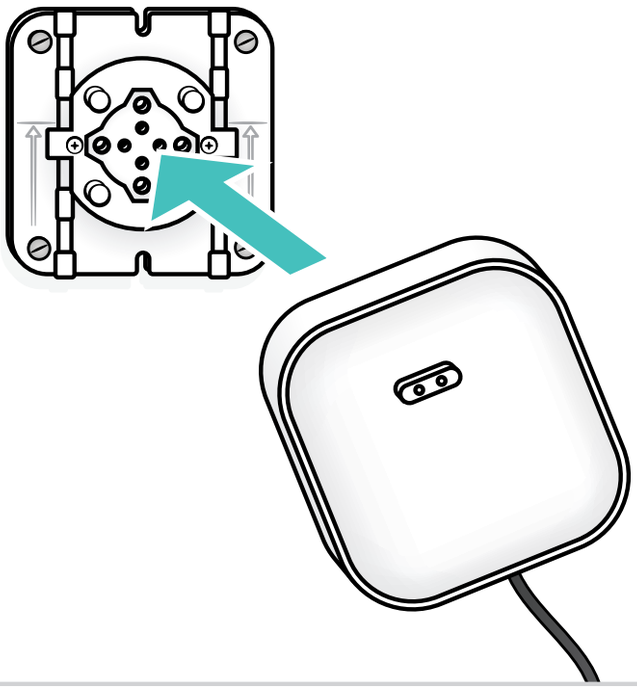

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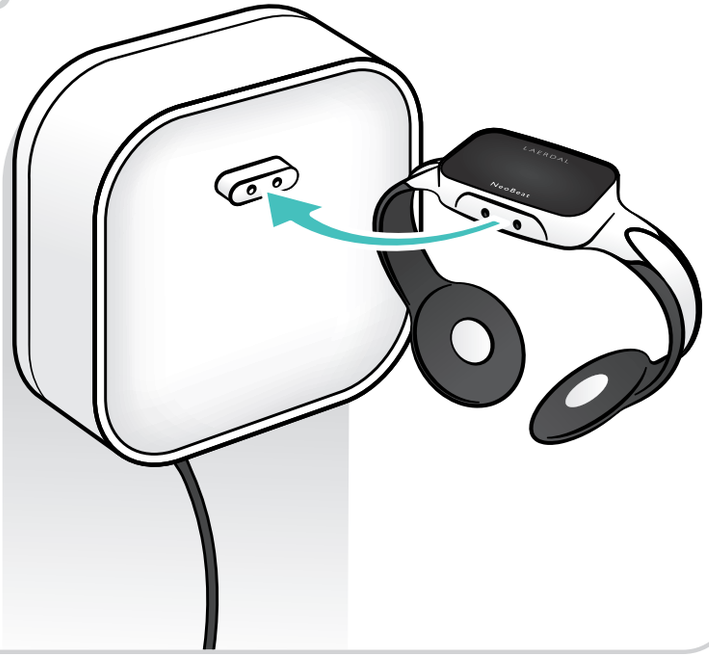


Service and Warranty

NeoBeat does not have any serviceable parts.

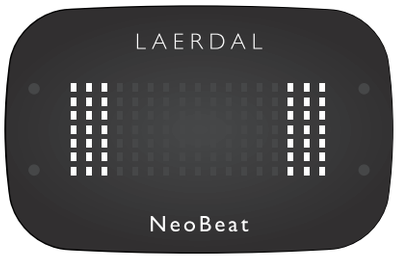
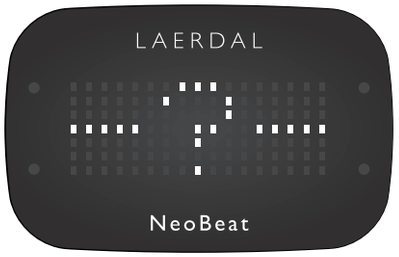
NeoBeat has a one-year limited warranty. Refer to company website for terms and conditions.

Main Device and System:

532-010xx NeoBeat Main Device
531-010xx NeoBeat Mini Main Device
532-000xx NeoBeat System
531-000xx NeoBeat Mini System

Accessories

532-21050 Power Supply and Plug Kit
532-20050 NeoBeat Charging Stand

Symptom/Display	Possible cause	Possible solution
Patient contact is not detected. 	Poor or no contact with skin. Or The skin is too dry for NeoBeat to detect patient contact.	Check for barriers or obstruction to skin contact, e.g. towel. Wet the electrodes with water and/or reposition the device.
Heart rate is not detected. 	The device is poorly positioned or not in direct skin contact with patient. Or Stimulation/movement/ handling of patient temporarily generating too much disturbance. Or Heart rate is outside detectable range.	Reposition the device. Moving the device closer to the heart may give a stronger signal. If the problem continues, use alternative means of measuring newborn heart rate, e.g. a stethoscope.

Troubleshooting

Symptom/Display	Error codes	Possible solution
Critical technical error. Error code is shown in the display and error light activated. 	x01 - Program memory x02 - Calibration memory x04 - Data memory x08 - RTC crystal x10 - Display driver communication x20 - Accelerometer communication x40 - Light sensor communication x80 - ECG analog signal chain	Continue clinical procedures without use of the device. Use alternative means of measuring newborn heart rate, e.g. a stethoscope. Place the device on the charging stand. If the problem persists, remove device from service.

Symptom	Possible cause	Possible solution
NeoBeat does not turn on or it turns off during use.	Battery depleted.	Continue standard procedure without use of the device. After the procedure, reprocess and charge the device. It may take up to 30 minutes before the device indicates charging if the battery is very depleted. If the problem persists, remove the device from service. A replacement NeoBeat may be ordered.
Nonfunctional or damaged device detected during equipment inspection.		Remove the device from service. A replacement NeoBeat may be ordered.

Specifications

Environmental	
Temperature	Operating: 0 – 40 °C (32 – 104 °F)
	Storage / shipping: Short-term: -20 - 60 °C (-4 - 140 °F) Long-term: 15 - 25 °C (59 - 77 °F)
Atmospheric Pressure	Operating: 620 – 1060 hPa (up to 4000 meters above sea level)
	Storage / shipping: 620 – 1060 hPa
Relative Humidity	Operating: 15% - 90%, non-condensing
	Storage / Shipping: 15% - 90%, non-condensing

Heart Rate Meter	
Dimensions	NeoBeat: 83 x 87 x 40 mm (3.2 x 3.4 x 1.6 inches) NeoBeat Mini: 70 x 70 x 40 mm (2.8 x 2.8 x 1.6 inches)
Weight:	NeoBeat: 31 g (1.1 oz) NeoBeat Mini: 27 g (1 oz)

Materials	
NeoBeat Body	Polyamide Conductive TPU
NeoBeat Metal Electrodes	Stainless steel

Power	
Battery	Internal rechargeable lithium-ion button cell, 3.7 V, 120 mAh Typical service life of battery: 3 – 6 years depending on use
Run time	>4 hours (full charge on new battery) >3 hours (full charge at expected end of battery service life)
Charge time	Up to 3 hours (full charge of empty battery)
Power supply	Input 100 – 240 V AC, 50 – 60 Hz, 0.3 A Output 5 V DC, 1 A

Lifetime parameters	
Shelf life	3 years
Expected Service Life	NeoBeat - typically 100 cycles of reprocessing
	NeoBeat Mini - typically 100 cycles of reprocessing

⚠ Caution

Only use provided power supply, PSAI05R-050QL6-R, or an alternative 5 W USB power supply, 5 V DC, 1 A, that is IEC 60950-1, IEC 62368-1 or IEC 60601-1 certified.

Heart Rate Measurement	
Accuracy	Short term average ±10% or ±5 bpm, whichever is greater, in the range 30 – 250 bpm and 0.2 - 5 mV QRS amplitude. No detectable heart rate is displayed as "-?-"

Specifications

Classification	
Ingress Protection	Heart rate meter: IP55 - Protected against ingress from dust and water jet spraying. All other components: IPX0 - Not protected against liquid ingress.
IEC 60601 - 1	Internally powered/class II equipment type BF

⚠ Warning

Do not modify this equipment without authorization of the manufacturer.

⚠ Caution

Changes or modifications not expressly approved by Laerdal Medical could void the user's authority to operate the equipment.

Technical Description

Federal Communications Commission (FCC) and Industry Canada (IC) Statement

This device complies with part 15 of the FCC Rules and Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions:
This device may not cause harmful interference, and
this device must accept any interference received, including interference that may cause undesired operation.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:
L'appareil ne doit pas produire de brouillage, et
L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

FCC ID: QHQ-20-09917
IC: 20263-2009917

Symbol Glossary	
MD	Medical Device
CE 2460	This medical device is in compliance with the general safety and performance requirements of Regulation (EU) 2017/745 on medical devices. This product is in compliance with Council Directive 2014/53/EU on Radio Equipment (RED) and Council Directive 2011/65/EU on restriction of the use of certain hazardous substances (RoHS).
	Australia Radiocommunications and EMC Compliance Mark
	This appliance is marked according to the European directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE).
IP55	Protected against ingress from dust and water jet spraying
	Meets IEC type BF applied part leakage current requirements
	Manufacturer
	Consult User Guide

Technical Description

Symbol Glossary	
	Temperature limitation
	Atmospheric pressure limitation
	Humidity limitation
XXX 	Machine readable Unique Device Identification (UDI). The last three digits of the UDI are printed above the machine readable UDI for easier distinction between devices.

Waste Handling

This appliance is marked according to the European directive 2012/19/EC on Waste Electrical and Electronic Equipment (WEEE). By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. The symbol on the product, or on the documents accompanying the product, indicates that this appliance may not be treated as household waste. Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment. Disposal must be carried out in accordance with local environmental regulations for waste disposal.
For more detailed information about treatment, recovery and recycling of this product, please contact your local city office, your household waste disposal service or Laerdal representative.

Electromagnetic Conformity

NeoBeat is intended for use in the following environments: Health care facilities except for near HF surgical equipment and the RF shielded room for magnetic resonance imaging.

No particular actions are required to maintain safety and performance with regard to electromagnetic disturbances for the expected service life.

⚠ Warnings

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NeoBeat, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical Description

Electromagnetic Emissions Tests

Emissions Test	Standard or test method	Compliance
Radiated RF emissions	CISPR 11	Group 1 Class B
Conducted RF emissions	CISPR 11	N/A
Harmonic distortion	IEC 61000-3-2	N/A
Voltage fluctuations/ flicker	IEC 61000-3-3	N/A

Electromagnetic Immunity Tests

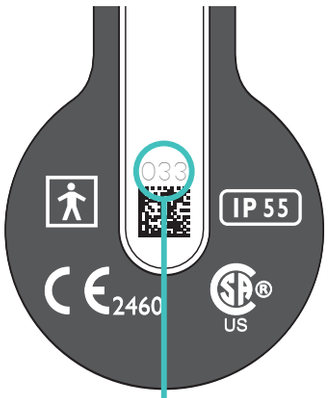
Immunity Test	Standard or test method	Immunity Test Level
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air Maximum recovery time following a TRANSIENT phenomenon: 2s
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 2 Hz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	380-390 MHz: 27 V/m 430-470 MHz: 28 V/m 704-787 MHz: 9 V/m 800-960 MHz: 28 V/m 1700-1990 MHz: 28 V/m 2400-2470 MHz: 28 V/m 5100-5800 MHz: 9 V/m

Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Immunity Test	Standard or test method	Immunity Test Level
Proximity magnetic fields	IEC 61000-4-39	30 kHz: 8 A/m 134.2 kHz: 65 A/m 13.56 kHz: 7.5 A/m
Electrical fast transients / bursts	IEC 61000-4-4	N/A
Surges: Line-to-line	IEC 61000-4-5	N/A
Surges: Line-to-ground	IEC 61000-4-5	N/A
Conducted disturbances induced by RF fields	IEC 61000-4-6	N/A
Voltage dips	IEC 61000-4-11	N/A
Voltage interruptions	IEC 61000-4-11	N/A

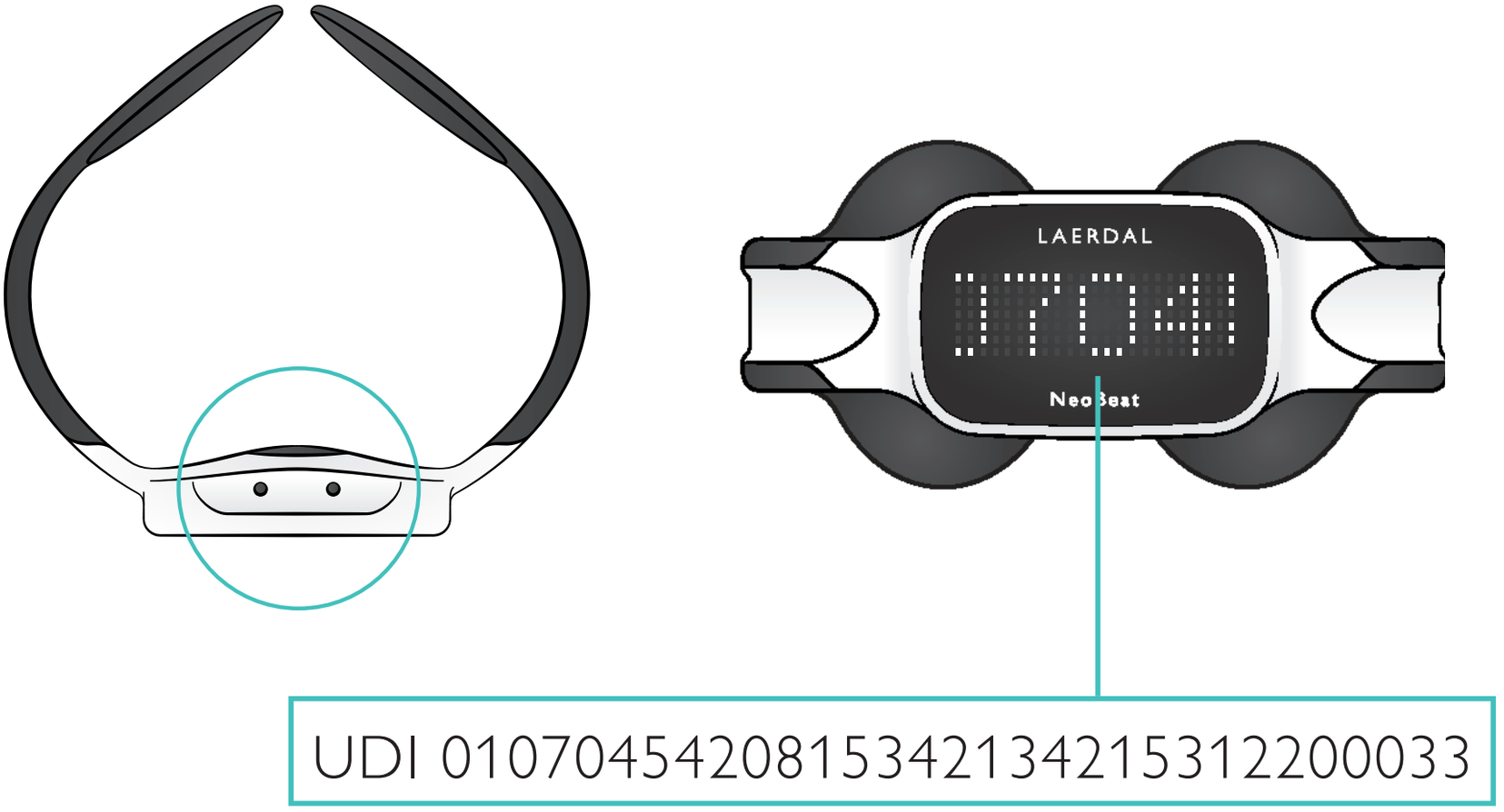
Machine Readable Unique Device Identification (UDI)

The GS1 DataMatrix located on the outside of the electrode arm of NeoBeat contains the UDI of the device. This barcode can be read using apps on a smart phone or tablet.

Identify the 3-digit short SN (serial number) and the GS1 2D datamatrix:	On a GS1 compliant scanner, or with a smartphone with a suitable App, capture the datamatrix.	For manual reading of the code, copy the numeric string that represents the UDI identifier.	For manual decoding of the serial number, the UDI code can be read as below example
 Example: Short SN printed on device	 Example	 Example	UDI code(example): 01070454208153421342 1**5312200033** SN is the last 10 digits: 531 22 00033 531 = NeoBeat Mini 532 = NeoBeat 22 = manufacturing year 00033 = unit production number, (033 is the short SN on the device)

Information Available Electronically

Hold NeoBeat upside down and double tap firmly on the charging pin side to display the unique device identification (UDI), FCC ID, IC certification number and software version.



Technical Description

Bluetooth® Low Energy transmitter

Frequency band: 2.400 – 2.4835 GHz
Modulation: Gaussian frequency shift modulation
Maximum radio-frequency power transmitted: 1 mW
Effective radiated power: 0 dBm

Restart NeoBeat

NeoBeat can be restarted by placing NeoBeat on and off the charging stand 10 consecutive times and then leaving it on the charging stand.

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