viQtor®

a smartQare solution

24/7 (home) monitoring solution

User manual

for the user of the viQtor wearable monitoring device

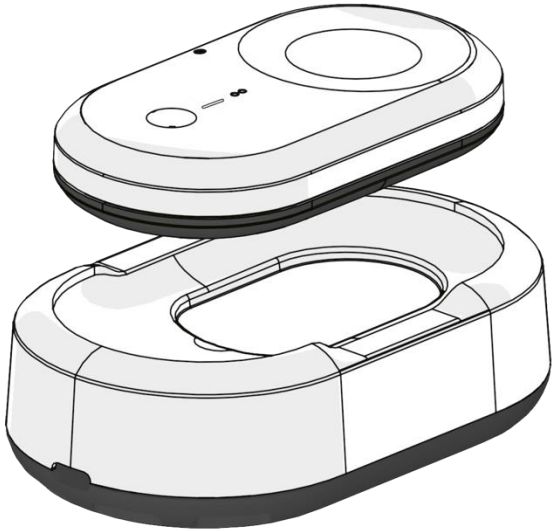


Table of contents

Table of contents

Table of contents

Introduction

viQtor is a medical device for 24/7 monitoring of clients/patients while they are in a hospital or healthcare organization or when they are at home.

The viQtor total monitoring solution comprises three essential components:

1. **The viQtor device**.
This device is worn on the upper arm using an armband. Equipped with smart sensor technology, it offers continuous measurements of vital functions, such as pulse rate (PR), respiratory rate (RR) and oxygen saturation (SpO2). Additionally, it includes a personal assistance request button, fall detection, activity monitoring and measure of the skin temperature. When the client/patient is outdoors, their location is communicated in the event of a detected fall or when the personal assistance button is activated.

2. **The viQtor Platform** for monitoring vital functions and events. This platform receives the data transmitted by the device 24/7. This data is securely stored in pseudonymized form to adhere to the EU's General Data Protection Regulation (GDPR). Healthcare professionals can access this data through web-based dashboards, supporting them in delivering the best care possible.

3. **The viQtor mobile application (App)**. This App presents a user-friendly interface for health monitoring. It displays the most recent vital functions and other important features.

Introduction

The different parts of the viQtor solution are relevant to its different users, with each part having its own set of instructions for use (IFU). Users are, therefore, advised to consult the other instructions for use wherever appropriate.

Instructions for use	User
The viQtor device	Healthcare professional, client/patient
The viQtor platform	Healthcare professional, medical call center/monitoring center
The viQtor Mobile Application (App)	Healthcare professional, client/patient, informal caregiver

Intended use

The intended use of the viQtor solution is to periodically transfer health data and events to a professional healthcare organization for assessment by healthcare professionals.

It measures oxygen saturation (SpO2), pulse rate (PR), respiratory rate (RR) of adult (18 years and older) users in hospitals, nursing homes, and home settings, allowing remote monitoring and assessment of trends by healthcare professionals.

Additionally, viQtor monitors skin temperature, user activity and detects potential falls. In case of a possible fall, the device sends a request for attention to the professional healthcare organization. The user also has the option to send a request for assistance to the professional healthcare organization a by pressing the assistance request button.

Non-Intended use

The viQtor solution is not intended for use in the following situations:

- The viQtor solution is not intended to detect acute life-threatening situations and is not intended for use in high-acuity environments, such as ICU or operating rooms.

- The viQtor solution is not intended for use on acutely ill (cardiac) patients with the potential to develop life threatening deterioration, like arrhythmias or very fast atrial fibrillation. These patients should be monitored using a device with continuous ECG. The viQtor solution is not a substitute for an ECG monitor.

Intended users

The viQtor solution consists of a wearable medical device, a platform, and a mobile application (App) for use by various users:

The intended users of the **medical device** are:

- Clients/Patients - Adults (18 years and older) with care needs for whom continuous monitoring is advantageous and receive care from healthcare professionals/organizations.

The intended users of **the platform** are:

- Healthcare professionals - Professionals working for healthcare organizations who provide care to clients/patients who use viQtor.
- Monitoring center personnel - Professional care practitioners appointed by the (responsible) healthcare organization to monitor client/patients' vital functions and events, such as the fall detections or personal assistance requests.

The intended users of the **mobile application (App)** are:

- Healthcare professionals - Professional working for healthcare organizations assigned to provide care to clients/patients.
- Informal caregivers - Relatives, neighbors and/or friends of clients/patients who wear viQtor.
- Clients/Patients (optional) - Adults with care needs for whom continuous monitoring is advantageous and receive care from healthcare professionals.

Intended users

Skill requirements of intended users:
The various users of the viQtor solution require various skills to correctly use viQtor.

The CLIENT/PATIENT
The client/patient that wears viQtor must understand the basic principles of the device and be capable of using it independently. They need to understand the following topics:

- Recognize the benefit of wearing the device.
- Know how to put on and remove the viQtor device (if a healthcare professional does not perform those tasks).
- Know how to wear the device (correct positioning).
- Know when the device should not be worn.
- Know how and when the device needs to be charged.
- Understand the significance of the different LED-indicators, the vibrations and sounds that the device makes.
- Be able to manually activate and cancel an assistance request.
- Know what to do if the device gets damaged.
- Know how to clean the device properly.

This information is provided in the instructions for use. In addition, the healthcare professional can explain to the client/patient how to use viQtor.

Intended users

The HEALTHCARE PROFESSIONAL

- All skills required to instruct the user regarding the use of viQtor.
- Knowledge of the possible consequences of wearing the device (or doing so incorrectly)
- Knowledge of the use of the viQtor platform and App.
- The ability to check that the device is correctly positioned on the upper arm and is functioning properly (generating measurements).
- Familiarity with the functions of viQtor and the protocols for follow-up action.

The MONITORING CENTER PERSONNEL

- Knowledge of and know how to use the viQtor platform.
- The ability to apply the healthcare organization's defined protocol for determining appropriate actions upon receiving various events, such as a detected fall, assistance request, or other events.
- The ability to communicate with the healthcare professional and/or informal caregivers responsible for the client/patient.

The INFORMAL CAREGIVER

- The ability to install the viQtor app on a mobile phone.
- Knowledge of the use of the viQtor app.
- The ability to assist the client/patient during an active event, or to contact a healthcare professional for assistance (if included in the monitoring center's protocol).

Getting started

Step 1: Check the contents of the box

Upon receipt, verify that the box contains:

1. Instructions for use.
2. The viQtor device.
3. The armband.
4. The charger.
5. At the bottom of the box, the power adapter with a charging cable and a second armband.

⚠ CAUTION

If any of the items listed above are missing, please contact Customer Service.

⚠ CAUTION

Make sure that the device is fully charged before the client/patient uses it (page 14, step 2).

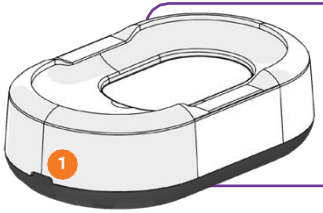
⚠ CAUTION

The device does not require time to start up before being used.
Placing it on the charger station is sufficient to turn it on.

Getting started

The medical device – viQtor

1. Personal assistance button
2. Battery status button

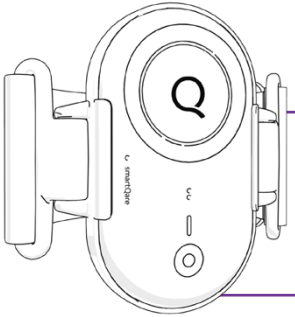


Charger

1. USB-C port

The charging cable and adapter

1. The adapter
2. Power cord with USB-C plug



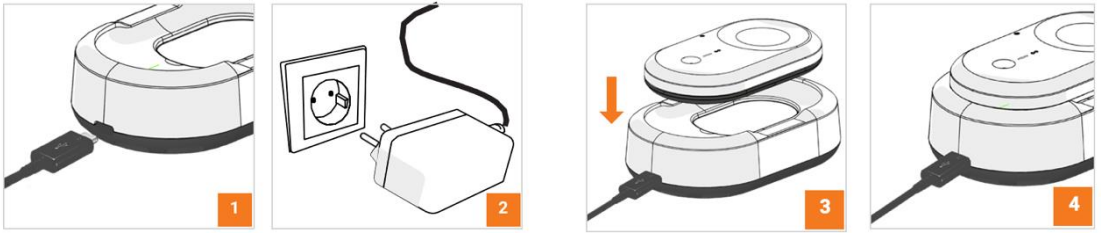
Armband with device holder

Step 2: Installing the charger

1. Insert the adapter cable into the charger's back.
2. Plug the power adapter into a standard power socket (100-240V AC).
3. Place the device on the charger with the LED sensors facing down.
4. Check viQtor's charging status using the LED above the battery status button:
   - Flashing orange: Battery below 20%
   - Flashing green: Battery between 20-80%
   - Constant green: Battery above 98%
   - If no light appears after 30 minutes of charging, contact Customer Service.

⚠ **CAUTION**

Ensure that the device is positioned on the charger so that the raised portion on the back of the device aligns with the recess on the charger. When properly aligned, the device will fit securely on the charger. The triangle on the back of the viQtor should be on the same side as the power cord, pointing towards it.



Getting started

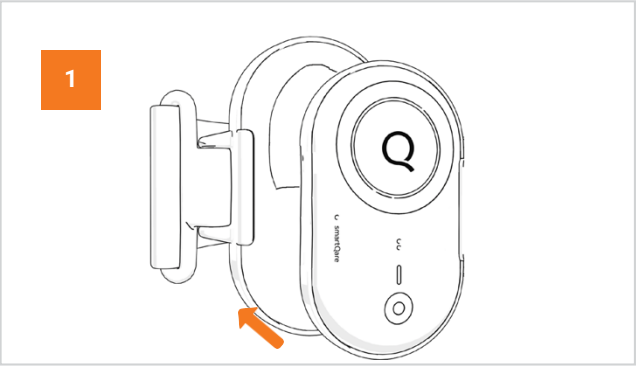
Step 3: Create your account

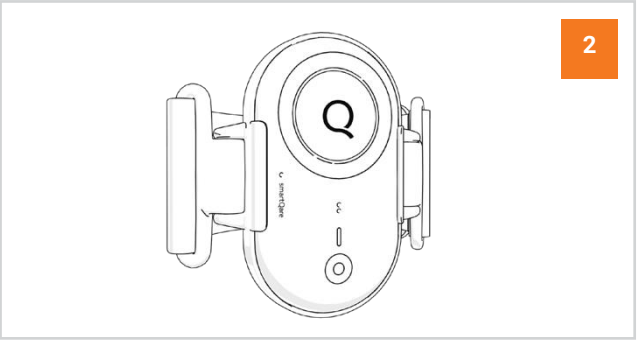
If necessary, ask the healthcare professional care provider or someone from your social support circle to help you.

1. Contact the healthcare organization.
2. The healthcare organization will create your account.
3. The healthcare professional will check your details on the viQtor platform.

Step 4: Place the device in the holder of the armband

1. Press the device into the holder of the armband, ensuring that the LED sensors are visible through the opening of the holder.
2. Click the device into the holder in such a way that the top of the holder cover the device. Turn the armband around and check whether the device's LED sensors are clearly visible through the opening of the holder.



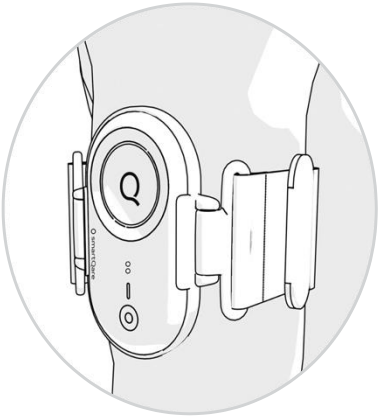


Step 5: Place the armband with the device on the outside of the upper arm

1. Adjust the clasp so that the armband is a comfortable fit around the upper arm.
2. Slide the armband with the device from the wrist to the upper arm. Fasten the clasp or readjust it until it feels comfortable.

The armband is the right size if it can be worn comfortably on the upper arm.
The armband and device should not slip out of position in response to movement.

The device can be worn on the outside of either the left or right arm.



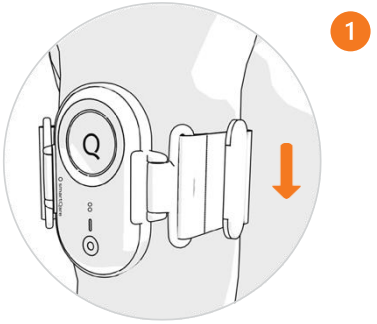
Step 6: Check your connection

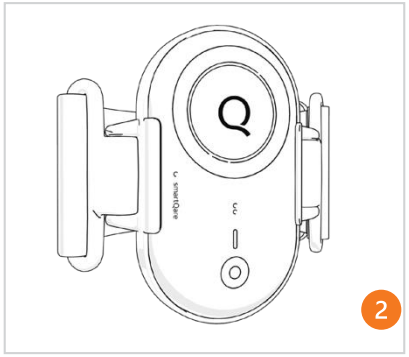
The healthcare professional will use the App or the viQtor platform to check if the device works properly.

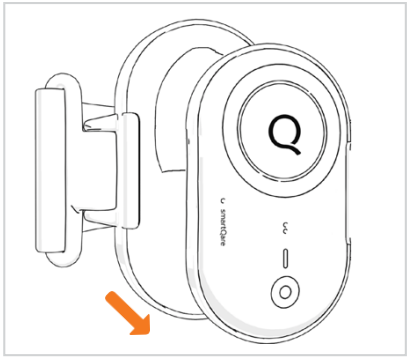
Getting started

Step 7: Removing and charging the device

1. Slide the armband with the device down from the upper arm and over the wrist.
1. Press the back of the device so it snaps out of the holder.
2. You can now charge the device, as shown in step 2 on page 14.







Operating the device – viQtor

The buttons and their functions

The small button is for checking the battery status 1

Press the small button to check the battery. The LED light will be green or orange. Green means that the battery still has sufficient charge. Green flashing means the device should be charged within 6 hours. Orange flashing means the battery is nearly empty and should be charged within 2 hours.

Battery status

When the small button is pushed	
100% - 80%	A constant green LED light
80% - 20%	Green LED light flashing (2Hz)
< 20%	Orange LED light flashing (2Hz)
0%	Constant red LED light

While charging	
> 0%	Orange LED light flashing (0.5Hz)
> 20%	Green LED light flashing (0.5Hz)
> 98%	Constant green LED light

Operating the device – viQtor

The large button is for activating and canceling a personal assistance request (help request). 2

Holding the large button pressed for 3 seconds sends an assistance request directly to the monitoring center.

Following activation, the LED flashes red, and the device vibrates and beeps for 30 seconds.
The assistance request can be cancelled within 30 seconds by pressing the large button again for 3 seconds.

The red LED light will then go out, the vibration and the beeping will stop, and the assistance request will be cancelled.

If a hard fall is detected and you do not get up again within 30 seconds, the device will automatically send an assistance request. Again, the LED will flash red, and the device will vibrate and beep. You can cancel the automatic assistance request by pressing the large button for 3 seconds. The light will then go out, the vibration and the beeping will stop, and the assistance request will be cancelled.

Meaning of the viQtor signals (LEDs, vibration, and sound)

Main functions

SITUATION	ACTION	LED	VIBRATION	AUDIO
You want to send an assistance request	Press large button for 3 seconds	LED light flashes red	Device vibrates for 40 seconds	Device beeps for 30 seconds (1x per second)
An automatic assistance request is generated due to pulse rate or oxygen saturation.	None.	None.	None.	None.
A fall has been detected and an automatic assistance request has been sent.	None (Unless you are fine and wish to cancel the assistance request).	LED light flashes red for 40 seconds.	Device vibrates for 40 seconds.	Device beeps for 30 seconds (1x per second).
You want to cancel an assistance request following a fall detection or manual activation of the assistance request button.	Press the large button again for 3 seconds within 30 seconds, before the beeping and vibrating stop.	LED light flashes green for 15 seconds to confirm that the assistance request has been cancelled.	Device vibrates briefly to confirm that the assistance request has been cancelled.	Device stops beeping.
Assistance request is not cancelled.	None: The healthcare professional will contact you.	LED light is constant red.	Device vibrates 2x per second for 15 seconds to confirm that the assistance request is active. Vibration is repeated every 5 minutes. Device stops vibrating after 40 minutes.	Device beeps 5x per 2.5 seconds. Beeping is repeated every 5 minutes. Device stops beeping after 40 minutes.

Meaning of the viQtor signals (LEDs, vibration, and sound)

Main functions

SITUATION	ACTION	LED	VIBRATION	AUDIO
Device is unable to connect to and communicate with the platform when assistance is required.	Call your healthcare professional, or, if in doubt, call the emergency number.	LED light flashes blue for 15 seconds 1x per minute for 5 minutes.	Device vibrates 4x per second for 15 seconds.	Device gives a high-pitched beep 1x per second for 15 seconds.
Battery is low.	Place the device on the charger soon.	LED light is orange for 2 hours (when not charging).	Device vibrates briefly every 5 minutes.	Device gives 3 short beeps.
Power-saving mode active (when the battery is low).	Place the monitoring device on the charger as soon as possible.	LED flashes orange for 3 seconds once per minute.	None.	None.
Device has been switched off. Device will switch off automatically if the battery is empty.	Place the device on the charger as soon as possible.	LED light flashes white for 5 seconds.	None.	None.
Device has been switched on. Device will switch on automatically.	None. Device will switch on automatically if the battery is recharged or following a reset.	LED light flashes purple for 15 seconds.	Device vibrates once a second for 15 seconds.	Device gives 1 'Welcome' beep.

Troubleshooting

Although the device is precision-engineered, problems may occur. Several problems you may encounter are listed below, together with advice on how to resolve them. If you encounter a problem not listed below, please contact your healthcare organization or smartQare.

Problem	You can try the following
1. Device does not charge.	Check that the power cord is firmly plugged into the power socket and firmly connected to the charger. Check that the device is properly seated on the charger. The device has a unique shape and must be positioned to fit neatly into the matching recess on the charger. When the device is placed on the charger correctly, the device will beep and vibrate briefly, and the LED light will go purple
2. An event appears on the viQtor platform or in the App saying that incoming measurements are poor quality.	Make sure the device and armband are correctly positioned on the upper arm. If necessary, perform a hard device reset by placing the device on the charger and pressing the small battery button for 15 seconds.
3. The device has stopped working.	First, make sure that the device is charged. If it is fully charged, see problem #4.
4. The device no longer works, even when charged.	Try performing a hard device reset by placing the device on the charger and holding the small (battery) button pressed for 15 seconds. If that does not resolve the problem, contact your healthcare organization or smartQare.
5. The device cannot connect to the platform.	First, wait up to 24 hours to see whether the connection is restored. If necessary, perform a hard device reset by placing the device on the charger and holding the small battery button pressed for 15 seconds. If that does not resolve the problem, contact your healthcare organization or smartQare.

Cleaning and maintenance

Cleaning the device and charger

In the interests of hygiene, the device should be cleaned regularly using a damp, lint-free cloth (without any cleaning agent).

Before cleaning the charger, make sure it has been disconnected from the power by removing the power cord from the charger. It can then be cleaned using a damp, lint-free cloth. After cleaning the charger, reconnect the power cord.

If the device, the sensor on the underside of the device or the charger appears dirty and you cannot remove the dirt using only a damp, lint-free cloth, try using a damp, lint-free cloth in combination with one of the following cleaning agents:

- Soap solution.
- Isopropyl alcohol (IPA 70%), which will also serve to disinfect the device.
- Ethanol (96%), which will also serve to disinfect the device.

⚠ CAUTION

It is advised to check visually the device after the cleaning and determine visually if the device is properly clean at the end of the cleaning step. If not, the user should repeat the previous cleaning steps or safely dispose of the device, so that a visibly soiled device is not used again.

⚠ CAUTION

DO NOT use bleach (chlorine) or other aggressive cleaning agents. When cleaning the charger, avoid using excessive fluid, so that there is no risk of fluid getting into the device and damaging the electronic components.

Cleaning and maintenance

Cleaning the armband

REMOVE the device from the holder before washing the armband. Wash the armband regularly in a washing machine (e.g. once a week, or whenever it looks dirty) at a maximum temperature of 30°C, using a mild detergent that does not contain bleach (chlorine) or fabric softener. After washing, hang the armband to dry.

⚠ **CAUTION**
Do NOT dry the armband in a tumble dryer. Do NOT iron the armband.

Maintenance of other components

Neither the device nor the charger has any user-serviceable parts.

Cessation of use

The viQtor solution is loaned to you. Once you have finished using it, the device must be returned to the healthcare organization that issued viQtor to you. The healthcare organization will then disconnect the device from the platform. Until the device has been (synchronized with the platform and) disconnected, it may contain digital data that has not yet been transmitted.

Safety - Contraindications

- Do not use on neonatal or pediatric.
- Do not use the device for a client/patient allergic to metals or plastics.
- Do not use the device for clients/patients with
- significant deformities, swellings, irritation, degenerative changes, or oedema of the upper arm.
- Do not use the device for clients/patients with local infections, ulceration or skin lesions affecting the upper arm.
- Do not use the device on any area of the body with a tattoo, broken skin and/or on an (upper) arm under medical treatment.
- Do not use the device for clients/patients whose bloodstream is impeded, e.g. by a tourniquet, pressure cuff or intravenous drip.
- Do not use the device on the arm of a client/patient for whom a blood pressure cuff is contraindicated.
- Do not use the device for clients/patients with tremors or convulsions.
- Consult your doctor before using viQtor if you have a common arrhythmia, such as atrial or ventricular premature beats or atrial fibrillation, or if you have arterial sclerosis, poor perfusion, diabetes,
- pre-eclampsia or kidney disease, or if you are pregnant.
- viQtor cannot be used as a substitute for an ECG monitor.
- Do not use the device for a client/patient who has had cardiopulmonary bypass surgery.

Safety - Contraindications

- Do not use the device in the vicinity of strong electromagnetic fields (e.g., electromagnetic anti-theft systems, metal detectors).
- Do not use the device near high frequency (HF) surgical equipment, MRI equipment or in a CT environment. Such use could cause the device to malfunction and/or could result in inaccurate measurements.
- Never diagnose or treat yourself based on data recorded by the device. ALWAYS discuss the situation with your doctor.
- Keep the charging cable out of the reach of babies, toddlers, and children to avoid the risk of strangulation.
- Do not use the device in conditions of high motion or when there is low arm perfusion.

Safety - Warnings and precautions for use

WARNING: *A WARNING statement provides important information about a potentially hazardous situation that, if not avoided, could result in death or serious injury.*

CAUTION: *A CAUTION provides important information on a potentially hazardous situation that, if not avoided, could result in minor or moderate injury to the user or client/*patient *or damage to the equipment or other property.*

WARNING

DO NOT USE the device in magnetic resonance imaging (MRI) environments. Such use could result in serious injury.

GENERAL

CAUTION

Any serious incident that occurs in relation to the device must be reported to the manufacturer and the competent authority in the member state where the user and/or client/patient is established.

CAUTION

The smartQare monitoring solution is designed exclusively for the purpose described under 'Intended purpose'. Observe all warnings and precautions in these instructions for use and the product labelling.

Safety - Warnings and precautions for use

⚠ **CAUTION**

DO NOT attempt to open or modify the device for any reason. Only suitably qualified technical personnel may do so.

⚠ **CAUTION**

Never place the charger in a wet environment, such as a bathroom or kitchen.

⚠ **CAUTION**

Check the device, the charger, the power adapter, and the armband for possible damage when you receive the box containing the equipment. You MUST NOT USE the device if any element of it is damaged. smartQare cannot guarantee that a damaged device is safe to use. If you discover damage, please contact Customer Service.

⚠ **CAUTION**

Before using the device for the first time, it is necessary to check that it works correctly and continues to do so when the wearer moves. Your healthcare professional can perform the checks. If it appears that the device is not working, or not working properly, DO NOT USE IT. Please contact Customer Service.

⚠ **CAUTION**

Follow the instructions under 'Getting Started' to position the device correctly.

The viQtor device

⚠ **CAUTION**

The device should not be used beside or stacked with other equipment. If such use is unavoidable, the device must be observed to check that it is working normally in the correct configuration.

⚠ **CAUTION**

The device may feel hot after charging. Remove it from the charger and let it cool down for a few minutes until it is a comfortable temperature before fitting it around the upper arm.

⚠ **CAUTION**

For optimum performance, the device should be charged for at least half an hour to an hour every day. Ask your healthcare organization or someone you know to help you choose a good time for charging.

⚠ **CAUTION**

The device CANNOT be switched off by the user. If you anticipate not using it for an ex- tended period, contact your care provider.

⚠ **CAUTION**

If the device switches off spontaneously, the battery is empty. If you then place it on the charger, the device should switch on again automatically. If it does not, please contact Customer Service.

Safety - Warnings and precautions for use

⚠ CAUTION

If you notice that the device is not working properly (e.g. it no longer charges up, the LED sensors do not illuminate, or the device provides no/excessive feedback), please contact Customer Service.

⚠ CAUTION

DO NOT connect anything that is not specified in the instructions for use to any element of the device, otherwise the device may be damaged. There is no guarantee that a damaged product will work safely.

⚠ CAUTION

Check that you can still operate the assistance request button on the device when wearing thick clothing (e.g., a jumper) over it. Other- wise, ask your healthcare professional for advice.

⚠ CAUTION

Make sure that the back of the device (where the sensors are) is in direct contact with the skin. If you wear the device over a shirt or jumper, for example, it won't work.

⚠ CAUTION

Do not use the device in combination with a wet armband. If you have taken a shower while wearing the device on your upper arm, you should afterwards swap the wet armband for a dry one. Prolonged wearing of a wet armband can cause skin irritation.

Safety - Warnings and precautions for use

⚠ **CAUTION**
Use of the device or the total solution for non-intended purposes can lead to incorrect measurement results and erroneous clinical interpretations.

⚠ **CAUTION**
The device makes wireless contact with your Medical Service Center or care institution via a mobile network, without you noticing. Be aware that, if you are in a place or area where the mobile network coverage is poor, the device may be temporarily unavailable. Please contact Customer Service if you would like to see a network coverage map.

⚠ **CAUTION**
The device is intended for use by a single client/patient. Do not let anyone else use the device.

⚠ **CAUTION**
Low skin temperature, restricted blood flow or excessive movement can lead to measurements not being taken and/or to measurement results being incorrect.

⚠ **CAUTION**
The device should not be placed over a tattoo, otherwise, the accuracy of the measurements may be reduced.

⚠ **CAUTION**
The device must not be used on damaged skin.

Safety - Warnings and precautions for use

⚠ **CAUTION**
The device must not be used as an apnea monitor.

⚠ **CAUTION**
The device should be used at a temperature of between 5º and 35º Celsius.

⚠ **CAUTION**
The device may not work properly if the temperature is less than 5º Celsius or more than 35º Celsius. Incorrect measurements may be transmitted, and the battery may not work properly.

⚠ **CAUTION**
If your device has been dropped, it may have been damaged (other than normal wear and tear). Always check the outside of the device for cracks and other signs of damage after falling. If you find any signs of damage, DO NOT USE the device (it may no longer be watertight). Please contact Customer Service.

⚠ **CAUTION**
To prevent damage to the device, repairs and maintenance must be carried out exclusively by authorized smartQare personnel.

⚠ **CAUTION**
If the device has been in storage or has been exposed to environmental conditions beyond the parameters of the operational specification, the device must be allowed to acclimatize under the specified operational conditions for at least 1 hour before being used.

Safety - Warnings and precautions for use

⚠ CAUTION
The device must be cleaned only in accordance with the instructions on page 24.

⚠ CAUTION
If a problem occurs, follow the advice given in the 'Troubleshooting' section on page 23.

⚠ CAUTION
ESD and strong EMC radiation can affect the working of the device.

⚠ CAUTION
Portable and mobile RF communications equipment can affect the working of the device. When using portable or mobile RF communications equipment, keep it at least 30 cm (12 inches) away from any element of the device. Other equipment can interfere with the device, even if the equipment meets the CISPR emission requirements.

⚠ CAUTION
The device does not have any user-service-able parts. Opening or modifying any part of the device may invalidate your warranty and cause a short circuit and/or electric shocks.

⚠ **CAUTION**

The accuracy of skin temperature measurements will be affected under the following circumstances:

- The sensor is not in contact with the skin.
- There is water between the sensor and the skin.

Skin temperature measurements from the device cannot be used to detect fever or hypothermia. The device does not measure core body temperature.

Activity index is reduced under the following conditions:

- Restricted movement in the upper arm.
- Involuntary or spastic movements of the upper arm.

The viQtor armband

⚠ **CAUTION**

Do not use any armband other than the one that came with the device. A non-original armband may not be the right size, causing the device to malfunction. A non-original armband may also cause skin irritation.

⚠ **CAUTION**

If you have difficulty putting on the armband, ask your care provider for help.

Safety - Warnings and precautions for use

⚠ **CAUTION**
Having the armband too loose or too tight may affect the measurement results.

⚠ **CAUTION**
Make sure that the armband is not too loose.
If it slides down your arm when you move or sit still, it may be unable to take measurements, or the measurements may be inaccurate.

⚠ **CAUTION**
The armband must hold the device firmly against the skin, but it must not be so tight that it could impede blood flow. If you find that the device is uncomfortable or is causing a rash or irritation, take it off and inform your care provider.

⚠ **CAUTION**
DO NOT dry the armband in a tumble dryer.
DO NOT iron the armband.
DO NOT place viQtor in a wet armband.

The viQtor charger

⚠ **CAUTION**

Do not charge the device using anything except the charger (charging station and adapter) that came with the device. Incorrect use of the charger can cause internal damage to the device. If you need a new charger, order one from Customer Service.

⚠ **CAUTION**

Charge the device only using the charger that came with the viQtor device, to avoid the risk of the battery overheating and the battery circuit being damaged.

⚠ **CAUTION**

The charger should be used at a temperature of between 5° and 30° Celsius. It is best to charge the device in a cool place, where it is not exposed to direct sunlight and away from any heating system.

⚠ **CAUTION**

CHECK that the voltage of the power socket you use for the charger is correct. It must be between 100- and 240-volts AC. If the voltage is not within that range, it may damage the device.

Safety - Warnings and precautions for use

⚠ CAUTION

The charging cable adapter can simply be plugged into and removed from a power socket. If the charger does not work properly (e.g. it gets too hot, makes a lot of noise, starts to smoke and/or smells bad), immediately remove the plug from the power socket as a precaution.

⚠ CAUTION

REPLACE both the device and the charger at the end of their intended lifespan (2 years). The performance of the device and the electronics is liable to deteriorate after that time.

⚠ CAUTION

Do not use any accessories, removable parts, or materials other than those described in these instructions for use.

Safety - Warnings and precautions for use

The viQtor application (app)

⚠ **CAUTION**

To use the viQtor app on an Apple iPhone, the iOS 12 operating system (or a newer operating system) and a screen resolution of 1334 x 768 pixels or higher are required.

⚠ **CAUTION**

Use of the viQtor solution on a PC or cell phone may involve previously unidentified risks for clients/patients, users, or others. For example, other software may be influenced by the installation and/or use of the viQtor solution.

Any change in the computer environment (cell phone, PC, network, internet connection) may introduce new risks. Consideration must be given to the potential risks associated with at least the following types of change:

- Changes to the network or internet connection configuration used.
- The installation, upgrading and/or removal of hardware, software platforms or software applications.

The healthcare organization should identify, analyze, evaluate, and manage such risks.

⚠ **CAUTION**

In the event of software and/or hardware changes, make sure that the changes do not interfere with the functionality of the viQtor solution. If you can successfully log in to the platform and/or the App, the viQtor solution is functioning properly.

⚠ **CAUTION**

Clients/patients cannot be monitored, and assistance requests cannot be processed if the internet connection is interrupted, insufficient band- width is available, or adverse changes are made to the network to which the device is connected. To minimize the impact of an internet connection outage, make sure that a failover internet connection is available (e.g. a mobile internet access point) and ensure that the phone number of the Technical Help Desk is written down near to the PC monitor.

The viQtor platform

⚠ CAUTION

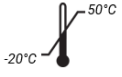
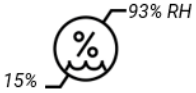
An ordinary PC can be used to view the platform, providing that it meets the following requirements:

- A screen resolution of 1366 x 768 pixels or higher must be supported.
- The Chrome web browser, version 97 or higher, must be supported.

⚠ CAUTION

If the system detects a security problem affecting your environment, the viQtor solution's server connection may be briefly interrupted for the installation of patches and updates, or for resolution of the security problem by other means. While the server connection is disabled, events will not be processed, and its client/patient-related data. The trend data and event data will be stored temporarily on the viQtor device, and event and data communication will resume as soon as the server connection is restored.

Symbols – viQtor box

Symbol	Meaning		Symbol	Meaning		Symbol	Meaning
viQtor	Model name		MD	Medical device			Temperature
UDI	UDI in Data Matrix (unique device ID)			Consult the instructions for use			Humidity
SN	Serial number			Separated collection of electrical and electronic equipment			Do not use if the packaging is damaged

Symbols – viQtor Device

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Caution		Serial number		Non-ionizing electromagnetic radiation
	Manufacturer's contact details		Medical device		FCC ID For USA only
	UDI in Data Matrix (unique device ID)		Classification Type BF Applied Part		Separated collection of electrical and electronic equipment
viQtor 	Model name USA requirement		Class II device USA requirement	**IP66**	IP classification
	Consult the instructions for use		MR unsafe USA requirement	CE 1912	The CE mark and the registration number of the notified body indicate that the device meets all the essential requirements of European Medical Device Regulation (EU) 2017/745
℞ ONLY	Prescription only USA requirement		Protect the product against moisture. USA requirement		

Symbols – Charger

Symbol	Meaning		Symbol	Meaning		Symbol	Meaning
	Manufacturer's contact details			Caution			Non-ionizing electromagnetic radiation USA requirement
viQtor Charger REF	Model name USA requirement			Consult the instructions for use		℞ ONLY	Prescription only USA requirement
UDI	UDI in Data Matrix (unique device ID)		CE 1912	The CE mark and the registration number of the notified body indicate that the device meets all the essential requirements of European Medical Device Regulation (EU) 2017/745		⎓	Direct current capacity
MD	Medical device			Separated collection of electrical and electronic equipment		**A**	Power supply
LOT	Batch number		**IP21**	IP classification		**W**	Maximum power

Symbols – Armband

Symbol	Meaning		Symbol	Meaning
	Manufacturer's contact details			Do not tumble dry
viQtor Armband	Model name			Do not iron
	UDI in Data Matrix (unique device ID)			Do not dry clean
	Medical device			Do not bleach
	The CE mark for a class 1 accessory			Wash at 30° C

Regulatory Information

Data privacy and security

smartQare provides customers with a secure digital platform and mobile app. The platform and app give secure electronic access to your recorded data, exclusively for you and – with your consent – your healthcare professional.

smartQare takes reasonable organizational, technical, and administrative steps to secure personal data within the organization. Unfortunately, however, no data transfer or storage system is ever 100% secure. Even the best technical security system can be bypassed, particularly if you do not protect your user ID and platform access password. If you have reason to believe that your interaction with us is no longer secure, you should inform us immediately.

Electromagnetic Compatibility (EMC)

The device is designed for use in an electromagnetic environment as described below. The customer or user should check that the environment in which the device is used is as described.

The device requires special precautions with regard to EMC, in accordance with the EMC information in this section. EMC tests performed in accordance with IEC 60601-1-2 and IEC 60601-1-11 are representative for the device function.

Radio frequency transmission

Bands used for communication: 3, 8 and 20(For NB-IoT [LTE Cat NB1] and LTE-M [LTE CAT M1])

Maximum transmitted radiofrequency power: Class 3 (23 dBm).

Specific Absorption Rate (SAR): 0,49 W/kg.

Bands used: 3, 8 and 20 with both NB-IoT and LTE-M technology. Effective radiated power: 25.4 dBm.

Technical documentation

Technical specifications: electronics

Specification	Device (viQtor)	Charger	Adapter
Weight	100 grams	Not applicable	Not applicable
Dimensions	94 x 55 x 21 mm	111.1 x 71.1 x 33.9 mm	Not applicable
IP classification	IP66	IP21	None
Input voltage	3.7 V	5V	100 - 240 Volt AC
Input frequency	Not applicable *	DC	50 - 60 Hz
Rated power consumption	Not applicable	2A max.	0.6 A max.
Typical power consumption	5 - 45 mA	Not applicable	Not applicable
Fuses	Internal, non-replaceable	Internal, non-replaceable	Not applicable
Operation	Continuous	Continuous	Continuous
IEC 60601-1 classification	Class II	Class II	Not applicable
Applied Part Type	BF	Not applicable	Not applicable
Communication	LTE/NB-IoT bands 3, 8 and 20	Not applicable	Not applicable
Wireless charging protocol	Wireless charging: inductive 127.7 kHz	Wireless charging: inductive 127.7 kHz	Not applicable

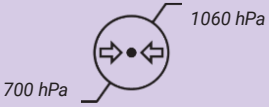
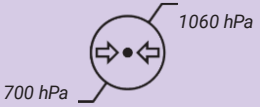
Technical documentation

Technical specifications: electronics

Specifications	Device (viQtor)	Charger	Adapter
Effective radiated power	25.4 dBm	8W	Not applicable
Optical characteristics* * for more info: support@smartqare.nl	LED for SpO2 and pulse rate measurement: Peak wavelengths: 526 nm, 660 nm, 950 nm. Maximum optical output power : green LED: 44 mW, red LED: 60 mW, infra red LED: 50 mW Exempt group under IEC 62471:2006 en IEC 60601-2-57:2011	Not applicable	Not applicable
Battery	Capacity:1500 mAh Type: Li-Ion polymer Rated voltage 3.7V non-replaceable	Not applicable	Not applicable
Normal lifespan	2 years	2 years	2 years

Technical documentation

Environmental conditions: electronics

Condition	Device (viQtor)	Charger	Adapter
Temperature when device is operating.	 Between 5° and 35° Celsius	 Between 5° and 30° Celsius	 Between 0° and 40° Celsius
Storage temperature	 Between -20° and 50° Celsius	 Between -20° and 50° Celsius	 Between -20° and 50° Celsius
Humidity	 15-93%, non-condensing	 15-93%, non-condensing	 15-93%, non-condensing
Ambient pressure	 700 until 1060 hPa	 700 until 1060 hPa	 700 until 1060 hPa
Maximum altitude	3000 m	3000 m	3000 m

Biocompatibility

smartQare system component	Parts in prolonged contact with the user	Material	Biocompatibility
Device (viQtor)	Housing (front)	TPE-E – Arnitel EL150 Shore A80 + 35HT-MAB SE 71471 MABS Terlux HD2802	Available on request
Device (viQtor)	Protective cover sensors	MABS Terlux HD2802 + 3% HT – MAB ABS 92022 LSA	Available on request
Device (viQtor)	Metal temperature sensor cover	Stainless steel	Available on request
Armband	Fabric	Polyester and lycra, or silicone	Available on request
Charger	Not applicable	Not applicable	Not applicable
Adapter	Not applicable	Not applicable	Not applicable

Technical documentation

Measurement accuracy and range

Sensor/function	Range	Resolution	Accuracy
Oxygen saturation (SpO2)	0% to 100%	0.1%	Between 70%-100% ≤ 2% ARMS[1,3]. 0%-70% SpO2: undefined.
Skin temperature	20°C to 42.5 °C	0.1 °C	≤ ±1°C RMSE[2]
Respiratory Rate	5 to 40 breaths per minute	1 BRPM[8]	±3 BRPM[3]
Pulse rate	30 to 240 beats per minute	1 beat per minute	≤ 3 RMSE[2,3]
(Hard) Fall detection	Not applicable	Not applicable	Sensitivity ≥ 95%[4] Accuracy ≥ 95%[4]
Activity monitoring	0 to 5 indicates broadly: [0] no movement at all to [2] slow movement to [4] active movement and [5] very active movement.	0.1	≤ 1.5 RMSE[2]
Geolocation [5]	Not applicable	Not applicable, location is shown on map	≤ 20m in clear open environment
Wear detection [6]	Not applicable	Not applicable	Normal usage: 100% Heavy motion: 58%[7]

Measurement accuracy and range

Explanation of footnotes of measurement accuracy and range of the page 51:

[1] Accuracy root mean square (ARMS) is a statistical expression of the deviation between device measurements and reference measurements. Roughly two thirds of the device measurements fell within +/- ARMS of the reference measurements in a controlled study.

[2] RMSE indicates Root Mean Square Error.

[3] Excluding motion conditions.

[4] Hard fall conditions involve uninterrupted falls with a fall distance of > 100 cm. Accuracy determined by a performance study under laboratory conditions.

[5] Using Global Navigation Satellite System (GNSS).

[6] Detection of whether the viQtor device is being worn.

[7] During vigorous and intensive exercise, wearing detection will be less accurate. Such exercise conditions are rarely prolonged and are corrected once intensive exercise stops.

[8] Breaths per minute (BRPM)

Early Warning Score (EWS)

The Early Warning Score (EWS) is a clinical decision support tool used to quickly assess the health status or deterioration of a disease/condition in a patient. It is based on physiological data, such as blood pressure, heart rate, breathing rate, oxygen saturation (SpO2) and temperature. Observational data, such as level of consciousness, are also often included.

There are several variants of the EWS in use, such as the Modified Early Warning Score (MEWS) or the National Early Warning Score (NEWS & NEWS2). Depending on the variant of the EWS, it is based on a series of 5 to 7 vital functions. The EWS or MEWS/NEWS is usually measured in a general department in the hospital at 3 times a day (every 4 or 8 hours), depending on the patient's status/condition and the standard care of the healthcare organization.

viQtor has a continuous Early Warning Score (cEWS), an adjustable Early Warning Score of the three (3) vital measurements and is calculated (semi-) continuously.
cEWS has the following input data:

- *Oxygen saturation (SpO2)*
- *Heartbeat*
- *Breathing rate*

The threshold values for warning based on measured vital signs and cEWS can be set and adjusted for each client/patient (taking into account gender, age and disease(s)).

Setting these alert thresholds can only be done by a healthcare facility or healthcare provider.

The platform will then be able to calculate the cEWS based on the following set of measurements:

- *Oxygen saturation (SpO2)*
- *Heartbeat*
- *Breathing rate*

Device active status

Device status	Active measurements/functions
The device is being worn	All measurements and functions are active
The device is not being worn	The large button can be used for assistance requests, no other measurements/functions are active.
The device is charging	The large button can be used for assistance requests, no other measurements/functions are active
The device is in energy-saving mode	The large button can be used for assistance requests, no other measurements/functions are active
The device is fully shut down	No functions active. This status occurs only if the battery is entirely empty or if the device has been deactivated by the healthcare organization
Assistance request mode (monitoring device activation)	All measurements and functions are active, except for the assistance button
Update mode	No functions active while update is in progress

Electromagnetic immunity

Phenomenon	Standard usage	Compliance level
Electrostatic discharge (ESD)	IEC 61000-4-2	≈2 kV, ≈4 kV contact ≈2 kV, ≈4 kV, ≈8 kV, ≈15 kV air
Immunity to radiant radio frequency (RF) electromagnetic fields	IEC 61000-4-3	10 V/m 80 mHz – 2,7 gHz 80 % AM at 1 kHz
Nearby RF communications equipment fields	IEC 61000-4-3	See table below
Immunity to electrical rapid transients/rapid peaks	IEC 61000-4-4	AC power port: ± 2 kV at 100 kHz DC power port: ± 2 kV at 100 kHz SIPS/SOPS: ± 1 kV at 100 KHz
Immunity to peaks (alternating current input port and direct current input port)	IEC 61000-4-5	Pulses:1.2/50 µs V; 8/20 µs A Line to line: ≈0.5 kV; ≈1.0 kV; Line to earth: ≈0.5 kV; ≈1.0 kV;≈2.0 kV;
Immunity to conducted disturbances caused by RF fields	IEC 61000-4-6	3 / 6 Vrms 150 kHz – 80 mHz 80 % AM at 1 kHz
Radiated power frequency of magnetic fields	IEC 61000-4-8	30 A/m 50 Hz of 60 Hz
Immunity to voltage dips	IEC 61000-4-11	Unom - 100% for 0.5 cycle (1 phase) Unom - 100% for 1 cycle Unom - 30% for 25/30 cycle (50/60 Hz)
Immunity to interruptions	IEC 61000-4-11	Unom - 100% for 250/300 cycles (50/60 Hz)

Frequency Range and Level: RF wireless communication equipment

Frequency (MHz)	Modulation	Immunity level (V/m)
Test	**Compliance level**	
80-1000 MHz	80% AM (1 kHz)	10 V/m
1000-2700 MHz	80% AM (1 kHz)	10 V/m
385	Pulse modulation:18Hz	27
450	Pulse modulation:18Hz	28
710 / 745 / 780	Pulse modulation: 217Hz	9
810 / 870 / 930	Pulse modulation: 18Hz	28
1720 / 1845 / 1970	Pulse modulation: 217Hz	28
2450	Pulse modulation: 217Hz	28
5240 / 5500 / 5785	Pulse modulation: 217Hz	9

Electromagnetic emissions

Emission test	Compliance
Conducted interference voltage (RF emissions, CISPR 11) – device (viQtor)	Group 2 Class B
Electromagnetic radiation interference (CISPR 11, <30 MHz) – device (viQtor)	Group 2 Class B
Radiated electromagnetic interference (CISPR 11, 30-1,000 MHz) – device (viQtor)	Group 1 Class B
Harmonic emissions (IEC 61000-3-2) – charger/power supply	Class A
Voltage fluctuations/flicker emissions – charger/power supply (IEC 61000-3-3)	Max change in voltage: ≤4%

Warranty

If you need to return the viQtor device for repair, all its components should be placed in their original packaging.

smartQare BV gives a two-year warranty on the device and the charger.

During the warranty period, smartQare or the reseller will repair or replace the device. Evidence of damage and the original purchase invoice must be provided before the device can be repaired or replaced. This warranty supersedes all other locally applicable statutory guarantees.

If the product does not work satisfactorily, or if assistance or service is required, please contact smartQare via one of the channels detailed under 'Contact' on page 59.

The warranty does not cover the following:

- Normal wear and tear, which affects all parts, including the armband and the smartQare rechargeable battery.
- Damage or defects resulting from incorrect use of or repairs to the device, or failure to store the device such as described in these instructions for use (see also 'Intended purpose' and 'Warning and precautions').

Contact

Manufacturer: smartQare BV

Kapteynstraat 1
2201 BB Noordwijk
The Netherlands

www.smartqare.com
+31718893959

Please contact your local distributor for assistance or contact smartQare BV customer service at +31718893959 or send a message to support@smartqare.nl.

Product information

The unique identifier (UDI-DI) for this medical device (the viQtor monitoring device) is:

08720299572409

The unique identification code (UDI-DI) of this medical device for use for up to 7 days (the viQtor device) is:

08721008086002

Go to www.smartqare.nl for more information.

SQ1-100_IFU_wearable_(ENG)
System version 2.0

Date of issue: 07-Dec-2023
Version 7.0

Frequently Asked Questions

1. Can I wear the monitoring device in the shower?
The device is splash resistant. So, you can wear it in the shower, but not while swimming.

2. If I press the big button, who sees my message?
The device will send the assistance request to the monitoring center. Someone at the center will contact you immediately. The wearer assigned to you by your healthcare organization will also be informed.

3. What happens if my pulse rate is too high?
The device will send an assistance request to the monitoring center or to your healthcare organization. That will happen without you being aware of it. If the heart rate measurement gives cause for concern, someone from the monitoring center or healthcare organization will contact you.

4. What is the best place to place the charger?
The charger needs to be somewhere dry, near to a power socket. Never put the charger in a damp environment, such as a bathroom or kitchen.

5. How often should I charge the device?
We recommend charging the device for at least half an hour to an hour every day. The best time to charge the device is during the daytime, while someone else is with you. See pages 18, 19 and 21.

6. How long does it take to charge the battery?
If the battery is completely empty, it takes about four and a half hours to fully charge it. See page 18 & 19.

7. How do I know the device is working properly?
You can tell whether the sensors on the back of the device are activated by checking whether the lights are on. The battery status can be checked by pressing the small button. You or your informal caregiver can also look at the app to see whether it is showing any measurements. See page 19.

Frequently Asked Questions

8. How can I clean the device?
You can clean the device using a damp cloth and possibly a cleaning agent. See pages 24 and 25.

9. Can I turn the device on and off?
The device can't be switched on or off manually. The device powers up automatically if the battery is charged. You don't need to switch it on. The device will go off only if the battery is completely empty.

10. What is the small button for?
The small button is for checking the battery status. See page 19.

11. Will my data be saved securely?
Your data will be protected in accordance with the General Data Protection Regulation (GDPR). See page 5 and 46.

12. What does the LED light mean?
The LED light can change color. The different colors have different meanings. For example, red means an assistance request has been sent, while green means everything is fin. See pages 13, 14, 19, 20, 21, 22 , 23 and 51.

13. Should I wear the device on the left or right arm?
You can wear the device on either upper arm. See page 17.

14. Is the charger waterproof?
No, only the monitoring device is splash proof.

All rights reserved

This device is subject to the EU Directive 2012/19/EU (WEEE).

The viQtor solution is loaned to you. If you decide to stop using the viQtor solution, you should return the device, including all its accessories, to your healthcare organization or to smartQare. For more detailed information, please contact smartQare BV.

Copyright notice

Notes

Notes


smartQare
24/7 REMOTE PATIENT MONITORING