NUKUTE

NUKUTE COLLARE HEALTHCARE PROFESSIONAL MANUAL

NUKUTE

CE
0598

NUKUTE COLLARE MANUAL

Version 9.0

Latest Revision May 2022

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MANUFACTURED BY

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NUKUTE

1. INTRODUCTION 6

1.1. CONTACT INFORMATION 7

1.2. INTENDED USE 7

1.3. DISCLAIMER 7

1.4. CONTARAINDICATIONS AND PRECAUTIONS 8

1.5. SYMBOLS 10

2. GETTING STARTED 13

2.1. UNPACKING 13

2.2. SYSTEM OVERVIEW 14

2.2.1. Carrying case (1) 14

2.2.2. Tablet (2) 14

2.2.3. Neckband and modules (3, 4, 5, 6, 7, 8) 15

2.2.4. Pulse oximeter, sensor and medical tape (9, 10, 19) 15

2.2.5. Cables and adapters (11, 12, 13, 14, 15, 16, 17, 18) 15

2.2.6. Quick start guide (18) 16

2.3. Accessory Kit 16

3. FREQUENTLY USED FUNCTIONS – PATIENT 16

3.1. Instructions 16

3.2. Starting the measurement 17

3.3. Ending the measurement 23

3.4. Charging 24

3.4.1. Charging the Collare 25
3.4.2. Charging the pulse oximeter 26
3.4.3. Charging the tablet 26
3.5. Packing instructions 27
4. FREQUENTLY USED FUNCTIONS - HEALTHCARE PROFESSIONAL - SLEEP APNEA 28
4.1. Instructions 28
4.2. Preparing the measurement 29
4.3. Starting the measurement 34
4.4. Ending the measurement 40
4.5. Return device set and transfer remaining data 41
4.6. Viewing the measurement 44
5. GENERAL FREQUENTLY USED FUNCTIONS - HEALTHCARE PROFESSIONAL 45
5.1. Charging 45
5.1.1. Charging the Collare 46
5.1.2. Charging the pulse oximeter 47
5.1.3. Charging the tablet 47
5.2. Packing instructions 48
5.3. Cleaning instructions 49
5.3.1. Cleaning and disinfecting the Collare 50
5.3.2. Cleaning and disinfecting the carry case 53
5.3.3. Cleaning and disinfecting Charging cables 54
5.3.4. Cleaning and disinfecting pulse oximeter 55

5.3.5. Cleaning and disinfecting the tablet 56
5.4. Maintenance and update 56
5.5. Software update 57
5.6. SIM card and connections 59
6. INFORMATION 61
6.1. Technical specification 61
6.2. Environmental conditions 62
6.3. Disposal instructions 63
6.4. Service and repair 63
6.5. Warranty 64
6.6. Compliance to Standards and classifications 64
6.7. Essential performance 64
6.8. Electromagnetic compatibility (EMC) information 64
6.9. Troubleshooting 70
6.10. Measuring Pulse Oxygen using Berry Electronics Pulse oximeter 72
6.11. Declaration of conformity 72
7. ABOUT 73

1. INTRODUCTION

This is Manual for Nukute Collare system. Latest version of the manual can be read in electric form in address: www.nukute.com/support/manual. Printed versions of the instructions are available at no additional cost: https://nukute.com/support/ifu

Instruction for use explains the safety issues and introduces the device and its usage. The device must be used according to this user manual.

Nukute Collare system is used for recording vitals of a person. The system is designed to be easy to use and comfortable to wear so that even during sleep, the quality of sleep is not impacted by the measurement. The system does not provide immediate results to the person after completing the measurement, since the results need to be analyzed by a healthcare professional. Measurement data is sent to a cloud service from where the physician can access the results and make diagnostic decisions accordingly. Patients should always consult the physician for results after the measurement.

The Nukute Collare device is classified according to the Annex IX of the Medical Device Directive 93/42/EEC. According to the definition 1.6, the device is an active device for diagnosis. Although not directly used for diagnosis, the device provides information by monitoring physiological conditions. Thus, according to implementing rule 10, Collare is classified as Class IIa device.

1.1. CONTACT INFORMATION

In case you want to contact Nukute:

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Mäkelininkatu 43
90100 Oulu
FINLAND
www.nukute.com
info@nukute.com
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1.2. INTENDED USE

Nukute Collare system is intended to be used for adult patients for primary monitoring, detection, and analysis. The acquired data is intended to be used by healthcare professionals and the analysis may aid in the diagnosis of sleeping related disorders.

Intended medical indication:

Nukute Collare system may aid in the detection of compromised breathing from the patient sleep.

1.3. DISCLAIMER

The manufacturer is responsible for safety, reliability and performance of this production only in the following conditions:

- All installation operations, expansions, changes, modifications, and repairs of this product are conducted by manufacturer authorized personnel.
- The product is operated under observance of this manual.
- Nukute does not accept any liability for the use or misuse whether direct or indirect of the products, or for damages arising out of the use of or inability to use the product.
- All clinical conclusions and decisions that are based on the use of this product are the responsibility of the medical specialist.

1.4. CONTARAINDICATIONS AND PRECAUTIONS

- Patient is younger than 18 years old
- Patient has neck injuries (skin in the neck area is not intact).
- Patient has a pacemaker or stimulators.
- Patient is not able to follow the instructions and use the device (Home use)

CAUTION!

- It is important to read the safety issues before using the Nukute Collare system.
- It is not allowed to use another power adapter other than provided inside the carrying package. The power adapter needs to be medically and tested against IEC 60601
- Maintenance while device is in use is not allowed. When maintenance is ongoing the device always needs to be powered off.
- Do not use Collare or its parts if the patient is under 18 years old.
- There are no user serviceable parts. The device should be serviced by authorized personnel only. Service performed by non-authorized personnel may affect the recorded data and result in possible incorrect treatment. The warranty is void if the Collare or its parts are opened.
- Patient is not allowed to perform maintenance. Only properly trained persons are allowed to perform maintenance operations.
- Use of accessories, transducers and cables other than specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.
- Make sure that Collare and its parts are not damaged. Using a damaged Collare or its parts may cause wrong diagnosis or patient injury.
- Do not use Collare and its parts during radiography / X-ray studies.
- Check the approved environmental conditions before transport / usage.
- Do not use Collare and its parts in sunlight or rain.
- It is not allowed to transport Collare and its parts without the specified carrying case.

- When using the Collare in the home, avoid exposing it to lint and dust.
- When using Collare in the home, keep it away from pets.
- Collare is compliant with biocompatibility IEC 10993-1. But using the device may cause temporary allergic reaction, rash or irritation. If symptoms persist contact your healthcare professional. To avoid rash, make sure that patient skin is clean and free from cream.
- Do not bend or stretch Collare neckband more than needed to put it on your neck.
- Make sure that the environment is quiet and/or other people's noises (snoring or child crying) is not disturbing the measurement.

WARNING!

- Keep the Collare and its parts away from children. Children should not in any circumstance wear the Collare and its parts.
- As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation.
- Make sure that Collare and its parts are not damaged. Using a damaged Collare or its parts may cause wrong diagnosis or patient injury.
- The Collare system is not certified to be used for continuous-time monitoring where failure to operate can cause injuries or death of the patient. Collare is intended to be used for approximately 10-hour measurement.
- No modification of this equipment is allowed.
- It is prohibited to connect Collare, or its parts, to anything other than provided devices.
- Follow defined environmental conditions and avoid using Collare when the device is overheated. In a case of overheating please contact your distributor.

1.5. SYMBOLS

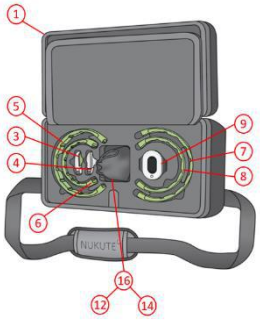
CE 0598	The CE mark on this product indicates it has been tested and conforms to the provisions noted within the 93/42/EEC Medical Device Directive. CE mark with notified body identification number indicates a product.
	Manufacturer – Name and the address of the manufacturer. Symbol also indica manufacturing date of the device.
SN	**Serial number** – Every part has a unique serial number.
	Fragile – Handle with care.
	Keep Away from water
	Temperature limitations – Collare has operational, storage and transportation tempe limits.
	Do not re-use – SpO2 sensor is disposable, not reuse it.
	Disposal information – European directive on waste electrical and electronic equi (WEEE) 2012/19/EU specifies the disposal.

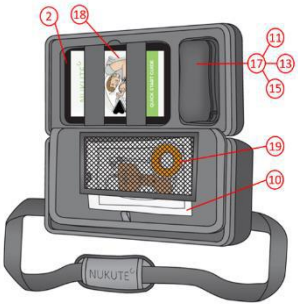
	Non-ionizing electromagnetic radiation – Collare has wireless connection.
	Number of packages – Symbol contains information on the amount of packages.
	Humidity limitations – Collare has humidity limitations.
	Atmospheric limitations – Collare has atmospheric limitations.
	This way Up – Indicates that packages need to be transferred in correct position.
	Refer to instruction manual/booklet – Read instruction for use before using the device
	Type BF applied part – Degree of protection (applied part) against electric shock: class of type BF. Parts in physical contact with the patient comply with IEC 60601-1. Collare system applied parts: Collare with battery and measurement module and pulse oximeter with sensor.

	Caution- Indicates a situation which could result in device harm, damage or malfu the appropriate precautions are not followed.
IP22	**Degree of protection-** The product with carrying case is protected against harmful of dripping water as per IES 60529. First number 2: Protected against solid foreign objects of 12,5mm Ø and greater. Second number 2: Protection against vertically falling water drops when enclosure to 15°
	WARNING- There are some warnings when using the device, read them carefully before us the device.
	CAUTION - There are some cautions and precautions when using the device, read them carefully before using the device.

2. GETTING STARTED

2.1. UNPACKING





1	Sales Package	10	Pulse Oximeter Finger Sensor
2	Tablet	11	Tablet Charging Cable
3	Battery Module	12	Tablet Charger
4	Measurement Module	13	Collare Charging Cable
5	Neckband Assy L	14	USB Charger Module
6	Neckband Assy X	15	Pulse Oximeter Charging Cable
7	Neckband Assy M	16	Charger Bag
8	Neckband Assy S	17	Cable Bag
9	Pulse Oximeter	18	Quick Guide
19	Medical Tape		

2.2. SYSTEM OVERVIEW

2.2.1. Carrying case (1)

CAUTION!

It is prohibited to transport Collare and its parts without the carrying case.

Carrying case is used for Collare and its components during storing and transportation. Carrying case provides protection against water and dust ingress (IP22).

2.2.2. Tablet (2)

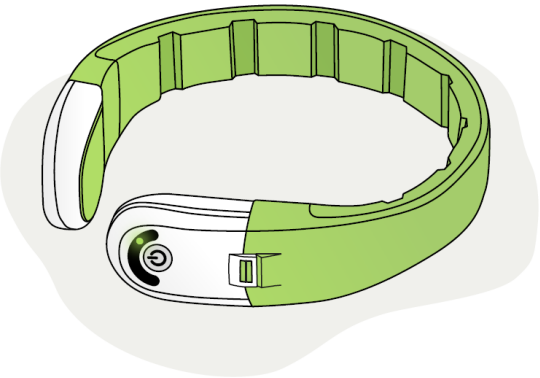
The tablet device delivered with the Nukute Collare system is the primary source of user instructions. The tablet is used as a router for receiving measurement data from the neckband and sending it to the cloud for analysis.

SIM card is delivered with the tablet and used for transferring measurement from the tablet to the cloud where measurement data is analyzed.

NOTE! User cannot modify the network settings.

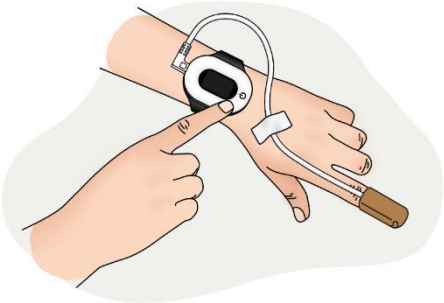
NOTE! It is not allowed to remove or change the SIM card, because it would result in delayed diagnosis.

2.2.3. Neckband and modules (3, 4, 5, 6, 7, 8)



There are four different size neckbands inside the carrying case (X, S, M and L). Measurement (4) and battery (3) modules are needed when using the neckband. Assembled neckband is used for recording breathing sound and detecting position of the patient. Measurement module (4) contains microphones for breathing sound measurement and a motion sensor for patient position definition.

2.2.4. Pulse oximeter, sensor and medical tape (9, 10, 19)



Pulse oximeter with sensor is us saturation. **Note!** Pulse oximeter sensor is not usable.

2.2.5. Cables and adapters (11, 12, 13, 14, 15, 16, 17, 18)

Collare and its accessories have specified power adapters and cables. Cables and adapters are verified and meet the IEC 60601 requirements. Store charger (12, 14) inside the charger bag (16) and all cables (11, 13, 15) inside the cable bag (17). See charging instructions on separate chapter.

2.2.6. Quick start guide (18)

Quick start guide is stored inside the carrying case and it is used for giving a quick overview on how to start the measurement. Full Collare Manual is needed only when tablet instructions, together with quick guide, are not sufficient to resolve the problem.

2.3. Accessory Kit

Accessory kit package can be purchased from Nukute or distributor.

Accessory Kit contains:

- 5 pcs Quick Start Guide (18)
- 20 pcs disposable pulse oximeter sensor (10)
- 3 pcs Medical tape (19)

3. FREQUENTLY USED FUNCTIONS VPATIENT

3.1. Instructions

Operator should contact Nukute customer service or distributor if:

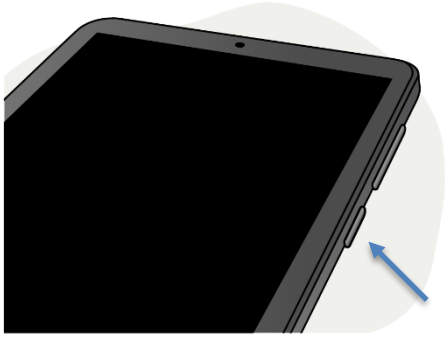
- assistance is needed in setting up, attaching, operating or maintaining the Collare System and its accessories
- to report unexpected operation or events
- only properly trained persons may perform disinfection of Collare or its accessories

Nukute customer service:

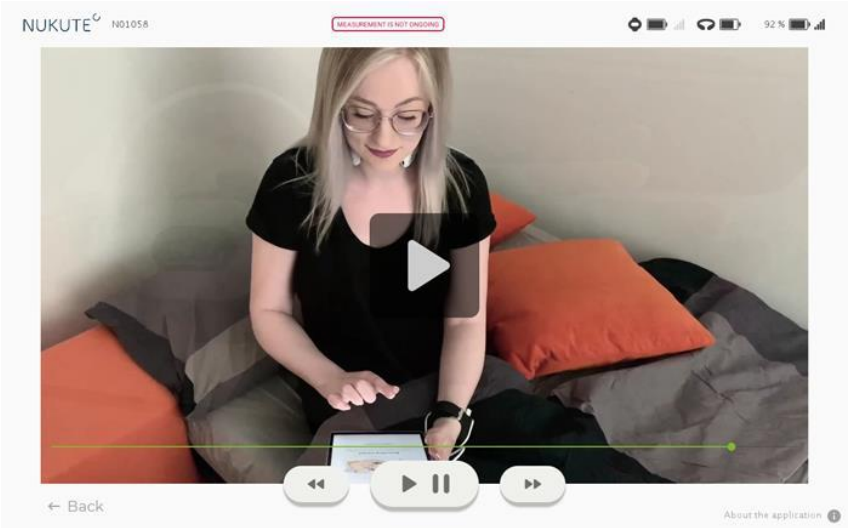
- contact form on Nukute webpage www.nukute.com/contact
- via email support@nukute.com
- call: +358 50 533 88 98

3.2. Starting the measurement

1. TURN THE TABLET ON

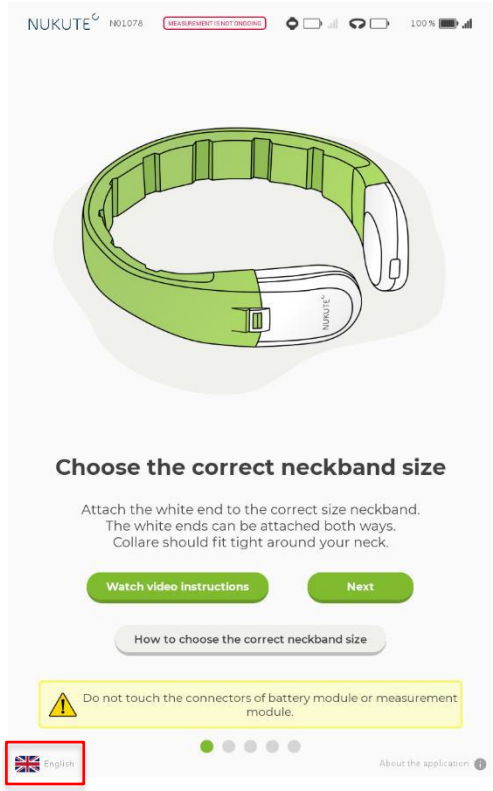


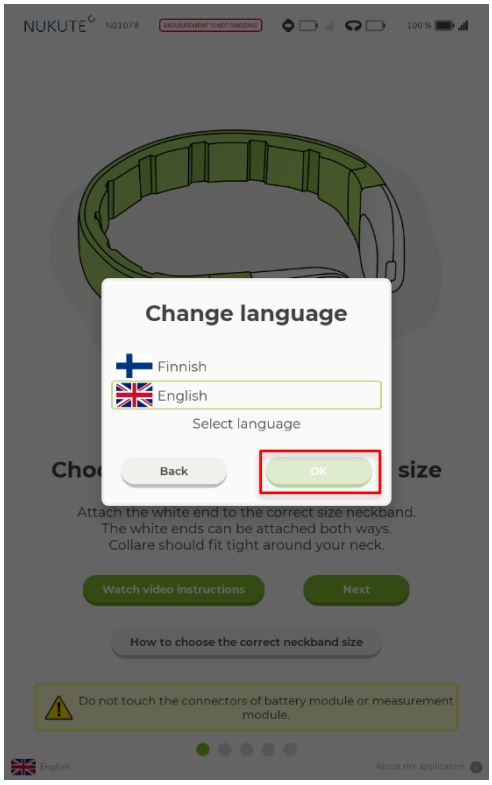
Tablet can be turned on by pressing tablet ON button. Tablet informs user how to start measurement. Tablet also provides video instructions for completing each step. Video instructions can be accessed by pressing the video instructions button.



Video instructions view.

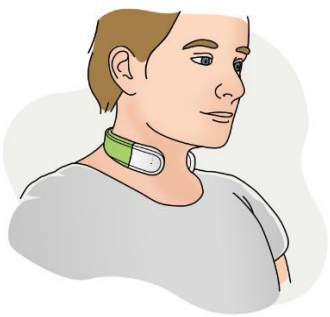
The tablet guides the user step by step on how to start the measurement. The language can be changed by pressing the flag symbol on the bottom left corner of the tablet. Select the preferred language and press OK. Available languages are English and Finnish.



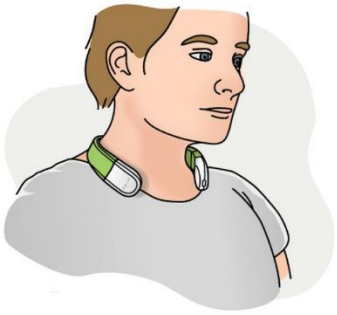


2. CHOOSE THE CORRECT SIZE NECKBAND

Before starting the measurement correct size neckband must be selected. Inside the carrying case are four different sizes neckbands (XS, S, M, L).



Correct size neckband: The correct neckband is for fitting around the neck. Measurement module needs to always have close contact with skin during measurement. Neckband should not feel constricting but should stay in place when turning your head.



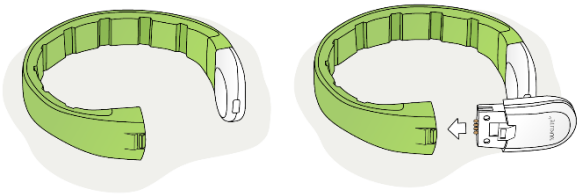
Neckband is too large Neckband modules are not in contact with your skin

Instructions: Try a smaller size

3. ASSEMBLE THE NECKBAND DEVICE

CAUTION!

Do not touch the connectors of battery module or measurement module

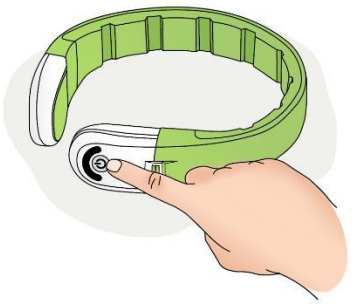


Device consists of parts:

- Measurement module (4)
- Battery module (3)
- Four different size neckbands (5, 6, 7, 8)

Select correct size neckband and assemble the battery module to neckband and then assemble the measurement module to neckband. Make sure you hear the ș c l i c measurement module and battery module.

4. TURN THE DEVICE ON



Turn the device on by pressing power button.

Device has LEDs indicating the status. When device is turning on, LED blinks, and its color is white. If LED color is RED, a failure has occurred, and you should follow the troubleshooting instructions. If the problem cannot be solved, contact your distributor/hospital or Nukute customer service.

5. WEAR THE NECKBAND

CAUTION!

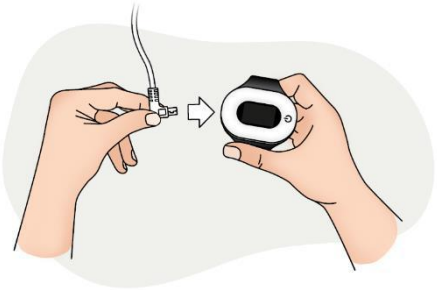
Do not bend or stretch neckband more than needed to put it on your neck.

When wearing the neckband around your neck, make sure that the neckband measurement module is in direct contact with skin. Make sure that the measurement and battery module are facing forward when wearing neckband.

Before wearing the neckband make sure that skin is clean and free from lotion.

During calibration indication LED blinks blue to indicate that neckband is connecting to tablet. After connection established, LED is stable and color blinks cyan.

6. ASSEMBLE THE PULSE OXIMETER



Inside the carrying case is pulse oximeter and disposable sensor. Take sensor from the bag and connect it to oximeter.

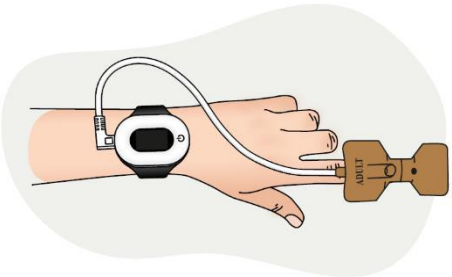
Note! Cover the sensor from strong light because it may cause inaccurate measurement.

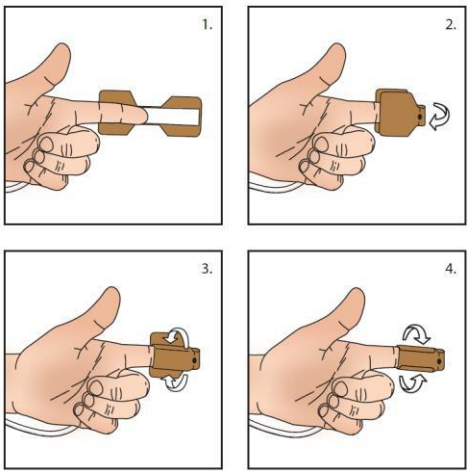
Note! When measuring make sure that fingernails are not too long.

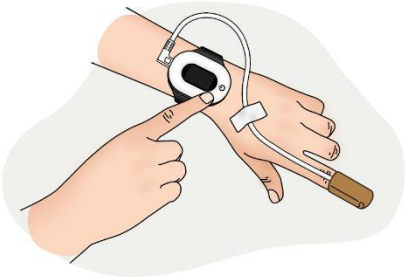
Note! Please remove the nail polish before the measurement

After attaching the sensor to pulse oximeter wear the pulse oximeter around the wrist and attach the sensor to your index finger.

Note! Make sure that sensor is attached as instructed, if sensor is not attached, it may cause inaccurate measurement







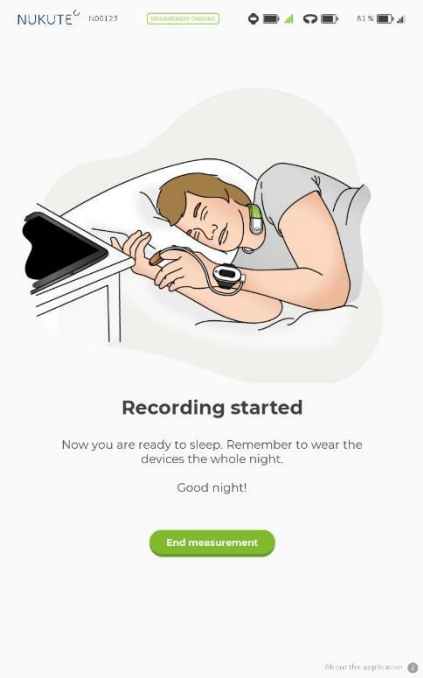
Secure the sensor with medical tape.

Turn device on by pressing power button. When pulse oximeter is connected neckband indication LED is stable blue.

7. START THE MEASUREMENT

CAUTION!

Make sure that environment noise (snoring or child crying) and/or is not disturbing the measurement



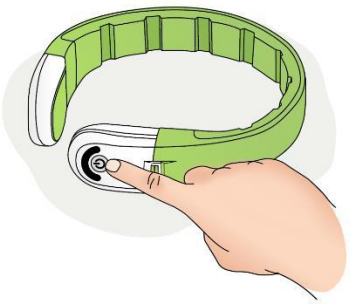
NOTE! Tablet informs the status of the neckband and pulse oximeter batteries

After pulse oximeter and tablet is connected neckband, measurement can be started. LED is stable blue indicating that measurement can be started.

Before starting the measurement, make sure that neckband and its parts are fully charged. See charging instructions in chapter Charging. Start the measurement button on tablet screen. Place tablet near (2m) on table and go to sleep.

Neckband indicator LED is stable green for 15s and then dims indicating that measurement is being taken.

3.3. Ending the measurement



After waking up, the system can be shut down by pressing neckband power button for 2s. Neckband white blinking LED indicates that device is turning off.

Tablet informs user that recording has ended. Tablet shows the estimated transfer time. Data transfer starts, but it is allowed to turn the devices off and follow the packing instructions.

3.4. Charging

Collare device is an internally powered medical device. Collare has rechargeable 500 mAh Li-ion battery.

Note! Place the power plug in a visible place that it is easy to disconnect when needed.

Note! Protection against electric shock: Class II during charging

CAUTION!

Use only power cable and adapter provided by Nukute for charging Nukute Collare or its parts. Do not use damaged cable or adapter. If replacement cables or adapter is needed contact Nukute customer service or distributor.

Collare power plug (14): FRIWO type: FW8002MUSB/05 or FRIWO type: FW8002M/USB 2nd Gen

Collare charging cable (13): GooBay type 45735

CAUTION!

Collare and its parts canû t be used when

CAUTION!

Do not leave Collare and its parts unattended when charging.

CAUTION!

Battery module is not allowed to be opened, the battery is not replaceable.

CAUTION!

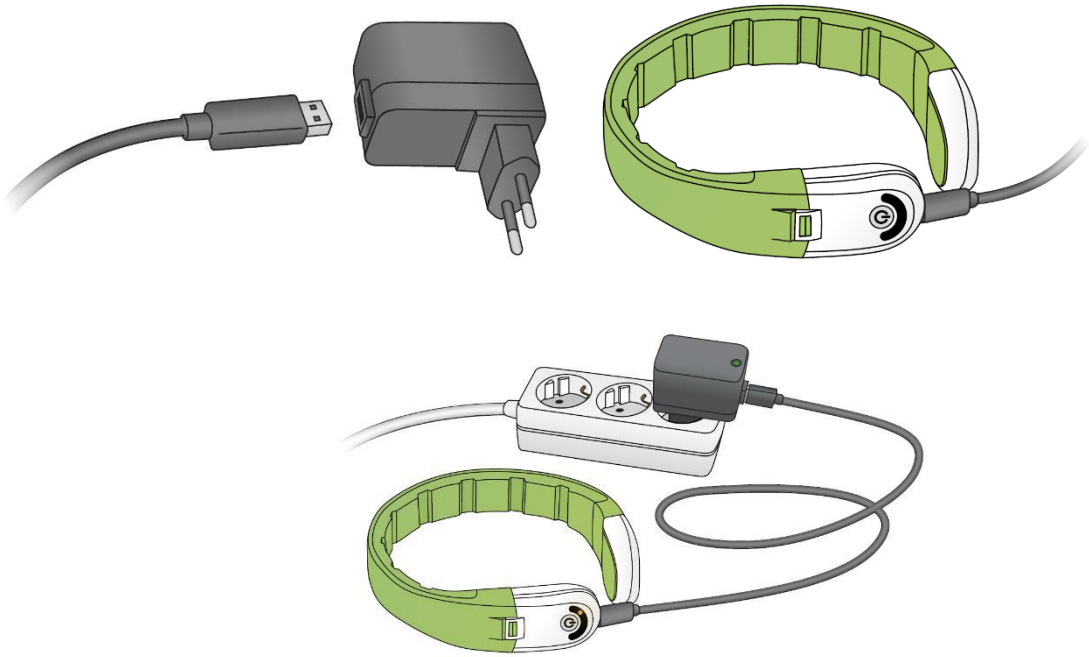
Do not touch the connectors of battery module or measurement module

CAUTION!

Do not charge Collare or its parts inside the patient area. Patient area is at least 1.5 meters from the patient.

3.4.1. Charging the Collare

Nukute Collare has a rechargeable Li-ion battery. Battery can only be charged when battery module and measurement module is attached to the neckband. Use Collare charging cable (13) and USB charger module (14) to charge the device. First take Collare charging cable (13) and USB charger module (14) from the carrying case. Insert charging cable USB plug to power supply. Connect cable to Collare and then connect charger in the socket.



LED in Collare indicates the status of charging, LED color depends on the status:

- Orange, device charging
- Green, battery full
- Red, overheating or malfunction

When charging is completed remove USB cable from the Collare and then you can remove battery and measurement module.

3.4.2. Charging the pulse oximeter

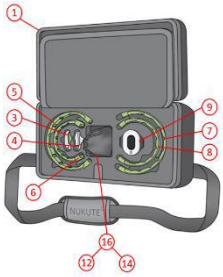
Pulse oximeter has a rechargeable Lithium battery. Battery can be charged by using Pulse oximeter charging cable (15) and USB charger module (14). Attach pulse oximeter cable to charger module and then connect cable to pulse oximeter.

3.4.3. Charging the tablet

The tablet is a commercial Lenovo TB-X306X. Tablet can be charged by attaching tablet charging cable (11) to tablet charger (12) and then attaching charging cable plug into tablet.

After fully charged, disconnect the charger from the device. Then, unplug the charger from the electric socket.

3.5. Packing instructions



After measurement pack the devices back into the carrying package (1). The image above shows the correct places Collare and its parts should be placed inside the carrying case. It is important to transport Collare and its parts in its accompanying carrying case (1) to ensure adequate protection and to prevent damage.

1	Sales Package	10	Pulse Oximeter Finger Sensor
2	Tablet	11	Tablet Charging Cable
3	Battery Module	12	Tablet Charger
4	Measurement Module	13	Collare Charging Cable
5	Neckband Assy L	14	USB Charger Module
6	Neckband Assy X	15	Pulse Oximeter Charging Cable
7	Neckband Assy M	16	Charger Bag
8	Neckband Assy S	17	Cable Bag
9	Pulse Oximeter	18	Quick Guide
19	Medical Tape		