NUKUTE

NUKUTE COLLARE MANUAL

NUKUTE

CE
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NUKUTE COLLARE MANUAL

Version 2.0

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MANUFACTURED BY

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1. **INTRODUCTION**

This is Manual for Nukute Collare system. Latest version of the manual can read in electric form in address: www.nukute.com/support/manual

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 the biosignals of a person during his or her sleep in order to determine whether the person might have sleep apnea. The system is designed to be easy to use and comfortable to wear so that the sleep quality of the person 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 first. Measurement data is sent automatically to a cloud service from where the doctor can access the results and make diagnostics decisions accordingly. Patient should always consult their doctor for the 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:

Nukute Oy
Mäkelininkatu 43
90100 Oulu
FINLAND
www.nukute.com,
info@nukute.com
Tel. +358 50 533 88 98

1.2. INTENDED USE

Nukute Collare device is intended for the screening of sleep apnea in adult patients.

The device can be used either in home environment or in the hospitals. A medical doctor´s referral is always required for the screening with Nukute Collare. The device is intended to be maintained at hospitals by healthcare professionals, who will charge and disinfect the devices after every use.

1.3. DISCLAIMER

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

- 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 sleep specialist.

1.4. CONTARAINDICATIONS AND PRECAUTIONS

- Patient must be 18 years or older.
- Patient has no neck injuries, skin in the neck area is intact.
- Patient should not have pacemaker or stimulators.
- Patient is able to follow the instructions and use the device in home environment. In hospital environment use patient state is not relevant

CAUTION!

- It is important to read safety issues before using the Nukute Collare system.
- It is not allowed to use other power adapter than that is inside the carrying package. Power adapter needs to be medical approved and tested against IEC 60601-1.
- Maintenance while device is in use is not allowed. Every time when maintenance is ongoing device needs to be powered off.
- Do not use Collare or its parts if 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 to recording 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 healthcare professionals 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 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 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 away from the pets.
- Collare is compliance 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 avoid free from cream.
- Do not bend or stretch Collare neckband more than needed to put it on your neck.
- Make sure that environment is quiet and/or other people noise (snoring or child crying) is not disturbing the measurement.

WARNING!

- Keep the Collare and its parts away from children. Children should not in any circumstances 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 damaged Collare or its parts may cause wrong diagnosis or patient injury.
- The Collare system is not certified to be used for continuous monitoring where failure to operate can cause injuries or death of the patient. Collare is intended to be used for measuring approximately 10 hours.
- No modification of this equipment is allowed.
- It is prohibited to connect Collare or its parts any other devices than provided.

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 class IIa product.
	**Manufacturer** – Name and the address of the manufacturer. Symbol also indicate the manufacturing date of the device.
SN	**Serial number –** Every part has unique serial number.
	**Fragile** – Handle with care
	**Keep Away from water**
	**Temperature limitations –** Collare has operational, storage and transportation temperature limits.
	**Do not re-use** – SpO2 sensor is disposable, not not re-use it
	**Disposal information** - European directive on waste electrical and electronic equipment (WEEE) 2012/19/EU specifies the disposal.
	**Non-ionizing electromagnetic radiation** – Collare has wireless connection.

	**Number of packages** – Symbol contains information amount of packages
	**Humidity limitations** - Collare has humidity limitations
	**Atmospheric limitations** - Collare has atmospheric limitations
	**This way Up** – Indicates that packages needs to be transferred in right 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: classified as 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 malfunction if the appropriate precautions are not followed.
IP22	**Degree of protection** - The product with carrying case is protected against harmful effects of dripping water 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 tilted up to 15°
	**WARNING -** There are some warnings when using Collare, read them carefully before using the device.
	**CAUTION** - There are some cautions and precautions when using Collare, read them carefully before using the device.

2. **GETTING STARTED**

2.1. UNPACKING

Item	Name
1	Sales Package
2	Tablet
3	Battery module
4	Measurement module
5	Neckband L
6	Neckband X
7	Neckband M
8	Neckband S
9	Pulse Oximeter
10	Pulse Oximeter Finger Sensor
11	Tablet Charging Cable
12	Tablet_Charger
13	Collare Charging Cable
14	USB Charger Module
15	Pulse Oximeter Charging Cable
16	Charger bag
17	Cable bag
18	Quick guide
19	Pulse oximeter finger 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.

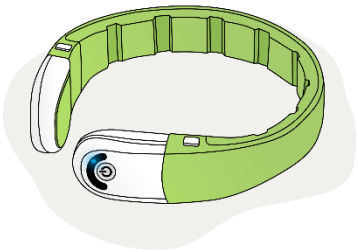
Carrying case is used for Collare and its parts storing and transportation. Carrying case provides protection against water and dust (IP22).

2.2.1. **Tablet (2)**

The tablet delivered with the Nukute sleep apnea measurement system is the primary source of user instructions. Tablet is used as a router, it receives measurement data from neckband and send it to cloud for analysis.

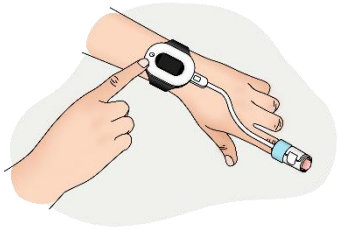
SIM card is delivered with the tablet, it is used for transferring measurement from tablet to cloud where measurement data is analyzed.

2.2.2. **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 and battery modules are needed when using neckband. Assembled neckband is used for recording breathing sound and detecting sleeping position. Measurement module contains microphones for breathing sound measurement and a motion sensor for sleeping position definition.

2.2.3. **Pulse oximeter (9, 10)**

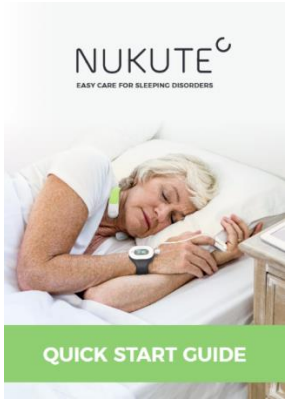


Pulse oximeter with sensor is used for measuring patients' oxygen saturation. **Note!** Pulse oximeter sensor is not re-usable.

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

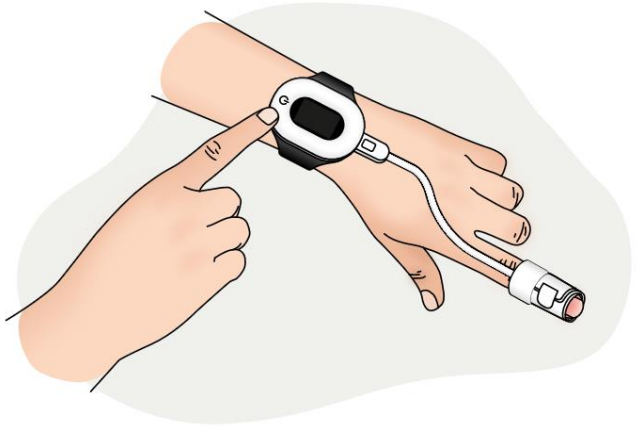
Collare and its parts have specified power adapters and charging cables. Cables and adapters are verified and meets the IEC 60601-1 requirements. Store chargers (12 , 14) inside the charger bag (16) and all cables (11, 14, 15) inside the cable bag (17). See charging instruction on separate chapter.

2.2.5. **Quick start guide (18)**



Quick start guide is stored inside the carrying case and it is used for giving quick instructions how to start the measurement. Full Collare Manual is needed only when quick quide with tablet is not giving answer for the problem.

2.2.6. **Pulse oximeter finger tape (19)**



Pulse oximeter finger tape is used to secure the pulse oximeter sensor in index finger during measuring.

2.3. Accessory Kit

Accessory kit package can be purchased from Nukute or distributor.

Accessory Kit contains:

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

3. FREQUENTLY USED FUNCTIONS

3.1. Instructions

Operator should contact Nukute customer service or your distributor if:

- Need for assistance, in setting up, attaching, operating or maintaining the Collare System and its accessories
- to report unexpected operation or events.

Nukute customer service:

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

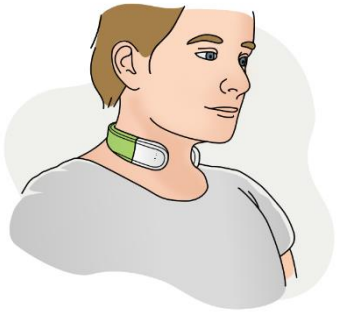
3.2. Starting the measurement

1. TURN THE TABLET ON

Tablet can be turned on by pressing tablet "On" (upper) button.

Tablet informs user how to start measurement.

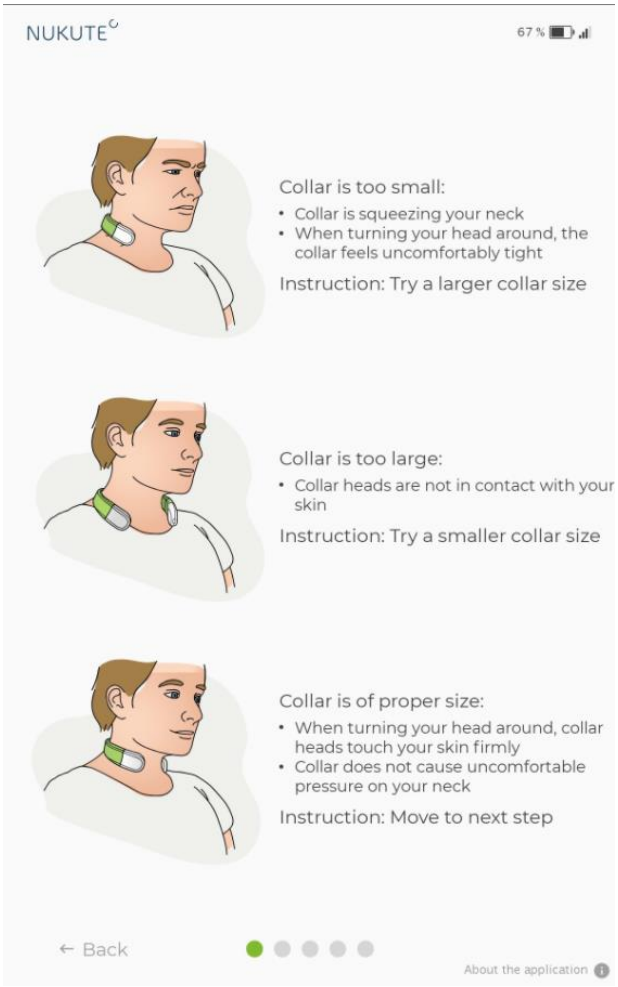
2. CHOOSE THE CORRECT SIZE NECKBAND



Before starting the measurement correct size Collare must be selected. Inside the carrying case are four different size Collares (X, S, M, L).

The correct neckband is form-fitting around the neck. Both measurement sensors need to have close contact with skin at all time during measurement. Neckband should not feel constricting but should stay in place when turning your head.

Tablet is instructing for selecting the correct neckband size.



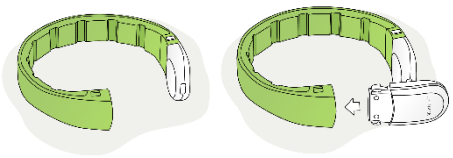
3. ASSEMBLE THE COLLARE

CAUTION!

Do not touch the connectors of battery module or measurement module

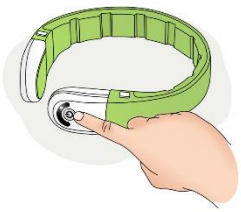
Collare system has three modules:

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



Select correct size collare and assemble the battery module to collare and then assemble the measurement module to collare. Make sure you can hear the “click” sound when attaching the Measurement module and battery module.

4. TURN THE COLLARE ON



Turn Collare on by pressing power button.

Collare has LEDs indicating the status of the Collare. When device is turning on, LED is blinking, and its color is white. If LED color is RED then failure is occurred, follow the Troubleshooting instructions and if problem cannot be solved contact your distributor / hospital or Nukute customer service.

5. WEAR THE COLLARE

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

Wear the Collare around your neck, make sure that Collare measurement head is contacting directly to skin.

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

Tablet informs user to stand still for preparation, tablet is connecting to Collare and ensuring the sound level. If neckband size is incorrect tablet informs user.

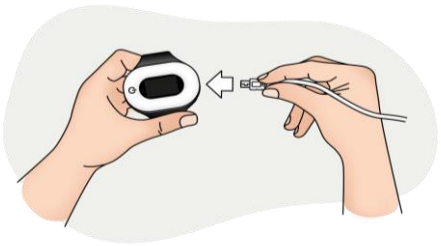
During calibration indication LED is stable orange for indicating that Collare is connecting to tablet. After connection is established LED is stable and color is blue.

6. ASSEMBLE THE PULSE OXIMETER

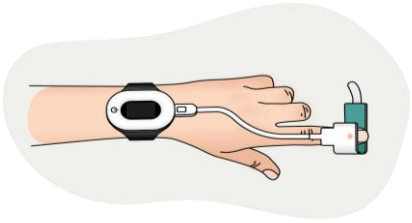
Inside the carrying case is pulse oximeter and disposable sensor. Take sensor from the bag and connect it to oximeter.

Note! Cover the sensor of strong light, it may cause inaccurate measurement.

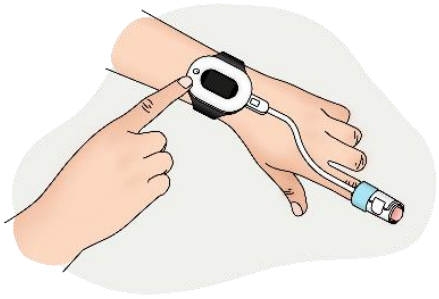
Note! When measuring make sure that fingernails are not too long.



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



Secure the sensor with medical tape.



Turn device on by pressing power button.

7. START THE MEASUREMENT

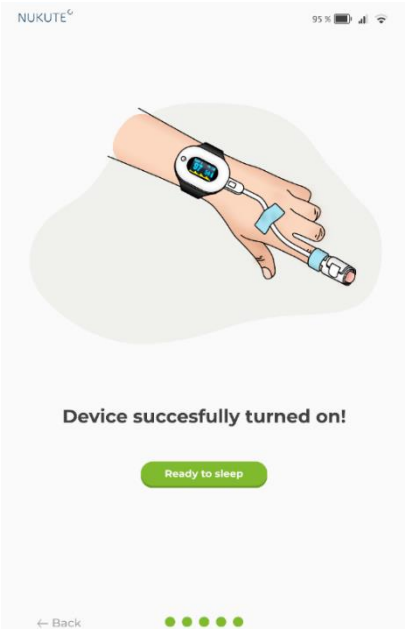
CAUTION!

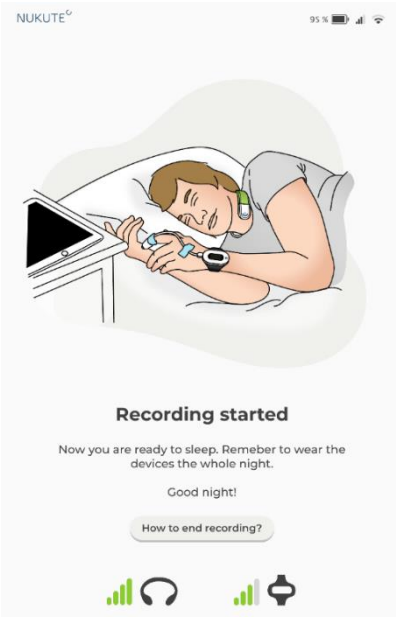
Make sure that environment is quiet and/or other people noise (snoring or child crying) is not disturbing the measurement

NOTE! Tablet informs the status on the Collare and pulse oximeter battery.

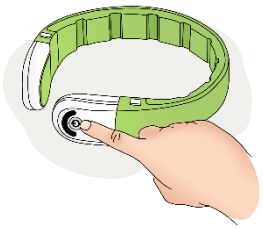
Before starting the measurement, make sure that Collare and its parts are fully charged. See charging instructions from chapter “Charging”. Start the measurement by pressing Start button on tablet screen and go to sleep. Place tablet on the table.

Collare indicator LED is stable green for 15s and then dimmed to indicating that measurement is on.

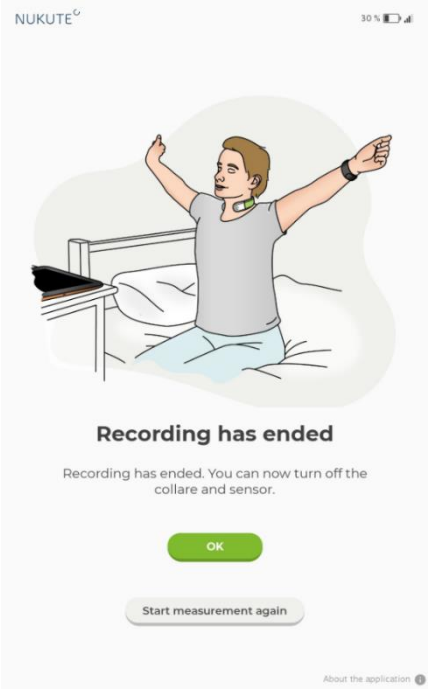




3.3. Ending of the measurement



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



Tablet informs user that recording has been ended. By pressing OK you can see packing instructions as in chapter 3.5.

3.4. Charging

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

Note! Place the power plug in 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 to charge 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
Collare charging cable (13): GooBay type 45735

CAUTION!

Collare and its parts can't be used when device is charging.

CAUTION!

Do not leave Collare and its parts unattended when charging.

CAUTION!

Battery cover is not allowed to be open, the battery is not replaceable.

CAUTION!

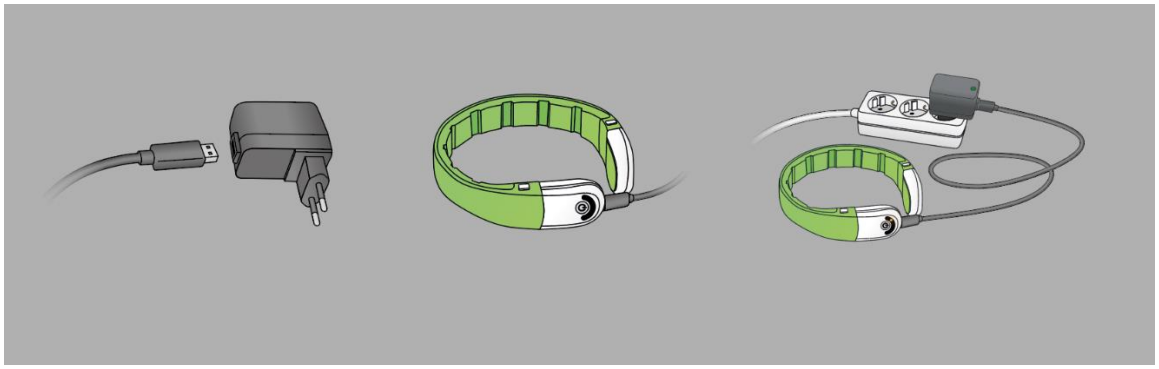
Do not touch the connectors of battery module or measurement module

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 be charged when battery module and measurement module is attached to Collare. 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 USB head 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:

- When device is charging LED is orange
- When battery is full, LED is green
- If overtemperature or error occurs, LED is red

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

3.4.2. **Charging the pulse oximeter**

Pulse oximeter has a rechargeable Lithium-Ion 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.

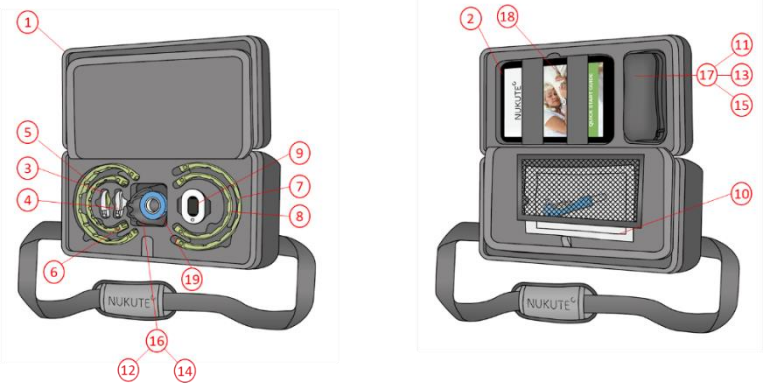
3.4.3. **Charging the tablet**

Tablet is commercial Samsung Galaxy Tab A. Tablet can be charged by attaching Tablet charging cable (11) to Tablet charger (12) and then attaching µUSB cord into tablet.

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

3.5. Packing instructions

After measurement it is time to pack devices back to carrying package (1). Image below shows the correct places Collare and its parts inside the carrying case. It is important to transport Collare and its parts in its accompanying carrying case (1) to ensure adequate protection and 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	Pulse oximeter finger tape		

4. INFORMATION

4.1. Technical specification

Model: Nukute Collare neckband with battery and measurement module
Connectivity: Wireless
Operating frequency: 2400-2500 MHz
Channel spacing: 1 MHz
Modulation: 250kbps O-QPSK PHY
Effective Radiated Power (ERP): 0.00569W
Linear acceleration measurement:
range in X,Y, Z, Range -2,+2g, data rate 208Hz, accuracy 90 µg/ √Hz,
Audio: 16 bit, two channel audio, 16kHz sample rate, dynamic gain
Size: Four different sizes (X, S, M and L)
Weight: 50-150 g (Collare)
Battery: Internal Li-Ion Polymer 500 mAh. Not replaceable.
Recording time: 16h
Charging time: 1.5h
Materials: Comfortable plastic and elastomer
Service lifetime: 3 years
Collare power plug (14): FRIWO type: FW8002MUSB/05
Collare charging cable (13): GooBay type 45735

Model: Pulse oximeter
Manufacturer: Shanghai Berry
Connectivity: Wireless
Size: 55 x 37 x 18mm
Weight: 52g
Battery: Lithium battery built-in battery 600 mAh
Service lifetime: 2 years

Model: Tablet – Samsung Galaxy Tab A
Manufacturer: Samsung
Connectivity: Wireless and cellular connectivity
Size: 245,2x149,4x7,5mm
Weight: 480g
Battery: 6150mAh

4.2. Environmental conditions

Temperature:

Operational: +5°C to + 40°C
Transport and Storage: -10°C to +50°C

Humidity:

Operational: 15% to 90% (non-condensing)
Transport and Storage: 10 to 90% (non-condensing)

Atmospheric pressure:

Operational: 700hPa to 1060hPa
Transport and storage: 700hPa to 1060hPa

NOTE!
Please note that when environment temperature is 20°C, the time required for Collare to warm from the minimum storage temperature between uses until it is ready for its intended use is approximately 30 minutes.

NOTE!
Please note that when environment temperature is 20°C, the time required for Collare to cool from the maximum storage temperature between uses until it is ready for its intended use is approximately 30 minutes

4.3. Disposal instructions

When the Healthcare Professional wishes to discard the product or its parts, it must be sent to separate collection facilities for recovery and recycling. Please contact the nearest authorities to determine the proper method of disposal of potentially bio-hazardous parts and accessories.

CAUTION!

Pulse oximeter sensor is disposable, do not re-use it.

4.4. Service and repair

CAUTION!

If repair is needed, only Nukute authorized repair service must be used.

CAUTION!

Battery is not replaceable, if battery is not working contact Nukute support or distributor.

WARNING!

Modification of this equipment is not allowed.

If service operation is needed contact Nukute support or distributor:

Nukute support email: support@nukute.com

4.5. Warranty

Nukute provides device 12month warranty for parts.

The warranty is void if:

- Collare is opened or modified
- Negligence of instruction for use
- Collare is used in environment that are not approved in this instruction for use
- The device has been deliberately broken

4.6. Compliance to Standards and classifications

Nukute holds an ISO 13485 certified Quality Management System which complies with the requirements of the Medical Device Directive (MDD - Council Directive 93/42/EEC as amended by Directive 2007/47/EC).

Nukute Collare is compliance with standard IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. Nukute Collare is compliance also with Radio Equipment Directive 2014/53/EU.

Nukute Collare complies with RoHS Directive 2011/65/EU.

4.7. Essential performance

When device appears to be working it must be able to store audio signals.

4.8. Electromagnetic compatibility (EMC) information

Nukute Collare needs special precautions regarding Electromagnetic Compatibility (EMC), and needs to be installed and put into service according to the EMC information detailed in the section “Electromagnetic Compatibility (EMC) Information” of this manual.

WARNING!

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.

WARNING!

Use of accessories, transducers and cables other than those 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.

WARNING!

Portable and mobile RF (radio frequency) communications equipment (for example mobile phone), (including peripherals such as antenna cables and external antennas) can cause Collare essential performance degradation. Portable and mobile RF devices should be used no closer than 30cm (12 inches) to any part of the Collare, including cables specified by the manufacturer.

CAUTION!

Replacement cables may be purchased only at Nukute or distributor. Using other cables than specified may cause degradation of the performance of this equipment.

CAUTION!

If measurement / charging stops or essential performance is degraded due to cause of RF RF (radio frequency) disturbance, remove Collare from the RF field and restart the device.

CAUTION!

This product complies with current required standards for electromagnetic interferences and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment

CAUTION!

In case this Product is used around the other wireless devices including microwave and wireless LAN, which operate same frequency band of this Product, there is a possibility that interference occurs between this Product and such other devices. If such interference occurs, please stop the operation of other devices or relocate this Product before using this Product or do not use this product around the other wireless devices.

The Nukute Collare system maintains basic safety and essential performance when used in the electromagnetic environment specified below. If the essential performance is lost or degraded it may cause device unintended operation like rebooting and charging failure. When malfunction occurs remove device from the disturbance area and restarts the device. If a malfunction cannot be rectified, please contact to customer service. The customer or the user of the Collare device should ensure that it is used in such an environment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Nukute Collare system is intended for use in the electromagnetic environment specified below. The customer or the user of the Collare system should assure that it is used in such environment.		
RF emissions CISPR 11	Group 1	Nukute Collare uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	Nukute Collare is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations and flickering IEC 61000-3-3	Complies	
Harmonic current emissions IEC 61000-3-2	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Nukute Collare system is intended for use in the electromagnetic environment specified below. The customer or the user of the Collare system should assure that it is used in such environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV, ±8 kV Contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV Air discharge	±2 kV, ±4 kV, ±8 kV Contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV Air discharge	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material humidity should be at least 30%
Rated power frequency (50/60 Hz) magnetic fields IEC 61000-4-8	30A/m, 50/60Hz	30A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality be that of a typical commercial or hospital environment
Voltage dips, interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% Ut: 0,5 cycle At 0°, 45°, 90°, 180°, 225°, 270° and 315° 0% Ut: 1 cycle And 70% Ut: 25/30 cycles Single phase: at 0° 0% Ut: 250/300 cycle	0% Ut: 0,5 cycle At 0°, 45°, 90°, 180°, 225°, 270° and 315° 0% Ut: 1 cycle And 70% Ut: 25/30 cycles Single phase: at 0° 0% Ut: 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.

Conducted RF [a)] IEC 61000-4-6	3Vrms, 0.15 MHz – 80 MHz and 6Vrms, in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3Vrms, 0.15 MHz – 80 MHz and 6Vrms, in ISM and amateur radio bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of Nukute Collare, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF EM fields IEC 61000-4-3	10V/m Home healthcare at 80 MHz – 2700 MHz, AM Modulation 3V/m at 2.7 GHz – 6 GHz, AM Modulation	10V/m Home healthcare at 80 MHz – 2700 MHz, AM Modulation 3V/m at 2.7 GHz – 6 GHz, AM Modulation	
a) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are: 6.765 MHz to 6.795 MHz; 13.553 MHz to 13 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are: 1.8 MHz to 2.0 MHz; 3.5 MHz to 4.0 MHz; 5.3 MHz to 5.4 MHz; 7 MHz to 7.3 MHz; 10.1 MHz to 10.15 MHz; 14 MHz to 14.2 MHz; 18.07 MHz to 18.17 MHz; 21.0 MHz to 21.4 MHz; 24.89 MHz to 24.99 MHz; 28.0 MHz to 29.7 MHz and 50 MHz to 54 MHz.			

Proximity fields test frequency's and test levels

Test frequency (MHz)	Band (MHz)	Modulation	Test level (V/m)	Compliance level (V/m)
385	380-390	Pulse modulation 18 Hz	27	27
450	430-470	Pulse modulation 18 Hz	28	28
710 745 780	704-787	Pulse modulation 217 Hz	9	9
810 870 930	800-960	Pulse modulation 18 Hz	28	28
1720 1845 1970	1700-1990	Pulse modulation 217 Hz	28	28
2450	2400-2570	Pulse modulation 217 Hz	28	28
5240 5500 5785	5100-5800	Pulse modulation 217 Hz	9	9

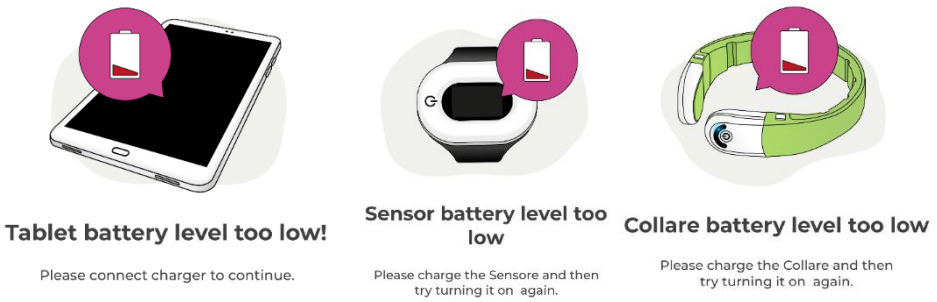
Separation distances

Nukute Collare maintains basic safety and essential performance when used in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Nukute Collare can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Nukute Collare as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	From 150 kHz to 80 MHz d = 1.2 √P	**From 80 MHz to 800 MHz d = 1.2 √P**	**From 800 MHz to 2.7 GHz d = 2.3 √P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

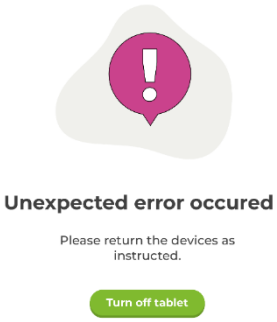
4.9. Troubleshooting

1. Collare / Tablet/ Pulse oximeter battery is empty



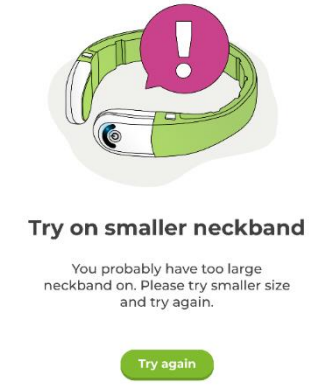
Tablet informs user in case battery level is too low. Please charge the device before continuing.

2. Unexpected error



If unexpected error occurs, please turn the tablet off and restart the measurement flow.

3. Neckband size is incorrect



When starting the measurement sound level is too low, tablet informs user to select another neckband size.

4. Problem during Collare start up

Problem occured while turning on the collare

Make sure the room temperature is not too hot or cold. If the room temperature is too hot, let the device to cool down and then try turning on the device again.

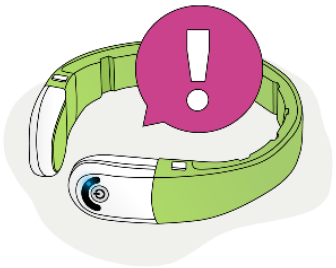
When starting the Collare and problem occurs, follow the instructions from the tablet.

5. Wireless signal problems

Sensor connection was lost

Make sure you the sensor is aroud your finger and the wire is attatced to the wrist device.

Try turning on the wrist device.



Connection to collare was lost

We still might have had succesfull measurement. Don't remove the devices untill te measurement is over.

When there are problems in wireless connection, follow instructions from the tablet.

6. Collare temperature is too low / high

If Collare temperature is too low / high tablet informs user to wait that temperature is stabilized to its intended temperature.

4.10. Measuring Pulse Oxygen using Berry Electronics Pulse oximeter

CAUTION!

The Berry Electronics pulse oximeter is not certified to be used for continuous measuring where failure to operate can cause injuries or death of the patient

CAUTION!

Do not fasten the pulse oximeter too tightly around the patient's wrist. Inaccurate readings and patient discomfort could result.

CAUTION!

Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.

CAUTION!

Pulse oximeter sensor is disposable, do not re-use it.

4.11. Declaration of conformity

Hereby, Nukute declares that the Nukute Collare complies with EU medical Device Directive (93/42/EEC). The full text of the EU declaration of conformity is available at the following internet address: http://www. nukute.com/support/doc