

- Instructions for Use -

All dates and times are in the project's default time zone and formatting.

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SAFETY INFORMATION

Symbols Used

	Date of Manufacture		Refer to the Instructions for Use
	Serial Number		Caution
	Humidity Limits for Storage and Transport		General Warning
	Temperature Limits for Storage and Transport		Maximum Stacking
	Keep Dry		General Prohibition
	Keep Away from Sunlight		General Mandatory Action
	Fragile		Do Not Dispose of in Household Waste
	Expiration Date		Applied Part Type BF
	This Side Up	IP	IP Protection Rating

Prohibitions

 Never use QuoreOne during Magnetic Resonance Imaging (MRI) procedures.

Never subject a patient with QuoreOne to an AED (Automated External Defibrillator) procedure. Before starting the procedure, remove QuoreOne.

 Never use QuoreOne in any means of transportation equipped with a longitudinal seat belt (commonly known as a 3-point seat belt), due to the risk of serious injury to the patient's health or even death.

 Do not submerge QuoreOne. Observe the product's IP protection rating.

 If it is necessary to perform an airway obstruction removal procedure (known as the Heimlich Man euver), remove QuoreOne before starting the procedure.

 Never dispose of QuoreOne or its batteries (internal battery not accessible to the patient or operat or) in household waste.



NEVER puncture or expose QuoreOne to excessive heat or fire. QuoreOne contains an internal lithium-ion battery that may explode, potentially causing serious injury or even death to the patient, operator, ser vice personnel, or any other person or animal.

 Operator: Never install any damaged QuoreOne on a patient. Contact Quoretech for replacement and repair procedures.

Warnings and Safety Notices

 Equipment not suitable for use in oxygen-rich environments.

 The equipment is not suitable for use in the presence of flammable gases.

 No modification or alteration of this equipment is permitted.

 Do not disassemble the product or its accessories.

Accidental Spills –To avoid electric shock or malfunction of QuoreOne, liquids or excessive moisture must not be allowed to enter the device. If liquids penetrate the device, discontinue use immediately and send it for technical service. Never place accessories on surfaces containing liquids. If any liquid enters an accessory, disconnect it immediately from all electrical connections and send it for technical service.


Electrical Leakage – Electric shock to the patient or operator may result from device failure or insulation failure.

 Electrosurgery – If an electrosurgical device is used, QuoreOne must be removed from the patient.

 Conductivity – Electric shock or malfunction of QuoreOne may occur if electrodes come into contact with conductive materials. Keep the conductive parts of the electrodes and their associated components away from other conductive parts, including the ground (earth conductor). An electric shock in accessories connected to the power supply may occur if the ground conductor fails.

 Radiofrequency Interference – Known RF sources such as mobile phones, radio or TV stations, and communication radios may cause adverse or unexpected operation of QuoreOne and its accessories. Consult qualified personnel for more information.

 Battery Leakage – If battery leakage occurs, immediately remove QuoreOne and contact the Service Personnel who installed it, reporting the incident. The accessories do not contain batteries.

 QuoreOne Docking Station and QuoreOne Charger are not intended for home use; their use is restricted to clinics and hospitals.

If you experience new or worsening symptoms such as chest pain, dizziness, fainting, shortness of breath, palpitations, or any other condition that causes concern while wearing the device at home, immediately contact your healthcare provider or seek emergency medical assistance.

Caution Notes

 It is advisable to observe the information on
the electromagnetic compatibility of this equipment described in these instructions for use.

 This product has no adjustable or repairable parts for the Patient, Operator, or Service Personnel. For any questions, contact Quoretech.

 If a low battery indication occurs during use, contact the service that installed QuoreOne for rechar ging arrangements.

 When the message “electrode disconnected” appears, follow the instructions described in the secti on “Installing QuoreOne.”

 The safe use of this product is guaranteed in accordance with IEC 60601-1 standard.

 The determination that this product is in operating condition is the responsibility of the Operator an d their team. The Operator is responsible for ensuring that the equipment is safe for
use by performing a pre-operational check. See section “INITIAL INSPECTION.”

 Read these instructions for use in full before operating the equipment and keep it for
future reference and information.

 This product is not a pacemaker or defibrillator and does not perform a similar function.

Messages

Safety messages can be found throughout these instructions for use.

Precautions

Before starting use – Check whether QuoreOne or its accessories are operating properly. See the chapter on “Service Information.” When using it with other devices or instruments, seek assistance from a specialist.

Disposal – QuoreOne and its accessories are not disposable. At the end of use, QuoreOne must be returned to the same qualified healthcare service that installed it. If you have any questions regarding returning the device to the medical service, contact Quoretech or one of its authorized representatives.

Equipment Configuration – QuoreOne must not be installed on, under, against, or in close proximity to any other equipment. If this condition cannot be avoided, tests must be carried out to verify that the device is operating as expected.

Interference – Electrical emissions from an electric blanket or heating blanket may degrade signal quality. Do not use QuoreOne together with an electric blanket or heating blanket.

Instructions for Use – For safe and continuous use of QuoreOne, the listed instructions must be followed. However, the instructions in these instructions for use in no way replace established medical practices regarding patient care.

Electrical Safety and Compatibility

Caution: QuoreOne and its accessories require special EMC precautions and must be used in accordance with the EMC information provided in the section “Guidelines and Declarations on Electromagnetic Immunity” contained in these instructions for use.

Caution: Mobile radiofrequency communication equipment may affect electromedical equipment.

Warning: QuoreOne must not be used stacked or in contact with any other equipment.

Warning: QuoreOne and its accessories may suffer interference from other equipment, even if such equipment complies with CISPR requirements.

Warning: Portable radiofrequency communication equipment (including peripherals such as cables and antennas, whether internal or external) must be used at least 30 cm away from any part of QuoreOne. Failure to maintain this distance may result in degradation or even loss of performance of QuoreOne.

INTRODUCTION

Product Description

The QuoreOne Device is a wearable, non-invasive electrocardiographic (ECG) monitoring unit designed to record multi-lead cardiac signals over extended periods in ambulatory settings. As the central hardware element in the QuoreOne system architecture, it functions as the primary data acquisition point for detecting and documenting cardiac arrhythmias.

Its role is to continuously monitor the heart’s electrical activity, capturing clinical-grade ECG signals that support diagnostic decisions made by healthcare professionals. Positioned at the beginning of the diagnostic workflow, the device is paired with the QuoreOne system software tools for setup and configuration, and operates in coordination with downstream components for data transmission, storage, analysis, and diagnostic reporting.

The QuoreOne Docking Station is a multi-functional accessory designed to support high-throughput ECG diagnostic workflows by automating the recharging and data upload processes for the QuoreOne Device. It plays a role in post-exam data consolidation and device readiness management, operating as a hands-free interface between the QuoreOne Device and the QuoreOne Diagnostic Platform. Integrated into the backend of the diagnostic workflow, the QuoreOne Docking Station facilitates secure, compliant data offloading while ensuring devices are charged and updated for subsequent use. It is primarily deployed in institutional healthcare settings where multiple devices are managed concurrently.

The QuoreOne Charger is a compact, single-device accessory designed specifically for recharging the QuoreOne Device via electromagnetic induction. It supports individualized or low-volume clinical workflows, particularly in decentralized care environments where high-capacity infrastructure such as the QuoreOne Docking Station is not required. The charger enables clinicians or support staff to maintain device readiness as part of standalone deployments, primarily when used in combination with the Uploader Desktop Software for ECG data upload.

Presentation
QuoreOne is presented in two forms:

- Individual packaging, with a plastic cradle fitted into a cardboard box and sealed with a plastic sleeve.



- Together with the **QuoreOne Docking Station** accessory, in a cardboard box sealed with a sleeve and a transparent plastic window. In this configuration, the packaging contains one **QuoreOne Docking Station** accessory and up to five **QuoreOne devices**.



- The **QuoreOne Docking Station** is presented in a cardboard box sealed with a sleeve and a transparent plastic window. In this configuration, the packaging contains one **Docking Station** and may be supplied with up to five **QuoreOne** devices.
- The Charger is presented in a translucent plastic package.



How does it work?
QuoreOne acquires the patient's cardiac electrical signals and transfers them in real time to mobile applications using Bluetooth technology or stores them in internal memory for later transfer.

The transfer of stored data, as well as recharging QuoreOne's battery, is carried out through accessory devices: Docking Station or Charger.

After data transfer, the information is processed by the digital platform, where the reporting operator has access to the electrocardiographic trace for cleaning, rhythm classification, and generation of the patient's report.

Docking Station: It connects to QuoreOne via Bluetooth technology, collecting the data of the signals captured during the exam. After receiving the data, it retransmits them via the internet, through wired or wireless networks, to the Diagnostic Platform. The Docking Station recharges QuoreOne's battery using

induction technology, requiring proper positioning of QuoreOne on the bases. It requires connection to the local power supply and the internet (wired or Wi-Fi). The Docking Station is capable of recharging batteries and collecting data from up to 5 QuoreOne devices simultaneously.

Charger: It recharges QuoreOne's battery through induction technology, with power supplied by the computer's USB port or another adapter (such as a cell phone charger) that provides 5 VDC. Data transfer is carried out via Bluetooth technology directly to a computer running the QuoreOne Uploader software, which retransmits the signals via the internet to the Diagnostic platform.

Note: If the computer does not have integrated Bluetooth technology, a USB–Bluetooth adapter must be installed.

After data transfer, the information is processed by the digital Diagnostic Platform, where the reporting operator has access to the electrocardiographic trace for cleaning, rhythm classification, and generation of the patient's report.

The QuoreOne system is designed to be simple and accessible, ensuring that it can be used without the need for special facilities, advanced training, or particular professional qualifications. Its guided workflows allow healthcare providers to operate the system effectively in standard clinical environments, without requiring additional infrastructure or specialized expertise. To support safe and proper use, the system is accompanied by these Instructions for Use.

Intended Use
The QuoreOne is a non-invasive, wearable medical device intended to acquire, store, and/or transmit multi-channel electrocardiographic (ECG) signals for up to 7 days. It supports both continuous and event-based cardiac monitoring to aid in the detection of transient and persistent rhythm disturbances in symptomatic or asymptomatic patients.

ECG data can be transmitted in real time, which securely forwards the information to a centralized diagnostic platform for clinician access and interpretation. When operating offline, data is stored locally and transferred later via the Docking Station during charging or through the Desktop Uploader.

The device is intended for use in clinical and home settings under medical prescription and supervision.

It enables both automated and user-triggered recordings, ensuring broad diagnostic coverage.

Intended Users
- Clinicians and technicians are responsible for prescribing, configuring, and retrieving data.
- Patients wear the device and may interact using the integrated event button.
- System administrators manage device lifecycle and fleet maintenance across deployments.

Indications for Use
The QuoreOne system is intended for patients who require ambulatory electrocardiographic (ECG) monitoring for the evaluation, detection, and documentation of cardiac rhythm disturbances. The system may be prescribed by a licensed healthcare professional for the following purposes:

- Evaluation of patients presenting with symptoms suggestive of cardiac arrhythmias, such as palpitations, syncope or presyncope, dizziness or light-headedness, chest discomfort, dyspnea or shortness of breath, fatigue, or irregular heartbeats and pauses.
- Screening of asymptomatic individuals at increased cardiovascular risk as part of preventive or primary care programs.
- Investigation of suspected arrhythmic causes in patients with cryptogenic stroke or transient ischemic attacks.
- Monitoring of cardiac rhythm in patients receiving medications known to affect electrophysiological parameters (e.g., antipsychotics, antidepressants, or antiarrhythmic agents).
- Cardiac rhythm surveillance in psychiatric, geriatric, or other populations with elevated arrhythmia-related risk.
- Post-procedural or post-intervention follow-up in patients undergoing electrophysiology studies, ablations, or device implantation (when compatible).
- Integration into primary care workflows to support early arrhythmia detection, triage, or referral by general practitioners.
- Participation in clinical trials, research protocols, or post-market surveillance activities involving ambulatory ECG endpoints.
- Routine rhythm monitoring in patients with underlying structural heart disease or a prior history of arrhythmia.

Contraindication

- The system is not intended or validated for monitoring fetal or neonatal ECG signals.
- The system is not designed for intracardiac monitoring or applications involving direct contact with cardiac tissue.
- Patients with severe skin irritation, open wounds, burns, or dermatological conditions at the intended electrode sites should not use the system without prior clinical evaluation.
- QuoreOne is contraindicated for patients weighing less than 10 kg. Do not use QuoreOne on patients weighing less than 10 kg.

Expected Clinical Benefits

The QuoreOne solution enables continuous or event-based ECG recording for up to seven days, improving the detection of intermittent and asymptomatic arrhythmias compared to traditional Holter exams. Its wearable, wireless design enhances patient comfort and adherence, ensuring high-quality diagnostic data. Real-time ECG transmission allows faster clinical assessment and decision-making. Overall, QuoreOne increases diagnostic yield and supports earlier, more accurate identification of cardiac rhythm disorders, contributing to improved patient outcomes.

Patient Population

The QuoreOne system is intended for use in individuals requiring ambulatory electrocardiographic (ECG) monitoring to support the detection, documentation, and analysis of cardiac rhythm disorders. It is suitable for both adult and pediatric patients, without predefined age limitations and 10kg weight limitation, provided anatomical compatibility and clinical judgment support safe and effective use. Until specific pediatric data are available, use in children should be undertaken under clinician judgment. Clinicians should consider pediatric-specific adhesive/skin considerations.

Accompanying Material
Items found inside the QuoreOne package:

Quantity	***Code***	***Item***
01	*SK-000000002*	*QuoreOne*
01	*SK-000000192*	*Quick Start Guide*

Items found inside **the QuoreOne Docking Station** package:

Quantity	***Item***
Up to 05	*QuoreOne*
01	*Quick Start Guide*
01	*QuoreOne Docking Station*
01	*Power Cord*
01	*Network Cable*

Items found inside the **Charger** package:

Quantity	***Item***
01	*Charger*

The instructions for use are available only in digital format. To access and download the instructions for use, visit the Quoretech website. If you prefer, access it on your smartphone by scanning the barcode below.

Access: www.quore.tech

Accessories

ELECTRODE: To attach **QuoreOne** to the patient, specific electrodes for cardiac monitoring are required. For each new installation of **QuoreOne**, four electrodes are used, and additional electrodes may be needed if replacement is required during the exam**. Quoretech** does not supply electrodes; they must be purchased directly from the market. For acquiring these electrodes, consider the information below:

Specification:

Electrode for cardiac monitoring in long-duration procedures, made of polyethylene foam with hypoallergenic adhesive. Conductive adhesive gel, metallic pin in stainless steel 304 or 316 coated with silver/chloride treatment..

Recommended Manufacturer and Model:

- Description: Monitoring Electrode – Foam
- Code: 2223BRQ
- Manufacturer: 3M

The information contained on the electrode packaging must be followed. Never use an electrode purchased with damaged packaging. Never use an expired electrode or one that has been improperly stored. Always respect the expiration date for using the electrode after the package has been opened. Failure to comply with these recommendations may result in loss of the product's essential performance.

The use of accessories and materials not described in these Instructions for Use may not be safe for the patient and service personnel..

In case of questions, consult Quoretech.

Docking Station and **Charger** are also **QuoreOne** accessories, and the information regarding these accessories is available throughout these instructions for use.

TECHNICAL SPECIFICATIONS

Essential Performance Statement

QUOREONE: It acquires, stores, and transmits ECG signals for subsequent data analysis. When one or more electrodes have poor contact or are disconnected, the essential performance is lost, and an information signal is emitted. See section "Alarms and Information Signals."

Table 1. Essential Performance Requirements.

Requirement	Reference	Essential Performance Lost – Evaluation in the report/printed copy.
		+/- 5% of the Reference and/or

Heart Rate	40 to 200 bpm	absence or failure to indicate lower, average, and higher heart rates in the printed report, as well as the total number of detected heartbeats.
Supraventricular Ectopy	Prematurity is a factor adjustable by the reporting physician.	+/- 10% over the factor adjusted by the reviewer and/or absence or failure in the indication of totals for BESV[1], single BSEV, paired BSEV, TSV1 measurements, and TSV duration (total beats), including the total number of each event, as well as an hourly tabular report and the overall total.
Narrow Ventricular Ectopy	QRS with duration < 120 ms	+12 ms from the Reference and/or absence or failure to indicate totals for BEV[1], single BEVs, paired BEVs, runs of three or more BEVs, and the duration of the runs (number of beats), as well as the total beats for ventricular tachycardia in each episode. The absence of the number of analyzed minutes is also considered a loss of essential performance.
Wide Ventricular Ectopy	QRS with duration N 120 ms	-12 ms from the Reference
Bradycardia Data	HR O 50 bpm	+/- 3 bpm from the Reference and/or absence or failure of the tabular report in presenting, hour by hour, the total number of bradycardia episodes, specifying the rate and duration of the episodes.
Pauses	RR interval N 2.5 seconds	+/- 200 ms from the Reference and/or absence or failure to indicate the total number of pauses detected, as well as the location and duration of the longest pauses.
ST Segment Shifts	Not available	Not applicable
		Failure in generating the print file. Failure or absence of the 25 mm/s ECG strip and/or channel indication. Failure or absence of time on the strip, heart rate, and/or strip annotation. Failure or absence of patient identification on the strips (at least one per page). Generation of a print file in a format other than A4 or “letter” size.

Printed Copy of the ECG	Printout with well-defined graphs and mandatory fields displayed.	Failure or absence of the channel calibration signal on each strip.

1 -

BESV – Supraventricular Ectopic Beat

BEV – Ventricular Ectopic Beats

TSV – Supraventricular Tachycardia

DOCKING STATION: It recharges **QuoreOne** batteries and connects to them to collect exam data and transfer it to the Diagnostic platform. Both recharging and data transfer are carried out using wireless technology, with the Docking Station connecting to **QuoreOne** via Bluetooth and communicating with the internet via Wi-Fi. Alternatively, the **QuoreOne Docking Station** can connect to the internet through a network cable.

Table 2. Essential Performance Requirements of the Docking Station

Requirement	Reference	Essential Performance Lost
Battery Recharge	Full recharge in 2h30.[1]	Recharge not performed or taking longer than 4 hours.
Exam Data Collection (“Download”)	30 minutes for the collection of each exam. [1-2-3]	Collection time exceeding 1 hour.
Data Upload to the Diagnostic Platform	30 minutes for the upload of each exam.[1-2-3]	Upload time exceeding 2 hours.

1- In case of a power outage in the local electrical network, battery recharging, data collection, and data upload are suspended until power is restored.

2- In case of an internet connection interruption, data collection and upload are suspended until the connection is restored.

3- Considering one QuoreOne unit on the accessory, a 24-hour exam, and 3 leads. Valid for Docking Station: The use of more than one QuoreOne, as well as longer-duration exams, may increase the data “download” time.

CHARGER: It recharges **QuoreOne’s** battery. Recharging is carried out using wireless technology..

Table 3. Essential Performance Requirements of the Charger

Requirement	Reference	Essential Performance Lost
Battery Recharge	Full recharge in 2h30.[1]	Recharge not performed or taking longer than 4 hours.

1- In case of a power outage in the local electrical network, battery recharging, data collection, and data upload are suspended until power is restored.

Applied Part Statement

QuoreOne makes contact with the patient through the electrodes (see item Accessories). The other parts of QuoreOne are considered Accessible Parts.

The Docking Stations have no applied part.

Classification
QuoreOne

Protection Against Electric Shock	*Internally Powered Equipment*
Applied Part	*Type BF equipment.* *The voltages of the internal power supply are low enough so that under no condition is there a perception of electric shock*
Degree of protection IP	*IP 44*
Degree of protection for use in the presence of flammable anesthetics mixed with air, with oxygen, or nitrous oxide	*Equipment not suitable for use in the presence of flammable anesthetics mixed with air or with oxygen or nitrous oxide*
Degree of protection for use in the presence of an oxygen-rich environment	*Equipment not suitable for use in an oxygen-rich environment*
Method of sterilization or disinfection recommended by the manufacturer	*This product must not be subjected to any sterilization process. For cleaning procedures, refer to the item “Cleaning, disinfection and sterilization”*
Modes of operation	*Continuous operation*
Transportable equipment	*Portable*

Docking Station.

Protection Against Electric Shock	*CLASS I EQUIPMENT*
Applied Part	*None*
Degree of protection IP	*IP 20*
Degree of protection for use in the presence of flammable anesthetics mixed with air, with oxygen or nitrous oxide	*Equipment not suitable for use in the presence of flammable anesthetics mixed with air or with oxygen or nitrous oxide*
Degree of protection for use in the presence of an oxygen-rich environment	*Equipment not suitable for use in an oxygen-rich environment*
Method of sterilization or disinfection recommended by the manufacturer	*This product must not be subjected to any sterilization process. For cleaning procedures, refer to the item “Cleaning, disinfection and sterilization”*
Modes of operation	*Continuous operation*
Transportable equipment	*Portable*

Charger.

Protection Against Electric Shock	*CLASS I EQUIPMENT*
Applied Part	*None*
Degree of protection IP	*IP 22*
Degree of protection for use in the presence of flammable anesthetics mixed with air, with oxygen, or nitrous oxide	*Equipment not suitable for use in the presence of flammable anesthetics mixed with air or with oxygen or nitrous oxide*
Degree of protection for use in the presence of an oxygen-rich environment	*Equipment not suitable for use in an oxygen-rich environment*
Method of sterilization or disinfection recommended by the manufacturer	*This product must not be subjected to any sterilization process. For cleaning procedures, refer to the item “Cleaning, disinfection and sterilization”*
Modes of operation	*Continuous operation*
Transportable equipment	*Portable*

Performance Characteristics
QuoreOne

ECG channels	*1, 2, or 3 channels. Selectable*
Memory Capacity	*For examination of up to 7 days*
Recording format	*Continuos*
Usage time	*Up to 7 days*
Storage time	*Up to 6 months*
Storage time outside the packaging	*Up to 30 days*
Internal battery recharge time	*Up to 2h30min for full recharge using Quoretech Docking*

Docking Station

Number of QuoreOne units that can be recharged simultaneously	*Up to 5 QuoreOnes*
Internal memory capacity	*16 GB*
Storage capacity without an internet connection	*5 tests.* [1-2]
Usage time	*Uninterrupted*
Storage time	*Undetermined*
Storage time outside the packaging	*Undetermined*

Battery recharge time	*Approximately 2h30min (depending on the battery condition and the charger model).*

1. *Considering 24-hour examinations and 3 leads. Longer examinations use proportionally more memory*
2. *For data collection to begin, the Docking must be connected to the internet. If the connection is lost during data collection, the Docking will continue collecting data from QuoreOne; however, data transmission to the Diagnostics Platform will be suspended until the internet connection is restored.*

Charger

Number of QuoreOne units that can be recharged simultaneously	*Only 1 QuoreOne*
Internal memory capacity	*No internal memory*
Storage capacity without an internet connection	*It is not possible to perform data collection without an internet connection*
Usage time	*Uninterrupted*
Storage time	*Undetermined*
Storage time outside the packaging	*Undetermined*
Battery recharge time	*Approximately 2h30min (depending on the battery condition and the charger model).*

Electrical Characteristics
QuoreOne

Applied Part Type	*BF (electrode - accessory)*
ECG Response Frequency	*0.67 to 40 Hz*
ECG input impedance	G 7 H
ECG differential range	*+/- 1.65 mV*
ECG A/D sampling rate	*200 H*
ECG resolution	*16 bits*
RF Transmission/Reception	*2.4 GHz* *Low Energy Bluetooth* *Effective Radiated Power < 1mW*
Transmission band frequency	*2.4 GHz*

Docking Station

Voltage	*100-240 VCA [1]*
Frequency	*50/60 Hz*
Power	*100 VA*
RF Transmission/Reception	*2.4 GHz and 5.0 GHz* *IEEE 802.11b/g/n/AC Wireless LAN* *Low Energy Bluetooth* *Effective Radiated Power < 1mW*
Transmission band frequency	*2.4 GHz and 5.0 GHz*

1 - This equipment must be connected to a power outlet with grounding (three pins), in accordance with the ABNT NBR 5410 standard for electrical installations, to ensure user safety against electric shocks.

Charger

Voltage	*5 VDC (powered exclusively through USB port)*
Frequency	*Not applicable*
Power	*2,5 W*
RF Transmission/Reception	*Induction charging, Qi standard*
Transmission band frequency	*110 to 205 kHz*

Physical Characteristics
QuoreOne

Dimensions	*130 x 140 x 23 mm*
Weight (without packaging and with battery)	*60 grams*

Docking Station

Dimensions	*168 x 168 x 280 mm*
Weight (without packaging and QuoreOne)	*730 grams*

Charger

Dimension	*180 x 8 x 35 mm*
Weight (without packaging and QuoreOne)	*70 grams*

Environmental Characteristics
QuoreOne, Docking Station e Charger.

Operating temperature	*5 to 43 ºC1-2*
Operating altitude	*-1 to 4.000 meters*
Operating atmospheric pressure	*700 hPa to 1060 hPa*
Operating and storage humidity	*10 to 95% (non-condensing)*
Transport and storage temperature (fast transport)3	*10 to 45 ºC*
Long-term storage temperature	*10 to 35 ºC*
Storage altitude	*-1 to 4.000 meters*
Storage and transport of atmospheric pressure	*700 hPa to 1060 hPa*
IP rating	*IP44 – QuoreOne* *IP20 – Docking Station* *IP22 - Charger*
Expected service life	*5 years*
Battery service life (QuoreOne)3	*5 years or 1.000 cycles*

1. During battery recharging, QuoreOne may reach temperatures higher than the operating temperature, see item “battery recharging procedure”.

During the examination, QuoreOne may occasionally reach temperatures above 41ºC, but never exceeding 43ºC. When this occurs (temperatures above 41ºC), the patient may feel mild discomfort due to the heat generated in the chest area where QuoreOne is attached. If the temperature exceeds 43ºC, QuoreOne must be immediately removed due to the risk of burns and/or damage to the patient’s tissue.

If the sensation of heat is uncomfortable, it is probably because part of the QuoreOne housing is touching the patient’s skin. In this case, it is recommended that the patient readjust their posture and

limbs so that only the electrodes remain in contact with the chest, leaving space for ventilation between the QuoreOne housing and the patient's skin. Older patients usually have more sensitive skin and may experience increased discomfort. Avoid using any topical medication under or near the area where QuoreOne is attached. The reaction of these medications may be intensified due to the elevated temperature.

Under normal conditions of use, QuoreOne does not exert superficial pressure on the patient. If the patient's body posture causes superficial pressure between the product and the patient, the sensation of heat may be intensified. In such cases, posture should be adjusted to relieve the applied pressure. In case of doubts about the heat generated and its consequences, contact Quoretech..

1. See item Battery replacement
2. When QuoreOne or its accessories are stored in a place with a temperature higher than the operating temperature, keep them in an environment with a temperature between 10 and 20ºC for 15 minutes before their next use..

Guidelines and Declarations on Eletrocmagnetic Emissions

QuoreOne and its accessories comply with ANATEL regulations. Operation is subject to the following two conditions: (1) this device may cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. The use of any accessory not listed in these instructions may not ensure compliance with ANATEL's RF exposure guidelines..

Changes or modifications not expressly approved by the party responsible for compliance may void the user's authority to operate the equipment. QuoreOne and the Docking have been tested and comply with ANATEL's RF exposure requirements when used and operated for their intended purpose and as instructed in the instructions.

Table 3. Guidelines and declarations on electromagnetic emissions

QuoreOne and its accessories are intended for use in the electromagnetic environment specified in the tables below. The user of QuoreOne must ensure that they are used in such an environment.		
Emission test	**Compliance**	**Guide on electromagnetic environment**
RF emissions CISPR 11	Group 1	QuoreOne and its accessories use an RF system only for CISPR 11 communication via Bluetooth technology, which may be with a mobile phone or even between QuoreOne and its accessories. Therefore, RF emission levels are very low and are unlikely to cause any interference with other electronic equipment nearby. For offline examinations, QuoreOne's RF system is only active during its configuration, while during online examinations, QuoreOne's RF system remains permanently active. The Docking Wall, Docking Station, and Charger accessories remain permanently active.

		The Docking Wall and Docking Station also feature Wi-Fi technology 2.4 GHz and 5.0 GHz IEEE 802.11ac.
RF emissions CISPR 11	Class B	QuoreOne and its accessories are suitable for use in all establishments, including domestic establishments
Harmonic emissions IEC 61000-3-2	Not applicable	Not applicable
Voltage fluctuations/flicker emissions IEC	Not applicable	Not applicable

Table 4 Guidelines and declarations on electromagnetic immunity.

QuoreOne and its accessories are intended for use in the electromagnetic environment specified in the table below. The customer or user of QuoreOne and its accessories must ensure that they are used in an environment whose restrictions are presented below.			
Immunity test	**NBR IEC 60601 test level**	**Test level compliance**	**Guidance on electromagnetic environment**
Electrostatic discharge (ESD) NBR IEC 61000-4-2	+/- 8 kV by contact +/- 15 kV by air	+/- 8 kV by contact +/- 15 kV by air	Floors should be wood, concrete, or ceramic. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 28 V/m 385, 450, 810, 870, 930 MHz 18 Hz pulsed 9 V/m 710, 745, 780 MHz 217 Hz pulsed 28 V/m 1720, 1845, 1970, 2450	10 V/m 28 V/m 9 V/m	Portable and mobile RF communication equipment should not be used near QuoreOne, including the cable, and the recommended separation distance is calculated by the equation applied to the transmission frequency. Recommended separation distance: d = & R 0 d = & R 0 80 MHz to 800 MHz d = & R 0 800 MHz to 2.5 GHz Where P is the maximum output power of the transmitter in watts (W) as stated by the transmitter manufacturer, and the recommended separation in meters (m). The field strengths of fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level at each frequency range . Interference may occur in equipment located near QuoreOne that bears the symbol. 

	MHz 217 Hz pulsed		
Mains frequency (50/60 Hz) Magnetic field NBR IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields from the mains should be at levels characteristic of a typical commercial or hospital environment
NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a *Magnetic fields from fixed stations, such as base stations (cellular/wireless), mobile radios, amateur radios, AM and FM radio stations, and TV transmitters cannot be predicted with theoretical accuracy. To assess the electromagnetic environment due to the presence of RF transmitters, an electromagnetic survey should be considered. If the measured field strength at the location where QuoreOne and/or its accessories are used exceeds the RF compliance level, QuoreOne and its accessories should be monitored to verify normal operation. If abnormal performance is detected, additional measures may be necessary, such as reorienting or repositioning QuoreOne or its accessories.* b*Above the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.*			

Table 5. Recommended separation distance between portable and mobile RF communication equipment and QuoreOne and its accessories.

QuoreOne is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or user of QuoreOne can help prevent electromagnetic interference by maintaining a minimum distance between the portable RF communication equipment (transmitter) and QuoreOne, as recommended in the table below according to the maximum output power of the communication equipment. The same rule applies to QuoreOne accessories.			
Maximum output power of the transmitter (watts)	**Separation distance according to transmitter frequency (meters)**		
	150 KHz to 80 MHz	80 MHz to 800 MHz	80 MHz to 2,5 GHz
	d = A R 0	d = A R 0	d = A R 0
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

INITIAL INSPECTION

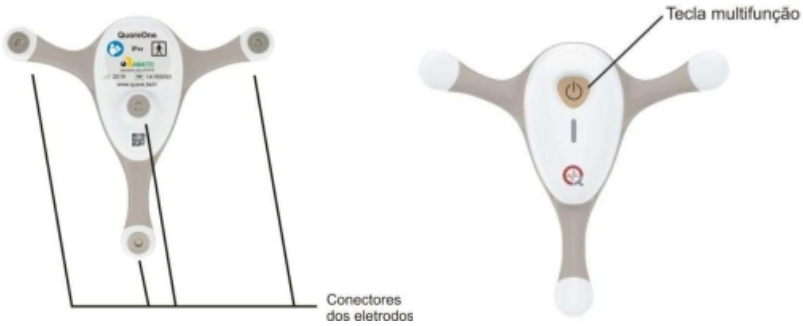
Upon receiving QuoreOne and/or its accessories, check if the packaging is intact and sealed. If there are any signs of tampering with the packaging, refuse to accept the product or contact Quoretech for replacement arrangements.

Pay attention to any sign of water or dust penetration inside the packaging. Refuse to use the product if it is wet or dirty.

These instructions for use are not provided in printed form. Inside the QuoreOne and Docking Station packaging, a quick guide is included with technical information about the product and instructions on how to download these instructions for use. If you consider it necessary to have these instructions in printed form, they must be printed and kept for future reference.

QuoreOne

Check if QuoreOne is intact, inspecting its parts, including, but not limited to: multifunction button and electrode connectors. The recordings, as well as the readability of the labels, must be in good condition.



QuoreOne has an internal battery rechargeable exclusively through induction technology..

Docking Station

Check if the charging cradles are firmly fixed to the vertical tube and if this tube is securely attached to the base. On the bottom of the base, there is a label with the product information. In the lower compartment of the box, the power cable required to connect the accessory to the outlet and the network cable for internet connection are available. The Docking Station does not have an internal battery.

Note: The Docking Station can be connected to the internet wirelessly, thus eliminating the need for a network cable.





Check the integrity of the label as well as the other markings on the product. Refuse to use it if any of its markings are illegible.

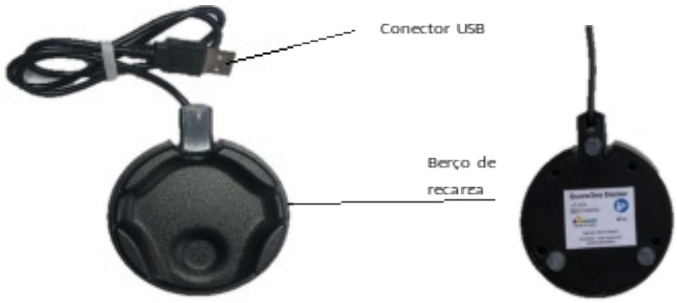
The Docking Station may be supplied with up to five QuoreOne units. Check the information on the number of items on the external label of the accessory's box.

Charger

The Charger has a non-detachable cable; check if the cable and the USB connector are intact.

The label is located at the bottom of the charging cradle. Refuse to use it if any of the markings are illegible.

The charger has no internal battery and is not connected to the power grid or the internet, either wired or wireless. For the charger to work, it must be connected to a computer.



INTRODUCTION TO USE

Expected Position for Use

QUOREONE - The patient may use QuoreOne in standing, sitting, and lying positions. Situations that should be avoided while using QuoreOne:

Avoid practicing sports or any other activities that produce excessive sweating, as sweat may impair the adhesion of the electrode to the skin.

Avoid entering environments with extreme temperatures, such as saunas, cold chambers, etc. Observe the declared limits of operating temperature and humidity in these instructions, as well as **QuoreOne**'s IP rating.

The expected position for installation, configuration, and uninstallation procedures, both for the Patient and the Operator, is described in these instructions in their respective sections.

⚠ For the use of QuoreOne in any situations other than those provided in these instructions, contact Quoretech before starting the installation of QuoreOne.

DOCKING STATION e CHARGER – The operator must be in a standing or sitting position, so that their eye level is close to the average height of the accessory. This position is important for the operator to clearly observe the status LED indicators (see item "Status light and Information Signals").

Observe the declared limits of operating temperature and humidity in these instructions, as well as the IP rating of QuoreOne accessories..

Battery Replacement

QuoreOne's battery is internal and rechargeable and must only be replaced by Quoretech. When nearing the end of its service life, Quoretech will provide the battery replacement. The battery's service life is declared as 5 years or 1,000 cycles, see note below.

Note: The degradation of charge retention capacity (commonly known as "battery health") in batteries is intrinsic to the technology. The factors that usually accelerate degradation are the number of charge and discharge cycles and the depth of battery discharge. QuoreOne units frequently used in short-duration examinations have longer battery health compared to QuoreOne units used in long-duration

examinations. Based on this information, Quoretech's platform monitors the condition of the batteries exam by exam, which may eventually block the configuration of a long-duration exam if the battery health of that QuoreOne could compromise the exam's longevity. In such blocking cases, a guidance message will appear during the exam configuration.

If you identify any issue related to low battery autonomy, contact Quoretech.

 *Patient, Operator, and Service personnel: Do not attempt to disassemble QuoreOne.*

*Service personnel: Inside QuoreOne, there is no fuse or component that requires adjustment.*

 *The QuoreOne battery is recharged exclusively using an induction charger. See item "Accessories." The QuoreOne does not have connectors or cables for battery charging..*

The Docking Station and the Charger do not have a battery.

Hazardous Materials or Substances
If battery leakage occurs, immediately remove the QuoreOne and promptly notify Quoretech. If the leakage comes into contact with the skin, remove the electrodes and wash the skin thoroughly with plenty of soap and water..

*Ideally, the QuoreOne and the electrodes should only be removed by a trained professional. However, in the event of battery leakage, it is understood that the risk of the patient performing the removal is lower than the risk of the patient continuing to wear the QuoreOne in a failure condition. For this, follow the steps described in the item *Uninstalling the QuoreOne*, asking a second person for assistance in removing the device from the patient. The patient should only perform self-removal as a last resort.*

Pause Determination - QuoreOne
A pause is defined as an R-R interval equal to or greater than 2.5 seconds..

Heart Rate Calculation - QuoreOne
The heart rate is calculated by the equation:

Where:

HR = *1.000X60/R-R*

HR = heart rate in beats per minute

R-R = R-R interval of the previous heartbeat cycle in milliseconds

Initialization Procedure

QUOREONE - To start the QuoreOne, press the multifunction key for 7 seconds. The status indicator light will turn on, indicating that the QuoreOne has been successfully powered on.

⚠*The QuoreOne has only one button, which functions as Power On, Power Off, and Event Marker. Refer to the item *"Multifunction key for Patient and Operator interface"* for more details on its operation.*

For better interpretation of the status light indications, refer to the item "Status light and Information Signals."

Refer to the item *"Installing the QuoreOne on the patient"* for the information required by the operator to begin operating the QuoreOne, including configurations via QuoreApp.

DOCKING STATION

⚠ For the Docking initialization procedure, remove all QuoreOne devices that are placed in the charging cradles.

The Docking Station does not have a power switch; to start it, simply connect it to the power supply using the power cord provided inside the package. A green indicator light will turn on, indicating that the Docking Station is powered. Connect the Docking to the internet using a standard TIA/EIA-568-A or B network cable with a maximum length of 25 meters.

Note: Alternatively, the Docking can be connected to a wireless / Wi-Fi network (IEEE 802.11b/g/n/ac). See the item Wi-Fi network configuration in the QuoreOne Docking Station.

Each charging cradle has two status indicator lights, one green and one blue.

- Green light – when lit, it indicates that the charging cradle has recognized a QuoreOne placed on it and that the battery is being recharged.
- Blue light – when lit, it indicates that the Docking Station is connected to the Quoretech platform.



As soon as it is powered on, the **Docking Station** will sequentially turn the green and blue lights of all charging cradles on and off, starting from the bottom cradle and finishing at the top one. The lighting of these lights indicates that the equipment initialization process is occurring successfully. The failure of any of the lights to turn on during the initialization process is an indicator of a malfunction.

After the first stage of initialization, the Docking Station may take up to two minutes to connect to the Quoretech platform. Once the Docking connects to the platform, the blue lights on all charging cradles will turn on, indicating that the Docking is in standby mode.

Note: This information is valid only for the Docking Station accessory and differs from the other accessories.

From this moment on, the charging cradles can be used. Refer to the item *“Status light and information signals”* for more details about the charging cradle status lights..

In cases of power supply interruption and restoration, the Docking Station may restart. If this occurs, it will be necessary to wait until the equipment initializes and returns to standby mode, without requiring any operator intervention.

CHARGER

⚠ *Before running the QuoreOne Uploader software, make sure that the Charger is connected to the computer’s USB port..*

The initialization of the Charger occurs when this accessory is connected to the USB (Type A) port of a desktop computer or notebook. Once connected, a blue light will turn on at the front of the accessory, indicating that it is powered and in standby mode. When a QuoreOne is placed on the accessory, a green light, also on the front, will turn on, indicating that the QuoreOne has been recognized for the charging procedure. For more information about the lights and charging, refer to “Status light and information signals.”

Although the Charger connector can be easily connected to a USB charger (such as those for cell phones), this action is not recommended unless a charger duly certified by INMETRO and with a power rating of 5 watts or higher is used.

Patient and Operator Interface
The QuoreOne has only one multifunction key for the patient and operator interface, and this key performs different functions depending on the current state of the QuoreOne.

QuoreOne State	Multifunction key press duration	Action executed when pressing the key
Powered off	7 seconds	Turns on the QuoreOne
Powered on, not performing exam	7 seconds	Turns off the QuoreOne
Powered on, performing exam	Any duration	Event marking.

⚠ *It is not possible to turn off the QuoreOne while an exam is in progress..*

The Docking Station and Charger accessories do not have an operator interface key. The interface of these accessories with the operator is only through software or an application. Refer to the item *Configuring the QuoreOne Docking Station*.

Event Marking During Exam Execution
The correlation between the time of occurrence of an external event (for example, drug administration, presence of symptoms, physical activities, etc.) and the patient's ECG complexes is essential for clinical interpretation.

QuoreOne provides the event marking feature. Thus, if during the exam the patient wishes to insert an event marker, they simply need to press the multifunction key for one second, and the marker will be visible to the operator or reporting physician when analyzing the captured exam signals.

Up to ten events per exam hour can be marked, with intervals of no less than 10 seconds between each marking.

⚠*Pressing the multifunction key does not mean requesting help or assistance.*

If necessary, ask anyone nearby for help or call the emergency service.

If the patient has the QuoreOne Patient App installed and paired with the QuoreOne, the event marking can be recorded directly in the App. For more details, refer to the item PATIENT APP – MONITORING THE EXAM.

Alerts and Information Signals
QUOREONE

The QuoreOne does not have an alarm.

The QuoreOne has two information signals: low battery and electrode disconnected or with poor contact.

⚠*The QuoreOne does not provide a direct indication of the battery charge level. To check the current battery level, connect the Requestor App to the QuoreOne and observe the percentage displayed in the App. See more in REQUESTOR APP – CONFIGURING EXAM.*

Low Battery:

When the QuoreOne detects a low battery level, it will notify the patient or operator through the status light (see *"Status light and Information Signals"*).

⚠*The QuoreOne Requestor App may block the creation of a new exam if the battery level is considered incompatible with the exam duration selected by the operator. In such cases, a blocking message will appear on the QuoreOne Requestor screen indicating that the battery level is insufficient for that configuration..*

Electrode disconnected or with poor contact:
When the QuoreOne detects one or more electrodes with poor contact or disconnected, it will notify the patient or operator in two ways: through the status light and through the QuoreApp Requestor. The latter is only possible if the patient has the App installed and running, and the QuoreOne is paired with the phone.

Status Light and Information Signals.
The situations below establish the relationship between the status light and the corresponding information signals for each QuoreOne condition..

When the QuoreOne is powered on using the multifunction key:

- The green light blinks once after the multifunction key is pressed for approximately seven seconds, and the QuoreOne is powered on.
- The green light remains on during the initialization phase and turns off when this phase is completed.
- The green light blinks twice after the multifunction key is pressed for approximately seven seconds, and the QuoreOne is powered off.

When the QuoreOne is powered on and not performing an exam:

- The green light blinks every five seconds, indicating standby mode.
- The green light blinks three times when Bluetooth is paired.
- The green light blinks five times when the exam is about to start.
- The blue light blinks twice every five seconds, indicating that the battery is at a low level.

When the QuoreOne is recharging the battery on the induction charger:

- The blue light blinks once every five seconds, indicating that the QuoreOne is being recharged.
- The blue light remains on, indicating that the QuoreOne is fully charged..

When the QuoreOne is performing an exam:

- The green light blinks when the multifunction key is pressed, indicating that an Event marking has been made.
- The green light blinks ten times, indicating that the exam has been completed and the QuoreOne will automatically power off.
- The blue light blinks once every two seconds, indicating that one or more electrodes are disconnected or have poor contact.
- The blue light blinks twice every five seconds, indicating that the battery is at a low level.
- The blue light blinks three times every five seconds, indicating that the battery is at a low level and that one or more electrodes are disconnected or have poor contact.

Note: When the QuoreOne is running an exam, with sufficient battery level and all electrodes properly connected, the status light remains off. If the patient or operator has any doubts about the status of the QuoreOne (whether it is on and performing an exam), press the multifunction key for one second and

check if the status light turns green. If it lights up, this indicates that the QuoreOne is on and an exam is in progress. Additionally, it also indicates that an event marking has been made. Record the time when this verification was performed and inform the operator so that this event marking can be disregarded in the report.

DOCKING STATION

The Docking Station does not have an alarm.

The Docking Station has information signals that are emitted through indicator lights located on each charging cradle, which operate independently:

During the accessory initialization:

- The green and blue lights turn on and off sequentially, starting from the bottom cradle up to the top cradle, with all lights turning off at the end of the initialization.

Note: The successful indication of the lights mentioned above does not mean that the accessory is in standby mode. For more details, refer to the item Initialization Procedure.

*A*fter the Docking Station is in standby mode:

- The green light remains off while there is no QuoreOne on the charging cradle.
- The green light remains on while a QuoreOne is on the charging cradle.
- The blue light indicates that the accessory is connected to the internet and to the Quoretech platform.

Note: The blue lights operate collectively; therefore, after initialization, all of them must be lit simultaneously..

During data collection:

- The green light must be on, indicating that a QuoreOne has been placed on the charging cradle for data collection [1]
- The blue light must be on, indicating that the accessory is connected to the internet and to the Quoretech platform.

1 – The green light on the cradle indicates that a QuoreOne has been recognized on the cradle for the charging procedure; however, this indication does not guarantee that charging is being carried out. To ensure that the QuoreOne is in charging mode, check the QuoreOne's indicator light and refer to its information signals.

There is no indication on the charging cradles that the battery is fully charged or that the exams have been successfully collected. This information signals are provided by the QuoreOne. For more details, refer to the section on the information signals emitted by the QuoreOne within this same section of the Instruction for Use.

CHARGER

The Charger does not have an alarm.

The Charger has information signals that are emitted through indicator lights located on the charging cradle. These signals are available once the accessory is in standby mode.

- The green light remains off while there is no QuoreOne on the charging cradle.
- The green light remains on while a QuoreOne is on the charging cradle[1].
- The blue light on indicates that the accessory is powered, either connected to a computer or to a USB adapter..

1-*The green light on the cradle indicates that a QuoreOne has been recognized on the cradle for the charging procedure; however, this indication does not guarantee that charging is being carried out. To ensure that the QuoreOne is in charging mode, check the QuoreOne's indicator light and refer to its information signals*.

Additional Information
QUOREONE

The QuoreOne is powered exclusively by a battery and has no connection to any external power source. There is no potential equalization point or conductor.

The QuoreOne does not have connection cables; the electrodes (see item "Accessories") must be connected directly to the QuoreOne connectors. Although the QuoreOne arms are flexible, the terminals and/or electrodes must never be placed in contact with each other..

The QuoreOne has an IP44 protection rating.:

- Protection against solid objects with a diameter of 1 mm or more
- Protection against water splashes from all directions

Therefore, the QuoreOne must not be used in environments with excessive dust, as there is a risk of penetration into the device, which may cause interference with the readings or even irreversible damage to the product.

 *Patient: Never use the QuoreOne during activities such as entering a swimming pool, hot tub, river, sea, sauna, or any other similar environments.*

The QuoreOne does not have a function to pause an exam. The QuoreOne detects when one or more channels are disconnected from the patient, such as during electrode replacement.

If it is necessary to remove the QuoreOne from the patient for any activity, such as traveling by car, it is not necessary to remove the electrodes or take any action to pause the exam. The period during which the QuoreOne is not receiving signals will not affect the results.

The QuoreOne was not designed to detect and/or measure ST-segment shifts; therefore, analyses of this segment are not performed.

DOCKING STATION

This accessory was developed to perform data collection and battery recharging of QuoreOne devices in environments where the demand for exams is considered high. The Docking Station can recharge the batteries and collect exams simultaneously from up to five QuoreOne units.

Data collection is carried out using Bluetooth technology and follows the guidelines of the telecommunications regulatory authority — in Brazil, ANATEL. The data collection speed is limited by the bandwidth offered by the available technology and may vary depending on the Bluetooth generation used. Another factor that significantly impacts data collection speed is the number of QuoreOne devices simultaneously allocated to each accessory. In such cases, bandwidth sharing is expected, and the data collection time may be longer than expected; however, this does not characterize a loss of the product's essential performance.

In environments with two or more accessories installed, cross-communication may occur. That is, a QuoreOne placed on the charging cradle of one Docking Station may eventually connect to another nearby Docking Station, and the data collection can still proceed normally.

The Docking Station collects the exam data, applies a data clustering algorithm (without quality loss), and sends it to the Quoretech platform for further analysis and classification of findings..

The battery recharging method provided by the accessories is commonly known as "induction charging" and uses standards similar to those applied in cell phones equipped with this technology. Induction charging also follows the guidelines of the telecommunications regulatory authority and has therefore been certified for this purpose.

CHARGER

Designed for low-demand use, the Charger has the capacity to recharge the battery of only one QuoreOne at a time.

Designed to be a compact accessory, the Charger does not have internal signal processing. For it to function, it must be connected to a computer (via USB-A port) running the QuoreOne Uploader application from Quoretech.

The Charger does not have a network cable port or a wireless network system for direct connection to the internet..

As with the other accessories, the Charger also provides induction charging.

Downloading and Installing the App on the Smartphone
The following instructions are intended for the Operator or the Patient who will install the app on the Smartphone..

The configuration of the QuoreOne, as well as some interactions between the operator/patient and the QuoreOne, are carried out through mobile applications.

The Operator must have access to a Smartphone in order to install the QuoreOne Requestor, and the Patient must also have a Smartphone in order to install the QuoreOne Patient.

⚠ *To install and successfully use the QuoreOne Requestor App, a Smartphone is required with Android version 7.0 (or higher) or iOS version 15.0 (or higher), and must support Bluetooth Low Energy (BLE) version 4.1 (or higher).*

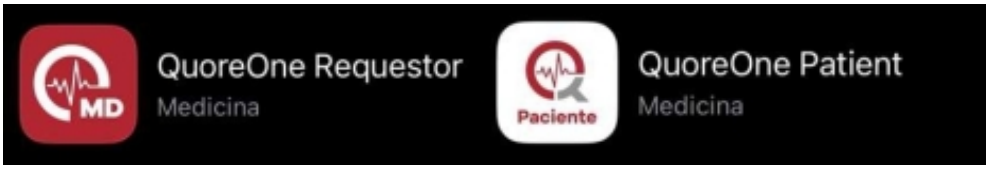
⚠ *The QuoreOne Requestor App is NOT compatible with Microsoft or BlackBerry.*

⚠ *The QuoreOne Requestor App is NOT compatible with tablets, notebooks, personal computers, or similar devices.*

⚠ *An internet connection is required to download the applications. The data transmitted may be subject to charges by your internet service provider. Quoretech does not reimburse these possible charges.*

Quoretech offers two applications, namely:

- **QuoreOne Requestor** – an application intended for use by the operator for exam configuration.
- **QuoreOne Patient** – application intended for use by the patient for inserting notes and transferring data.



Both applications are available for Android and iOS users. To download them, visit the official app store and download the app..

⚠ *The applications must be downloaded ONLY from the Google Play Store or the Apple Store. Do not download the applications from alternative sources. Make sure that the developer of the App is "Quoretech S.A."*

After installing the application, open the app on your Smartphone.

⚠ *The application will request permission to access your Smartphone to connect to Bluetooth and to send notifications. In both cases, choose the option* ***ALLOW.*** *If you have selected* ***DENY*** *one or more times, delete the application and restart the installation procedure.*

After the permissions are granted, the installed application will request login credentials.

QUOREONE REQUESTOR:



Operator, contact Quoretech to request your access credentials.

For information on exam configuration, refer to the item CONFIGURING EXAMS in these instructions for use.

For information on configuring the Docking Wall or Docking Station, refer to the item CONFIGURING DOCKING in these instructions for use.

QUOREONE PATIENT:



Patient, enter your CPF number in the "*Document*" field and click **Access**.

For additional information, refer to the item EXECUTING EXAM in these instructions.

Installing the QuoreOne on the Patient
These instructions are intended for the operator who will install the QuoreOne on the patient. If you are a patient, do not attempt to self-install the QuoreOne; seek a professional to perform the installation for you.

⚠ *The installation of the QuoreOne must be performed only by personnel trained and qualified for this activity.*

⚠ *The installation of the QuoreOne, when performed by untrained personnel, may cause injury to the patient's skin as well as damage to the product.*

🚫 *Do not use the QuoreOne on patients weighing less than 10 kg.*

⚠ *If the patient has a lesion, redness, or itching in the area to be shaved, suspend the installation of the QuoreOne until the skin is healthy. Ask the patient about the sensitivity of the area to be shaved and cleaned..*

⚠ *Potential allergic reactions: Patients with sensitivity to thermoplastic elastomers or ABS (plastic resin derived from petroleum – acrylonitrile, butadiene, and styrene) may experience an allergic reaction. In the event of an allergic reaction, discontinue the use of the QuoreOne immediately, remove the device from the body, and hand it over to the service personnel, informing them of the reaction that occurred.*

Contact injury – Prolonged exposure: If the patient's skin in contact with the QuoreOne or electrodes shows signs of injury, redness, or itching, discontinue the use of the QuoreOne immediately, remove the device from the body, and hand it over to the service personnel, informing them of the reaction that occurred.

Materials required for installing the QuoreOne:

01 - QuoreOne

04 - Monitoring electrodes (see item "Accessories"*)

01 - Razor blade

01 - Disposable gauze pad

25 ml of isopropyl alcohol solution.

Expected operator position for installing the QuoreOne:

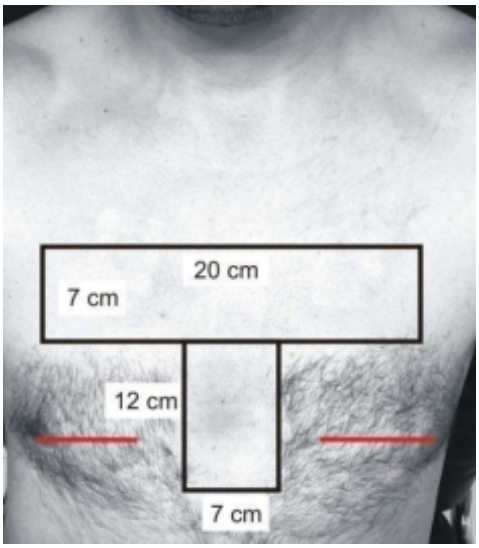
The professional installing the QuoreOne on the patient must position themselves facing the patient at a distance of 30 to 40 cm.

Procedure for shaving, cleaning, electrode placement, and QuoreOne installation:

Note: Keep in mind that the following instructions are essential to ensure the good quality of the acquired signal.

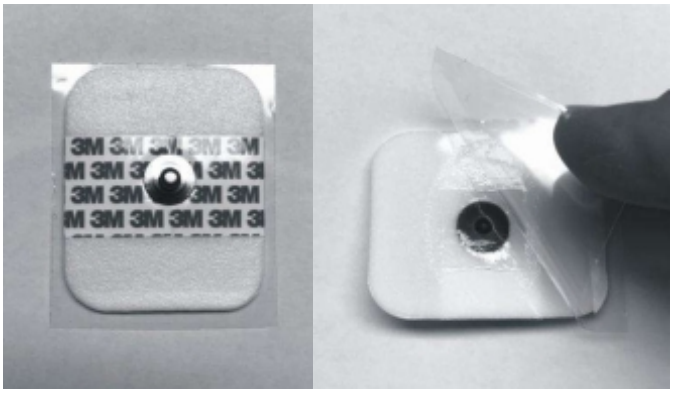
Using the razor blade, shave the area indicated in the picture. Considering the midline of the nipples (red line), perform the shaving as guided by the rectangles. Note that the vertical rectangle has 2/3 of its height above the nipple midline..

Note: Although some patients may not have visible hair in this area of the body, it is recommended that the procedure be performed regardless of the patient's race, sex, weight, height, or age.



Using a disposable gauze pad soaked in isopropyl alcohol solution, clean the shaved area by pressing the gauze firmly against the patient's skin. This procedure should last about 3 minutes. If necessary, replace the gauze during the process, always using gauze soaked with isopropyl alcohol solution.

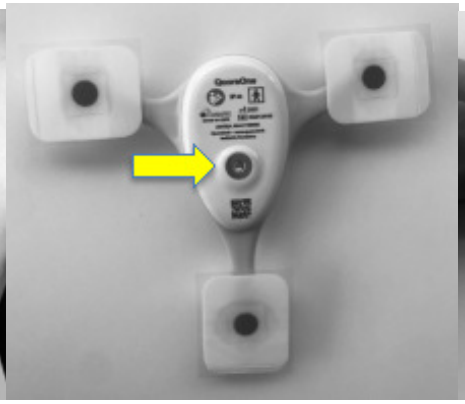
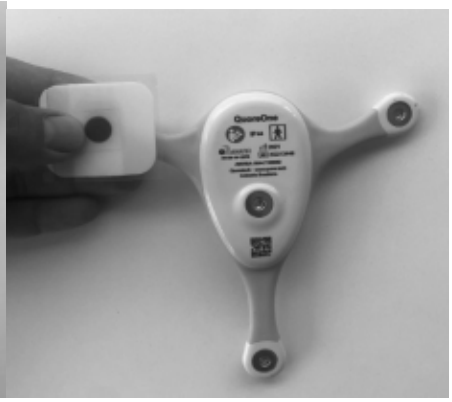
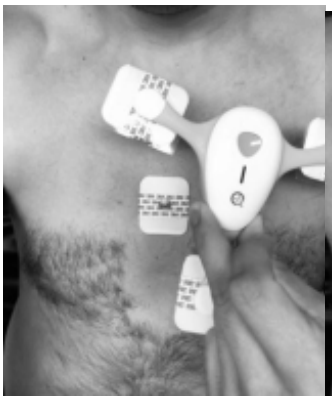
Take one of the foam electrodes and remove the protective plastic film.



Place the electrode on the patient's chest in the position shown in the picture. Using your fingertips, press the electrode firmly against the patient's chest to ensure good adhesion.

Install the other three electrodes (without removing the protective plastic film) onto the QuoreOne.

Bring the QuoreOne close to the chest by holding it by the main body. Fit the central connector of the QuoreOne into the metallic terminal of the electrode already placed on the patient. Press the QuoreOne against the patient's chest until a "click" is heard, indicating that the attachment has been successfully made.


After the QuoreOne is fitted onto the central electrode and is suspended on the patient's chest, remove the protective film from the electrode near the left arm and, aligning the QuoreOne, press it against the patient's chest only by the extremity. Repeat this action with the electrode near the right arm, and finally with the lower electrode.

⚠ *If any electrode does not adhere properly, remove that electrode and repeat the shaving, cleaning, and installation procedure with a new electrode.*





Requestor App - Configuring Exam

These instructions are intended for the Operator who will configure the QuoreOne through the QuoreOne Requestor App.

⚠ *The configuration of the QuoreOne is exclusively accessible to the Operator. The patient does not have access to the QuoreOne Requestor App..*

The following messages refer exclusively to the Smartphone being used in the QuoreOne configuration procedure.

⚠*To configure the QuoreOne, the Operator must have the QuoreOne Requestor App installed. See the item “Downloading and Installing the App on the Smartphone” in these instructions for use.*

⚠ *Before starting the configuration of the QuoreOne, close all other applications that are running.*

⚠ *Do not share the Bluetooth connection with any process other than the QuoreOne.*

⚠ *Do not answer calls, whether through the mobile network or through applications, during the configuration of the QuoreOne.*

Expected position for configuring the QuoreOne:

The Operator must remain within a radius of no more than one meter from the patient to ensure effective Bluetooth configuration.

Configuration Procedure:

Open the QuoreOne Requestor App on your smartphone. The opening screen will indicate the current status of your smartphone.

The information and warnings below refer to the opening screen.

⚠ *An active internet connection is required for the configuration of QuoreOne.*

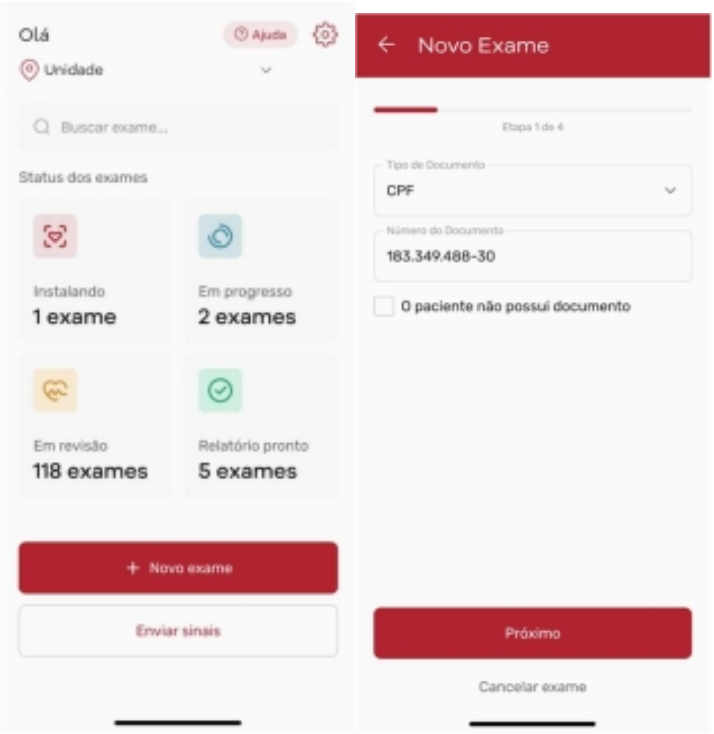
⚠ *QuoreOne may prevent the start of an exam if the battery charge level is incompatible with the duration of the exam to be performed.*

⚠ *DO NOT start the configuration of QuoreOne if the Smartphone's battery level is below 20%.*

⚠ *The Bluetooth on your smartphone must be active and not paired with any other device.*

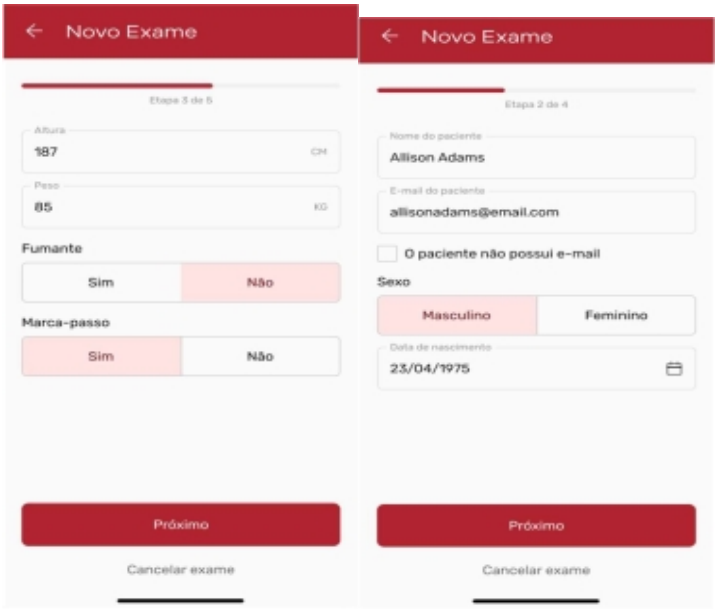
On the start screen, enter your username and password.

To create a new exam, go to the option “+ New Exam”. On the next screen, select the patient's "Document Type." Typically, the CPF is used. Enter the document number in the "Document" field.



After entering the patient’s documents, provide additional information about the patient.

On the screen shown in the picture, enter the patient’s Height and Weight. Also, indicate whether the patient has a pacemaker and whether they are a smoker.



Select the Complaints and Reasons for the exam.

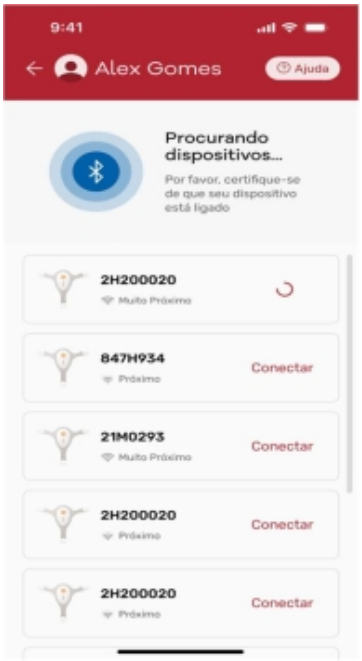


All dates and times are in the project's default time zone and formatting.

Still on the New Exam screen, select the option indicating whether there is a prescribing physician if you wish to enter information about the physician requesting the exam.

Once you choose to enter the requester's identification, fill in the fields with the physician's information.

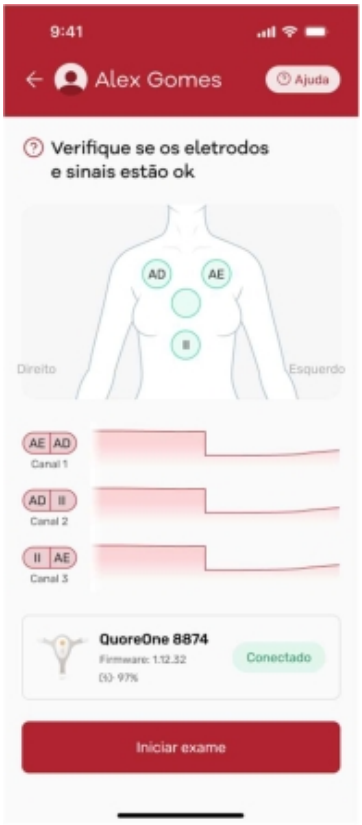
Next, select the exam period and click 'Next".



When switching screens, you will notice that the patient's name appears at the top of the screen. Select the QuoreOne to be paired by clicking on the 'Connect' option.

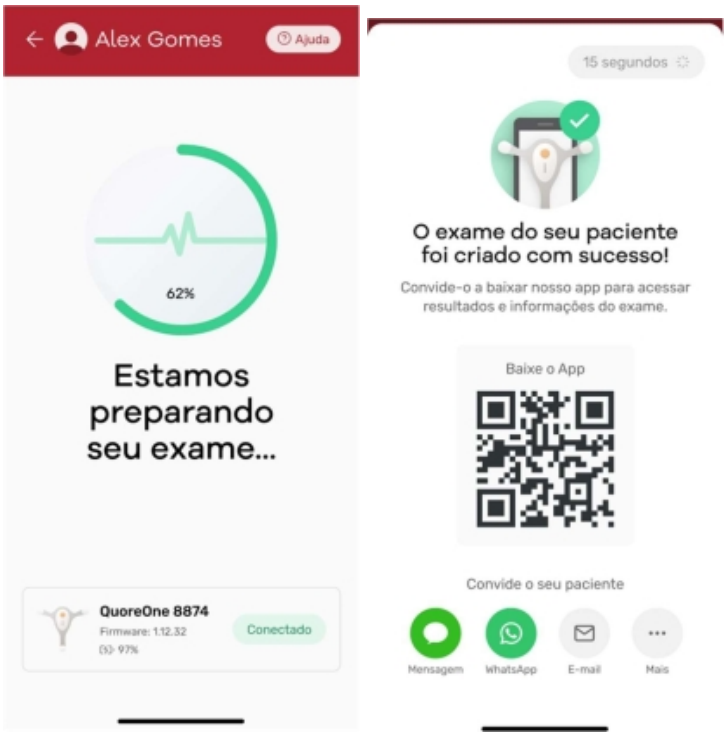
⚠ *The QuoreOne must be turned on in order to be detected by the QuoreApp. To turn on the QuoreOne, refer to the item 'Initialization Procedure'.*

Once the QuoreOne is properly placed on the patient's chest, the ECG signal will begin to be displayed on the App screen. Evaluate the signal quality and proceed to start the exam if you consider the signal to be of good quality.



If the signal quality of the test is considered adequate (this assessment is operator-dependent), proceed; otherwise, return to the signal test. If the signal quality is still not adequate, check the electrodes and, if necessary, replace them.

After choosing to proceed, the App will begin configuring the exam on QuoreOne. Once the exam has been successfully started, the option will appear on the App screen to send an invitation for the patient to download the data transfer application, called the Patient App. The invitation can be sent via SMS, QR Code, or through a shared link.



From that point on, the patient will have the QuoreOne properly installed and may be released to carry out their daily activities, respecting the restrictions outlined in these instructions for use.

Patient App - Monitoring the Exam
These instructions are intended for the Patient who is undergoing an examination with a QuoreOne installed on their body.

⚠ *This App does not change the exam settings defined by the Operator.*

⚠ *To monitor the exam, the Patient must have the QuoreOne Patient application installed. See the item 'Downloading and Installing the App on the Smartphone' in these instructions for use..*

⚠ *Before starting the pairing of QuoreOne with the QuoreOne Patient App, close all other applications that are running.*

⚠ *Do not share the Bluetooth connection with any process other than QuoreOne.*

⚠*Do not answer calls, whether through the mobile network or via applications, during the configuration of the QuoreOne Patient App. After monitoring has started, calls and messages can be received and answered normally.*

Expected position for the configuration/pairing of the QuoreOne Patient App.
The configuration must be carried out by the patient themselves or by another person who is within a distance not greater than one meter from the patient. This distance limit is justified to ensure effective Bluetooth communication.

Configuration Procedure:

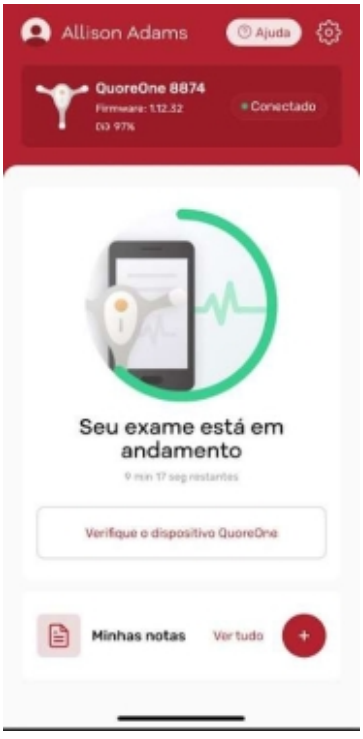
Patient: After downloading and installing the QuoreOne Patient App on your Smartphone (see the item 'Downloading and Installing the Application on the Smartphone'), log in using your CPF number.

Read the Terms of Use displayed on the screen. To accept, click 'I Accept'.

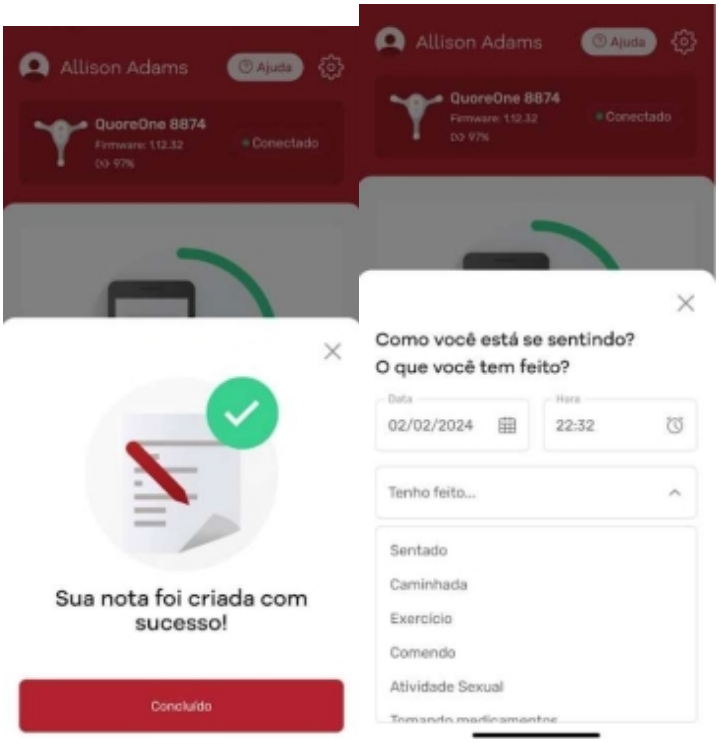
Note: It is not possible to proceed with exam monitoring without accepting this term. If you have any questions, consult your physician or Quoretech.

After accepting the terms, the QuoreOne Patient will search for the QuoreOne signal. Remember that it is essential for your smartphone’s Bluetooth to be active and available for pairing.

After finding and pairing with QuoreOne, the QuoreOne Patient will display the screen shown in the picture below.



During the exam, the patient may record events; see the item 'Event Marking During the Exam' in these instructions.



To insert event marking in QuoreOne Patient, the Patient just needs to click on 'Add Note. '

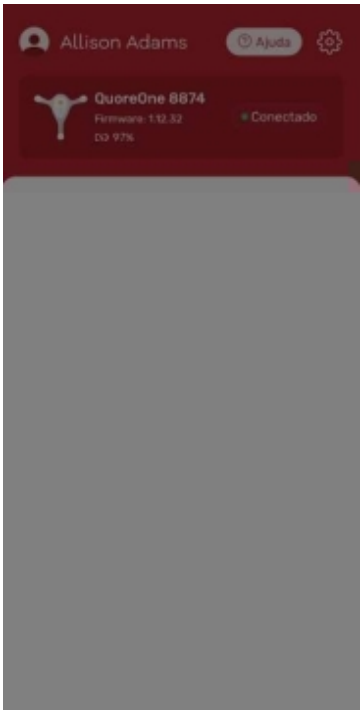
The Patient may select the activity being performed and provide more details about the activity or how they are feeling in the field just below the selector. If the Patient forgot or was unable to enter the note at the time of the event, the note may be entered later, but it is important that the date and time of the event are correctly provided.

The creation of the Note was successfully completed and is indicated by the message shown in the picture.

⚠*Event marking plays an important role in correlating the patient's event with possible changes in the electrocardiographic tracing. Therefore, it is important that the notes entered are accurate both in timing and in the richness of detail in their description.*

During the exam, the patient can also check, through the QuoreOne Patient, the QuoreOne's battery level, the remaining time for the exam to be completed, and whether the signals are OK.

If one of the electrodes is displayed in red, it means that the electrode has a poor connection. It may eventually be necessary to replace the electrode; for this, refer to the item INSTALLING QUOREONE ON THE PATIENT in these instructions.



After the exam is finished, keep the QuoreOne Patient App open on your smartphone. This action is necessary to complete the data transfer between the app and the platform.

When all data related to the exam has been sent to the Quoretech platform, the message 'Your exam is already being analyzed' will be displayed.

With this, the exam is considered finished. Contact the medical service that installed the QuoreOne for removal and return of the equipment.

Frequently Use Functions
Holter procedures are frequently used for a period of 24 hours, but they can be selected for up to 7 days.

Uninstalling the QuoreOne

These instructions are intended for the Operator who will uninstall the QuoreOne from the patient. If you are a patient, do not attempt to remove the QuoreOne yourself; seek a professional to remove it for you.

When to uninstall the QuoreOne?

The QuoreOne must be uninstalled after the end of the exam period.

Note 1. It is not necessary to turn off the QuoreOne, as it is automatically turned off at the end of the exam period.

⚠*The uninstallation of the QuoreOne must be carried out only by trained and qualified personnel for these activities.*

⚠ *The removal of the QuoreOne, when performed by untrained personnel, may cause injury to the patient's skin as well as damage to the product.*

Materials Required for the Uninstallation of QuoreOne:

01 - Disposable gauze pad

15 ml of isopropyl alcohol solution.

Expected Position for the Uninstallation of QuoreOne:

The professional who will install the QuoreOne on the patient must position themselves facing the patient at a distance of 30 to 40 cm.

Procedure for Electrode Removal and Cleaning of QuoreOne:

Disconnect the ends of the QuoreOne from the electrodes by pulling on the plastic part of the QuoreOne.

Pull the QuoreOne by the main body of the product, holding it with your index finger and thumb.

After removing the QuoreOne, the electrodes will remain installed on the patient’s chest. Using your fingertips, remove all the electrodes from the patient’s chest, pulling gently to avoid damaging the tissue.

Dispose of the electrodes in regular waste.

With a disposable gauze pad soaked in isopropyl alcohol solution, clean the electrode area by gently pressing the gauze against the patient’s skin. Repeat this process until no electrode adhesive residue remains on the patient’s chest

 *If the patient’s skin shows signs of irritation, advise the patient to seek medical assistance for evaluation and treatment.*

Configuring the QuoreOne Docking Station

Wi-Fi Network Configuration on the QuoreOne Docking Station

To connect the QuoreOne Docking Station to the Wi-Fi network, start the process by connecting the accessory to a power source. The QuoreOne Docking Station is automatic bivolt and can be used in 110V or 220V outlets. After confirming that it is powered on, open the QuoreOne Requestor application on a smartphone with an iOS or Android operating system. On the home screen of the application, locate the settings icon in the upper right corner and tap it to access the menu.

Within the settings menu, select the 'Docking Station' option. The application will begin searching for the nearby QuoreOne Docking Station to connect via Bluetooth. After finding the accessory you wish to configure, select 'Connect'. On the next screen, the information about the connected QuoreOne Docking Station will be displayed.

Select the 'configure network' option, and the application will list the Wi-Fi networks available for connection. Select the network on which you want to configure the accessory and enter the corresponding password, taking care to type, including uppercase and lowercase letters, special characters, and spaces, if any.

After entering the information correctly, select the 'Update' button to save the settings. The application will connect the QuoreOne Docking Station to the Wi-Fi network using the provided data.

To ensure proper communication and functionality of the QuoreOne Docking Station, specific network configurations must be allowed through the local or institutional firewall. The Docking Station requires secure access to Quoretech's cloud services and external systems for data transmission, updates, authentication, and monitoring.

The following outbound connections must be enabled:

- HTTPS, https://quoretech-debian-repo.s3.amazonaws.com, port 443 – Enables access to device and software update repositories.
- HTTPS, https://quoretech-exams-offline-prd.s3.us-east-1.amazonaws.com, port 443 – Allows secure upload and synchronization of exam data collected in offline mode.
- HTTPS, https://api.quore.tech, port 443 – Provides communication with Quoretech's central diagnostic and management platform.
- HTTPS, https://quoretech-users-prd.auth.us-east-1.amazoncognito.com, port 443 – Supports user authentication and authorization via Quoretech's identity management service.
- CP, intake.logs.datadoghq.com, port 10514 – Transmits operational logs securely to Quoretech's monitoring system for performance and security oversight.
- UDP, ntp.ubuntu.com, port 123 – Synchronizes the Docking Station system clock through a secure Network Time Protocol (NTP) server.

Make sure that the QuoreOne Docking Station is connected to the Wi-Fi network and working properly before proceeding with use. If problems occur during the process, check the information entered and try again. If the problem persists, contact technical support.

Checking the Connection of the QuoreOne Docking Station
To check if the QuoreOne Docking Station is connected to the internet and working properly, first make sure that the base is connected to a power source. Then, open the QuoreOne Requestor application and, on the main interface of the app, locate the settings icon positioned in the upper right corner of the screen.

After accessing the settings menu, select the 'Docking Station' option. The application will begin searching for the powered-on QuoreOne Docking Station available for Bluetooth connection. After finding the accessory you wish to configure, select 'Connect'. On the next screen, the information about the connected QuoreOne Docking Station will be displayed. Select the 'Self-Diagnosis' option. The application will display a list of checks related to the connection. Each item will be marked as correct (in green) or with problems (in red). If any item appears in red, this indicates a specific fault that needs to be corrected.

If any irregularity is detected, capture an image of the diagnostic screen and contact Quoretech technical support for further assistance.

If all the items on the list are marked in green, it means that the QuoreOne Docking Station is connected and ready for use.

Installation of the QuoreOne Uploader Software

To download and install the QuoreOne Uploader software, open an internet browser on the computer where you want to perform the installation and contact Quoretech support to request the installation link. The download will start automatically. Once the download is complete, locate the downloaded file on your computer and double-click it to start the installation. If you need additional guidance, watch the demonstration video available on the Quoretech support website.

After installing the software, connect the QuoreOne Charger to a USB port on the computer or to an adapter connected to a power outlet. Make sure that the computer's Bluetooth is enabled. With the QuoreOne Uploader software running, check if the LEDs on the base are lit, indicating that it is powered and ready for use. The program icon will appear in the Windows taskbar, indicating that the QuoreOne Uploader is in standby mode.

Minimum requirements for operation include a Windows 10 or higher operating system, Bluetooth connection (native or via adapter), and specific firewall settings. If there are network restrictions, contact your IT administrator to ensure the necessary ports are open. For additional support, consult the support website or contact Quoretech customer service.

Make sure that the computer will not be turned off or shut down during installation or data transfer.

Sending QuoreOne Data to the Diagnostic Platform

The sending of QuoreOne data to the Diagnostic Platform can be carried out in four ways: through the QuoreOne Requestor application, the QuoreOne Patient application, the QuoreOne Docking Station, or the QuoreOne Uploader software.

Sending Data through the QuoreOne Requestor Application

In the QuoreOne Requestor application, data transfer is performed by the Operator and initiated directly from the QuoreOne device connected to the application. After completing the exam, to start the process, the operator must place the QuoreOne on a wireless charger and then open the QuoreOne Requestor application and select the 'Send Signals' option.

On the next screen, the application will begin searching for a QuoreOne to connect via Bluetooth. Select the QuoreOne from which you want to transfer data and wait for the connection. Once the QuoreOne has been selected and the Bluetooth connection has been established, data transmission to the platform will begin through the connected data network. The application will display a progress bar indicating the upload status. After completion, the data will be automatically sent to the Diagnostic Platform for analysis.

During the process, the QuoreOne's blue LED will blink, indicating that the transfer is in progress. After the data has been successfully sent, the blue LED will remain lit. See the item 'Status Light and Information Signals".

Sending Data through the QuoreOne Patient Application

The sending of data through the QuoreOne Patient application is done in real time while the application is connected to the QuoreOne. Once the patient logs into the application and connects the QuoreOne to

the smartphone, real-time data transmission will begin. If there is any disconnection, the QuoreOne will keep the recording stored in its internal memory and will send the retroactive data once the connection is reestablished.

After the exam period is finished, the patient must keep the QuoreOne Patient application open until the application completes the data transmission.

Sending Data through the QuoreOne Docking Station

To send data through the QuoreOne Docking Station, make sure that the accessory is powered on and connected to the internet. The connection is indicated by the blue light on the docks; all lights must be on. If any light is off, check the connection through the QuoreOne Requestor application; see the item 'Checking the Connection of the QuoreOne Docking Station' in these instructions.

The QuoreOne must be placed in one of the docks, which serves as both a charging base and a data transfer point. As soon as the QuoreOne is positioned, the green light corresponding to the dock will turn on, indicating that the device has been detected. At that moment, the connection with the QuoreOne Docking Station will automatically start via Bluetooth.

The QuoreOne Docking Station automatically detects the stored data and transfers it to the Diagnostic Platform through a Wi-Fi or wired network connection.

During the process, the QuoreOne’s blue LED will blink, indicating that the transfer is in progress. After the data has been successfully sent, the blue LED will remain lit. See the item 'Status Light and Information Signals'.

No manual interaction is required after the QuoreOne is placed in the QuoreOne Docking Station.

Sending Data through the QuoreOne Uploader

To perform exam data extraction using the QuoreOne Uploader, ensure that the Bluetooth on the computer where it is installed is enabled and that the QuoreOne Uploader is running.

To verify that the QuoreOne Uploader software is active, make sure Bluetooth is enabled on the computer, then double-click the program icon on the desktop. The QuoreOne Uploader window will automatically close after loading, but the icon will remain visible in the taskbar, indicating that it is running correctly. The program icon will appear in the Windows taskbar, showing that the QuoreOne Uploader is in standby mode.

Once the exam monitoring period has ended and the QuoreOne has automatically powered off, place the QuoreOne on the QuoreOne Charger. After being positioned, the QuoreOne Uploader software will connect via Bluetooth with the QuoreOne and automatically detect the stored data to begin the transfer. The data will be automatically transferred to the Diagnostic Platform. Do not close the laptop or shut down the computer during the process. The transfer will be completed when the exam status on the Diagnostic Platform changes from 'In Progress' to 'A.I'.

During the process, the QuoreOne's blue LED will blink, indicating that the transfer is in progress. After the data has been successfully sent, the blue LED will remain lit. See the item 'Status Light and Information Signals'.

Report Generation

The generation of the final report or medical opinion is carried out by Quoretech.

At the end of the exam, Quoretech, through the Diagnostic Platform, will generate the report, which will be made available to the service personnel who configured the QuoreOne on the patient.

Quoretech has a team of reporting physicians who fully analyze the captured signals and proceed with the classification of the signals and assisted report generation.

*To access the Diagnostic Platform, use a modern browser with automatic updates enabled. The use of outdated browsers may hide functions, impair navigation, or even prevent access to the platform.*

Exam Settings on QuoreOne

Exam Period Configuration.

Exam Period

QuoreOne can perform exams ranging from one minute to seven consecutive days (Check the available intervals in the selector on QuoreOne Requestor).

Channels

QuoreOne has three leads or differential monitoring channels. The central electrode, located in the middle part of the device, is known as the reference electrode.

Differential Channels: The three channels of QuoreOne are differential measurement channels, with measurements occurring at the following polarities:

C1	-	*Terminals RA (+) e LA (-)*
C2	-	*Terminals RA (+) e LL (-)*
C3	-	*Terminals LL (+) e LA (-)*

Onde:

RA – Right Arm

LA – Left Arm

LL – Left Leg

The indication of the channels is shown on each ECG strip in the exam report.

PRECAUTIONS AND SPECIAL CARE

Service Information
Requirements

Contact Quoretech maintenance service through the contacts described in the item 'CONTACT QUORETECH'. Any repair attempt carried out by unauthorized technical service voids the equipment warranty. It is the user's responsibility to report the need for service to Quoretech or one of its authorized agents.

Serial Number

The device's serial number is a unique number used for its identification. The serial number is available on the back or bottom of the device.

Cleaning, Disinfection, and Sterilization

 *NEVER subject the QuoreOne, Docking, or Charger to any sterilization procedure*

After each use, the QuoreOne must be cleaned and disinfected with a soft cloth slightly moistened with 70º INPM hydrated ethyl alcohol solution.

 If you observe or suspect a battery leak, send the QuoreOne for maintenance. Do not disassemble the QuoreOne.

The cleaning and disinfection procedure must be carried out in a clean, ventilated, well-lit location, with good air circulation and at room temperature. There is no limit on how many times the QuoreOne can undergo the cleaning and disinfection procedure; however, the readability of the QuoreOne markings must be checked after each cleaning. For more information on the effects of multiple cleanings and the condition of the QuoreOne, refer to the item 'Information for Service Personnel' in these instructions for use.

 Wear latex surgical gloves, a mask that covers at least the nose and mouth, and protective glasses to carry out this procedure.

Information for Service Personnel
Minimum qualifications: 'Service Personnel' is defined as a professional with at least a technical degree in electronics or telecommunications, with documented training in the general items of ABNT NBR 60601-1, ISO 14971, and with proper and certified training conducted and recorded on 'General Aspects of QuoreOne' by Quoretech.

The QuoreOne and the Charger do not have an internal fuse. The Docking Station has an internal fuse, but it is not replaceable by the operator.

The internal power supply of the QuoreOne and the Docking Station is not replaceable. The Charger does not have an internal power supply.

There are no internal components that can be adjusted in any of the products covered by these instructions.

To replace the QuoreOne battery, send the QuoreOne to Quoretech. The Docking Station and the Charger do not have internal batteries.

Calibration: Quoretech recommends periodic calibration of the QuoreOne every four years, with the period counted from the first use since the last calibration performed. For calibration procedures, see the 'Declaration' item below. The Docking Station and Charger are not subject to calibration.

Declaration: Quoretech does not provide circuit diagrams, component lists, descriptions, or calibration instructions. Any calibration, adjustment, or repair, when necessary, must be carried out exclusively by Quoretech. For this purpose, contact us through the channels mentioned at the end of these instructions for use.

Check frequently, at least every 10 exams:

1. The readability of the QuoreOne markings. Performing multiple cleanings/disinfections may compromise their readability. Monitor the wear throughout the useful life of the QuoreOne and, if necessary, send the QuoreOne to Quoretech before the markings become illegible.[1]
2. The integrity of the QuoreOne parts.
    1. The metal electrode connectors must be free of oxidation and show no signs of dents or any other damage.
    2. Rigid parts must be intact, without cracks or fractures, and without peeling or wear;
    3. Flexible parts (arms) must retain their flexibility, without drying, discoloration, or any cuts or tears.

Docking Station and Charger, as they are restricted to professional use, must be constantly checked for the integrity of their cables and the readability of their markings.

1- If one or more of the above items are non-compliant, send the QuoreOne for maintenance at Quoretech.

Firmware Version
Firmware 1.2.3

Terminologies and Definitions

Declaration: The following terminologies were extracted from ABNT_NBR IEC 60601-1 2010 and amendment 2016. Eventually, some information may have been omitted only for the purpose of summarizing the text, without any prejudice to its interpretation in its application to QuoreOne.

Patient – Living being (person or animal) subject to a medical, surgical, or dental procedure. A patient can be an operator.

Operator – Person who works with the equipment*. In the case of QuoreOne, the patient is exclusively the person on whom the QuoreOne is installed, and this person does not perform the role of operator.*

Reporting Operator – Healthcare professional duly qualified to interpret and issue a report on a cardiac Holter exam,

Service personnel – Individuals or an entity that is legally or morally responsible to the Responsible Organization for installing, assembling, maintaining, and repairing Electromedical Equipment.

Procedure – Specific way of carrying out an activity or a process.

Process – Set of interrelated or interacting activities that transforms inputs into products (outputs).

Access cover – Part of an enclosure or guard that provides the possibility of access to parts of the electrical equipment for the purpose of adjustment, inspection, replacement, or repair.

Accessible part – Part of the electrical equipment, other than an Applied Part, that can be touched by means of a standard test finger.

Applied Part – Part of an electromedical equipment that, in normal use, necessarily comes into physical contact with the patient for the electromedical equipment to perform its function.

Basic safety – Absence of unacceptable risk directly caused by physical hazards when the electromedical equipment is used under normal conditions and under single-fault conditions.

Continuous operation – Operation under normal use for an unlimited time without exceeding the specified temperature limits.

Enclosure – External surface of the electrical equipment or its parts.

Essential performance – Performance of a clinical function other than that related to Basic Safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk.

Expected service life – Period of time specified by the manufacturer during which the Electromedical Equipment or Electromedical System is expected to remain safe for use (i.e., maintain Basic Safety and Essential Performance).

Internally powered – Term that refers to electrical equipment that can operate through an internal power supply.

Internal electrical power supply – Power supply for the operation of the equipment, which is part of the equipment and produces electric current from another form of energy. Example: chemical, mechanical, solar, or nuclear.

Normal condition – Condition in which all available means of protection against hazards remain intact.

Intended use or Intended purpose – Use of a product, process, or service in accordance with the specifications, instructions, and information provided by the manufacture**r**.

Normal use – Operation, including routine inspection, adjustments by any Operator, and standby condition, in accordance with the instructions for use.

Oxygen-enriched atmosphere – Environment in which the concentration is greater than 25% at ambient pressure up to 110 kPa, or such that the partial pressure of oxygen is greater than 27.5 kPa at ambient pressure exceeding 110 kPa.

Accessory – Additional part for use with the equipment in order to: provide the Intended Use; adapt it for some special use; facilitate its use; increase its performance; allow its functions to be integrated with those of another equipment.

TROUBLESHOOTING GUIDE

Problem	**Cause**	**Solution**
QuoreOne does not turn on	*Battery discharged*	*Recharge the battery*
QuoreOne does not turn on	*Restart required*	*Place the QuoreOne on the charging base and press the power button for 7 seconds*
QuoreOne does not turn off during an exam	*QuoreOne was designed not to turn off while performing an exam*	*Not necessary*
QuoreOne is not charging the battery	*Positioning failure*	*Charger and Docking Station: check if the QuoreOne is properly positioned on the charging cradle*
QuoreOne is not charging the battery	*Power failure*	*Charger: Check if the Charger cable is connected to a USB power source. If connected to a computer USB port, consider plugging it directly into a 5V power source (outlet)*
QuoreOne is not charging the battery	*Power failure*	*Docking: If using a Docking Station, check if the green LED on the back of the Docking is lit, indicating it is powered.*
QuoreOne is not charging the battery	*Damaged battery*	*Contact service*
QuoreOne blinks blue during an exam	*Low battery*	*Refer to the item "information signals" in the Instructions for Use.*

QuoreOne blinks blue during an exam	*Electrode connection failure*	*Refer to the item "information signals" in the Instructions for Use.*
QuoreOne stopped the exam before the programmed time	*Battery failure*	*Contact service*
Charger light does not turn on	*No power source*	*Check if the cable is connected to a USB power source. If connected to a computer USB port, consider plugging it directly into a 5V power source (outlet)*
Charger light does not turn on	*Module failure*	*Contact service*
Docking Station does not light green LED on the base	*Power failure*	*Verifique se a Docking Station está conectada a uma tomada e se a tomada está devidamente energizada*
Docking Station does not light green LED on the base	*Power failure*	*Check the integrity of the power cable.*
Docking Station does not light green LED on the base	*Power supply or module error*	*Contact service*
Docking Station does not light blue LED	*Initialization failure*	*Restart the Docking Station by removing the power cable from the outlet, waiting at least 30 seconds, and plugging it back in.*
Docking Station does not light blue LED	*Internet connection failure*	*Check if the network cable is properly connected or if the WiFi settings have been correctly configured. Check the Firewall conditions*
Docking Station does not light blue LED	*WiFi or Ethernet module error*	*Contact service*
Docking Station does not light green LED when a QuoreOne is placed for charging	*Positioning failure*	*Check if the QuoreOne is properly positioned on the charging cradle*
Docking Station does not light green LED when a	*Charging module failure*	*Contact service*

QuoreOne is placed for charging		
QuoreOne does not connect to the QuoreOne Requestor App	*Bluetooth disabled*	*Check if the smartphone's Bluetooth is enabled and has permission for use*
Login in the App	*Access credentials failure*	*Contact service*
QuoreOne and accessories: markings not legible	*Missing or erased markings*	*Contact service*

CE MARK

ANVISA
Register: 82424409001

ANATEL APPROVAL
QuoreOne

80447-19-12676

QuoreOne Docking Station

11270-21-12676

CONTACT QUORETECH

Any serious incident that occurs in relation to the use of this device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

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Indústria Brasileira

Everyone deserves a healthy heart.