

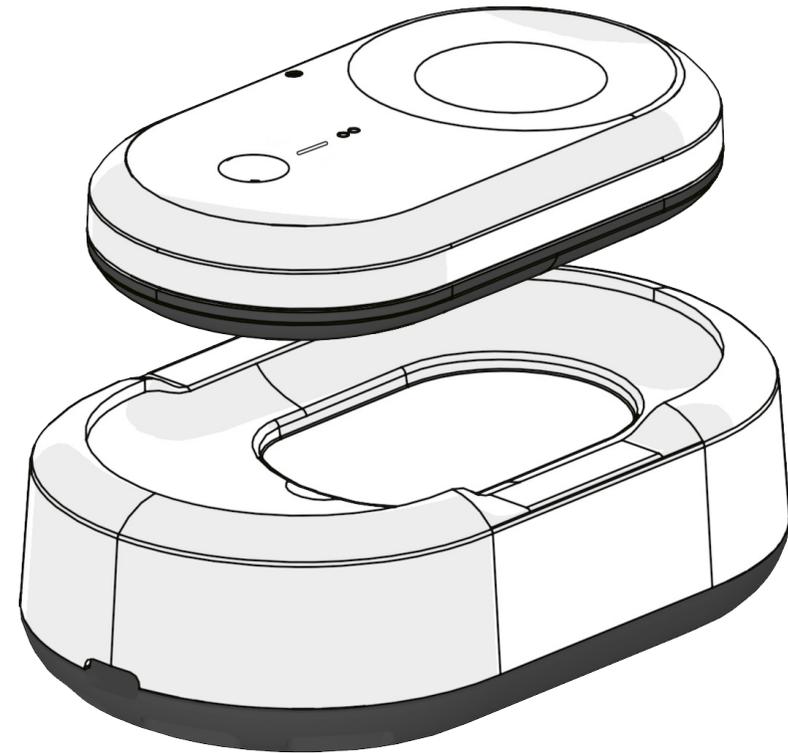
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# viQtor

24/7 (home) monitoring solution

## User manual

for the user of the viQtor wearable  
monitoring device



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## EU Declaration of Conformity

smartQare BV hereby declares that the radio equipment type sQ1 (viQtor) and 001 (viQtor charger) comply with Directive 2014/53/EU and EU MDR 2017/745.

The full text of the EU Declaration of Conformity is available at <https://www.smartqare.com>

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# Introduction

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Congratulations! You are about to start using your device. To ensure that the viQtor solution works optimally and safely for you, it is important that you first read this user manual carefully. You can do this yourself or together with your caregiver. If you are unsure whether this solution is suitable for you, contact your healthcare facility or physician.

You can also contact our customer service at [support@smartqare.com](mailto:support@smartqare.com) or via the website: [www.smartqare.com/contact](http://www.smartqare.com/contact) (see page 59).

viQtor is a medical device that is worn on the upper arm. It is equipped with smart sensor technology to continuously measure vital body functions

such as heart rate, oxygen saturation and skin temperature. The smartQare total monitoring solution consists of a smart, wearable device (viQtor), the monitoring platform for tracking vital signs and activities and mobile applications (viQtor apps).

Measurement values are transmitted wirelessly 24/7 to the monitoring platform, hereinafter also called the viQtor portal. Data are securely stored (pseudonymised) in accordance with the GDPR (General Data Protection Regulation) standard and are available in near-real-time web dashboards for healthcare professionals to perform trend analyses to support care.



## **WARNING:**

*To use this medical device correctly, read this manual carefully and follow the instructions.*

# Introduction

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The medical monitoring device includes a personal assistance button, (hard) fall detection and activity monitoring. The (outdoor) location is transmitted in case something happens and is provided by GNSS (including GPS and Galileo, the European Global Navigation Satellite System of the European Space Agency).

**This manual provides the information needed to operate and use the wearable viQtor monitoring device and charger. If you are a user of the mobile application, you are also required to understand the manual and the installation process of the mobile application before using the device.**

The wearable viQtor monitoring device is part of the viQtor solution. The following parts of the solution are relevant for the different users:

- For the user: the viQtor wearable monitoring device and (optionally) the viQtor app.
- For the informal caregiver: the viQtor app.
- For the healthcare professional: the viQtor portal and the viQtor app.
- For the monitoring centre staff: the viQtor portal.
- For the administration of the care organisation: the viQtor portal.

Each component of the viQtor solution has its own specific operating instructions. If applicable to you, also consult the other user manual(s).

# Introduction

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Various training modules are available for the training of the staff of care organisations / monitoring centres:

- For the administration of a care organisation:
  - Use of the portal for the administration of the care organisation.
  
- For healthcare professionals:
  - Use of the app and the portal for healthcare professionals;
  - Onboarding of patients and informal caregivers.
  
- For monitoring centre staff:
  - Use of the portal for employees of the monitoring centre;
  - Onboarding of patients and informal caregivers.

Ensure that all staff who will be using the viQtor solution have completed the relevant training courses. This can be done by contacting smartQare.

## Intended use

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The viQtor solution is intended for monitoring adult patients in professional healthcare facilities, such as hospitals or nursing homes, or in their home environment. It is intended for monitoring of patients by trained healthcare professionals

The viQtor solution is intended for continuous monitoring of the following parameters in adults:

	Parameter	Measurement
1	Oxygen saturation (SpO2 in %)	Continuously measured and sent every 5 minutes
2	Pulse (in beats per minute)	Continuously measured and sent every 5 minutes
3	Skin temperature (in °C)	Continuously measured and sent every 5 minutes
4	Activity	Continuously measured and sent every 5 minutes
5	Fall detection	Detection of a possible fall, sends a help request to the care organisation
6	Personal assistance button	Can be activated manually by the user and sends an alert to the care organisation

# Intended use

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The viQtor solution is not intended to detect acute life-threatening situations and is not intended for use in high-intensity care environments such as intensive care units or operating theatres. The viQtor solution is not intended for use in acutely ill (cardiac) patients with the potential to develop life-threatening deteriorations, such as arrhythmias or very fast atrial fibrillation. These patients must be monitored using a device with continuous ECG. The viQtor solution is not a substitute for an ECG monitor.

viQtor can detect a possible fall. In case of a possible fall, the device sends an alert to the professional care organisation. The user also has the option of sending a help request to the professional care organisation by pressing the help button.

## Intended users

The intended users of the wearable monitoring device of the viQtor solution are:

- Patients - Adults who require monitoring or who would benefit from continuous monitoring.

The intended users of the vital signs and activities monitoring platform/portal of the viQtor solution are:

- Care organisations - The care organisation is responsible for providing medical care to patients and remotely monitors the health and well-being of patients;

# Intended use

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- Monitoring centre staff - Staff members of the care organisation who monitor a group of patients remotely;
- Healthcare professionals - Professional care workers (with or without medical training) of the care organisation who are associated with the patients as a caregiver.

The intended users of the mobile app of the viQtor solution are:

- Healthcare professionals - Professional care workers (with or without medical training) of the care organisation who are associated with the patients as a caregiver;
- Informal caregivers - Family, neighbours and friends who are associated with the patients as informal caregivers;

- Patients (optional) - Adults being monitored.

## **Intended target group/intended population**

- Patients - Adults who require monitoring or who would benefit from continuous monitoring.

# Intended use

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## Intended users and required skills:

The smartQare solution is designed to communicate with the following groups users:

### The MAIN USER (patient)

The smartQare solution has been developed for adults who are not in entirely good health, e.g. who have one or more risk factors as determined by care workers.

Typical examples:

- Independent living (vulnerable) senior citizens;
- Adults with one or more chronic diseases;
- Adults living in a rehabilitation centre, sheltered accommodation or in a care institution and patients in a hospital.

## Required skills main user:

The main user must be familiar with the basic principles of the smartQare solution and be able to act accordingly, such as:

- Understanding the value of wearing the device;
- How to wear the device (proper positioning);
- How to put on and take off the device (if not done by a healthcare professional);
- How and when to charge the device;
- The meanings of the LED indicators and the vibrations and sounds the device makes;
- The value of wearing the device;

# Intended use

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- How to manually activate and cancel a help request;
- What to do if the appliance is damaged;
- How to clean the device;
- When the device should not be worn.

You will find this information in this manual. Your healthcare professional will guide you in the use of the viQtor solution.

## **The HEALTHCARE PROFESSIONAL (e.g. a doctor or nurse)**

A person trained to help or care for people.

## **Skills required by healthcare professionals:**

- All the skills required of the main user;
- Knowledge of the possible consequences (irritation/injury) of wearing the device incorrectly;
- The skills required to train the main user in the use of the viQtor solution;
- Checking that the device is correctly positioned on the upper arm and is working properly (generating measured values).

# Intended use

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## The MONITOR

- A person who can check the collected medical data of the user when a notification has been generated and take appropriate action.

### The required skills for a monitor:

- Training in the use of the viQtor portal;
- Ability to consider what action to take if a help request (alert) is received;
- The ability to contact the healthcare professional and/or informal caregivers.

## The INFORMAL CAREGIVER

Person with a personal relationship with the main user (selected by yourself, for example family,

friends or neighbours).

### Required skills informal caregiver / social circle:

- Having the smartQare app installed on a frequently used device (e.g. mobile phone);
- Understand the use of the smartQare app;
- Being able to help the main user in case of a notification or to call someone for this.

# Intended use

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## Clinical advantages of the viQtor solution

### In home care or nursing home care:

- Continuous monitoring of vital signs can lead to earlier detection of health deterioration and earlier intervention.
- Fall detection, alert button and GNSS positioning (GPS and Galileo) can lead to faster intervention after an incident (fall).
- Remote monitoring can increase the efficiency of home care.
- Remote monitoring can lead to longer independent living.

## For hospital-related care:

- Continuous monitoring of vital signs can lead to earlier detection of health deterioration and earlier intervention;
- Continuous monitoring of vital functions can lead to a reduction in the length of stay in the hospital;
- Remote monitoring can increase the efficiency of care provision.

# Contraindications

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- Do not use on neonatal or paediatric patients;
- Do not use if there is a known allergy to metals or plastics;
- Do not use in patients with significant deformity, swelling, irritation, degenerative changes or edema of the upper arm;
- Do not use the device in patients with localised infection, ulceration or skin lesions involving the upper arm;
- Do not use the device on an area with a tattoo, damaged skin and/or an arm or upper arm under medical treatment;
- Do not use the device on patients with restricted blood flow, e.g., tourniquet, pressure cuff or IV line;
- Do not use the device on the arm of a patient where the use of a blood pressure cuff is contraindicated;
- Do not use the device on patients with tremors or convulsions;
- Consult your physician before using the viQtor solution if you have any common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pregnancy, pre-eclampsia, or renal disease.

## NOTE

All of these conditions, in addition to movement, tremor or shaking of the patient, can affect the measurement value.

# Contraindications

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- viQtor cannot be used as a replacement for an ECG monitor;
- Do not use the device on a patient on cardio-pulmonary bypass;
- 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 in high frequency (HF) surgical equipment, MRI equipment or CT environment. This may result in incorrect operation of the device and/or inaccurate measurement;
- Never diagnose or treat yourself based on your measurements. ALWAYS consult your physician;
- Keep the charging cable away from babies, toddlers and children to avoid strangulation.

# Warnings and precautions for use



## **WARNING:**

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



## **CAUTION:**

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



## **WARNING**

Any serious incident involving the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is located.



## **WARNING**

smartQare's monitoring solution is designed for the purpose specified under 'Intended use' only. Observe all warnings and precautions in this manual and on the product labels.



## **WARNING**

Before using the monitoring device for the first time, verify that it operates correctly and continues to operate correctly when the user moves. Your healthcare professional can do this. If it does not work, or does not work properly, DO NOT USE it. Contact customer service.



## **WARNING**

Do NOT attempt to open or modify the monitoring device for any reason. This may only be done by qualified technical personnel.

# Warnings and precautions for use

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## **WARNING**

The monitoring device contains no user-serviceable parts. Opening or modifying any components may affect your warranty and cause short circuits and/or electrical shock.

## **WARNING**

Reduced availability and accuracy of SpO<sub>2</sub> and pulse rate measurements may be caused by:

- viQtor cannot be used as a replacement for an ECG monitor;
- Low arterial perfusion;
- High ambient light;
- Arm motion;
- Cardiovascular abnormalities;
- Darker pigmentation skin types;
- Elevated levels of COHb and/or MetHb;
- A blood pressure cuff is applied on the same arm as the device (viQtor);
- EMI radiation interference;

- Moisture, birthmarks, tattoos, applied skin coloring, skin discoloration or foreign objects or substances in the light path of the PPG sensor;
- Elevated levels of bilirubin;
- Hemoglobinopathies and synthesis disorders such as thalassemias, HbS, HbC, sickle cell disease, etc.

## **WARNING**

Skin temperature measurements will deteriorate under the following conditions:

- No contact between sensor and skin;
- Water between sensor and skin.

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

# Warnings and precautions for use

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Activity index is reduced under the following conditions:

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

 **WARNING**

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

 **WARNING**

Patients cannot be monitored, and attention requests are not processed when the Internet connection is interrupted, lacks bandwidth, or there is an adverse change in the connected Internet. To reduce the impact of no Internet connection, make sure a failover Internet connection is available (e.g., mobile Internet access point) and have the technical help

desk phone number on file at the monitor PC.

 **WARNING**

In the event that the system detects a security issue in your environment, the viQtor solution may be subject to temporary server connection failure to install patches and updates or to resolve the security issue in manners. During this server connection outage, events are not handled, and trend data or patient-related data cannot be accessed. The trend data and events will be temporarily stored on the viQtor device and event and data communication will be resumed once the server connection is restored.

# Warnings and precautions for use

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## **WARNING**

In the case of changes to software and/or hardware, make sure that the changes do not interfere with the functionality of the viQtor solution. If you can successfully log into the portal and/or the app, the viQtor solution functions properly.

## **WARNING**

Use of the viQtor solution on PCs or mobile phones may result in previously unidentified risks to patients, users or third parties. E.g. other software may be affected by the installation/use of the viQtor solution;

Any change in the computer environment (mobile phone, PC, network, Internet connection) may create new risks. The following changes should be considered in any case:

- Changes in the network or internet connection configuration used.
- Installation, upgrade and/or removal of hardware, software platforms or software applications.

The care organisation should identify, analyse, evaluate and manage these risks.

# Warnings and precautions for use

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## General

-  **CAUTION**  
Check the contents of the viQtor box. If any of these items are missing on arrival, contact Customer Service.
-  **CAUTION**  
Check the device, charger, mains adapter and armband for any damage when you receive the box with the equipment. Do NOT USE the device if any part is damaged. smartQare cannot guarantee that a damaged device is safe to use. In case of damage, contact customer service.
-  **CAUTION**  
Follow the instructions in the 'Getting Started' section to place the device correctly.

## The viQtor monitoring device

-  **CAUTION**  
Make sure you fully charge the device before use.
-  **CAUTION**  
The device may not be used alongside or stacked with other equipment. If it is necessary to use it in this way, the device must be observed to verify normal operation in the correct configuration.
-  **CAUTION**  
The device does not require time to start up before being used.

# Warnings and precautions for use

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-  **CAUTION**  
The device may feel hot after charging. Remove it from the charger and allow it to cool to a comfortable temperature for a few minutes before applying it to your upper arm.
-  **CAUTION**  
Make sure to place the device on the charger so that the raised edge on the back of the monitoring device falls into the cut-out on the charger. When positioned correctly, the device fits snugly onto the charger.
-  **CAUTION**  
For optimal performance, charge the device for at least 30 minutes to 1 hour each day. Ask your care organisation or family to help you choose a good time.
-  **CAUTION**  
The device CANNOT be switched off by the user. If you expect not to use it for a long period of time, contact your caregiver.
-  **CAUTION**  
If the device does switch off, the battery is empty. Place it on the charger and the device should turn itself back on. If not, contact customer service.
-  **CAUTION**  
If you notice that the device is not working properly: for example, it does not charge anymore, the LED sensors do not light up or the device gives no or too much feedback, contact customer service.

# Warnings and precautions for use

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 **CAUTION**  
NEVER connect anything to the device that is not specified in the manual, as this may damage the device. A damaged product cannot be guaranteed to work safely.

 **CAUTION**  
Check whether you can still press the help button on the device when wearing thick clothing over it (e.g. a jumper). Otherwise ask your healthcare professional for advice.

 **CAUTION**  
Make sure the back (with sensors) of the monitoring device is in direct contact with the skin. For example, if you put it on over a shirt or jumper, it will not work.

 **CAUTION**  
Do not place the device in a wet armband. If

you have showered with the device on your upper arm, change the wet armband for a dry one. Prolonged wearing of a wet armband can cause skin irritation.

 **CAUTION**  
Using the device or the total solution for unintended purposes may lead to incorrect results and clinical misinterpretations.

 **CAUTION**  
The device makes wireless contact with your Medical Service Centre or care institution via your mobile network. You will not notice this. Note that if you are in a location or area with poor network coverage, the device may be temporarily unavailable.

Check the mobile network provider website for the coverage map.

# Warnings and precautions for use

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 **CAUTION**  
The device is intended for single patient use. It is not to be used by anyone other than yourself.

 **CAUTION**  
Low skin temperature, restricted blood flow or excessive movement can lead to incorrect and/or missing readings.

 **CAUTION**  
The device may not be placed over a tattoo, otherwise the accuracy of the pulse rate measurement may be reduced.

 **CAUTION**  
The device may not be used on damaged skin.

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

 **CAUTION**  
The monitoring device must be used in temperatures between 5° en 35° Celsius.

 **CAUTION**  
The monitoring device may not operate properly below 5°C or above 35°C. It may transmit incorrect readings and the battery may not function properly.

## Warnings and precautions for use

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-  **CAUTION**  
Damage (other than slight traces of use) may occur if your device has been dropped. Always check the outside for cracks or other signs of damage from the fall. If so, **DO NOT USE** the device (it may no longer be waterproof). Please contact customer service.
-  **CAUTION**  
In order to prevent damage to the device, repairs and maintenance may only be carried out by authorised smartQare personnel.
-  **CAUTION**  
When the device is stored or subjected to environmental classifications outside of the operational specification, the device must acclimate for at least 1 hour before use to reach the specified operational conditions.
-  **CAUTION**  
The device must only be cleaned according to the instructions on page 41.
-  **CAUTION**  
**DO NOT USE** bleach (chlorine) or other aggressive cleaning agents. Avoid excessive amounts of liquid when cleaning the charger so that no liquid leaks into the device and this may damage the electronics.
-  **CAUTION**  
If a problem occurs: Solutions for possible problems are described in 'Troubleshooting' on page 43.

# Warnings and precautions for use

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## **CAUTION**

ESD and EMC radiation may affect the operation of the device.



## **CAUTION**

Wearable and mobile RF communications equipment, including antennas, can affect the operation of the device. NEVER use wearable or mobile RF communications equipment closer than 30 cm (12 inches) from the device, including cables specified by the manufacturer. Other equipment may interfere with the device, even if it complies with CISPR emission requirements.

# Warnings and precautions for use

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## The viQtor armband

-  **CAUTION**  
Use only the original armband supplied. A non-original armband may be the wrong size and the device will not measure properly. It may also cause irritation.
-  **CAUTION**  
If you have trouble putting on the armband, ask your caregiver to help you.
-  **CAUTION**  
An excessively loose or tight armband can affect the measurement results.
-  **CAUTION**  
The armband and charger are accessories for the viQtor wearable medical device.

-  **CAUTION**  
Make sure that the armband is not too loose. If it slips down when you move or sit still, it may not measure properly or not at all.
-  **CAUTION**  
The armband must press the device firmly against the skin, but it should not be too tight, as this may impede blood flow. If you find that the device is uncomfortable or causes a rash or irritation, remove it and inform your caregiver.
-  **CAUTION**  
Do NOT dry the armband in a tumble dryer. Do NOT iron the armband. Do NOT place the device in a wet armband.

# Warnings and precautions for use

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## The viQtor charger

 **CAUTION**  
Only use the supplied charger (both charging station and adaptor) to charge the device. Improper use of the charger may cause internal damage to the device. If you need a new charger, order one from customer service.

 **CAUTION**  
Only use the supplied charger and power adapter to charge the viQtor device, in order to prevent the battery from overheating or the battery circuit from being damaged.

 **CAUTION**  
Use the charger in temperatures between 5° and 30° Celsius. Charging the device is best done in a cool environment, not fully exposed to the sun or near a heating system.

 **CAUTION**  
Make sure that the power outlet you are using for charging provides the correct voltage, i.e. 100V and 240V AC. If the voltage is not within that range, you may damage the device.

 **CAUTION**  
Make sure that the charging cable adapter can be easily plugged in and out of a wall socket. If the charger is not working properly (e.g., too hot, too noisy, causing smoke and/or stench), as a precautionary measure, unplug it as soon as possible.

# Warnings and precautions for use

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## **CAUTION**

REPLACE both the device and charger at the end of their service life (after 2 years). The performance of the device and the electronics may deteriorate at the end of their service life.



## **CAUTION**

Only use accessories, detachable parts and materials as described in this user guide.

## The viQtor app



## **CAUTION**

To use the viQtor app, Apple iPhones must have a version of the operating system iOS 12 or newer and a screen resolution of 1334 x 768 pixels or higher.

## The viQtor portal

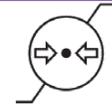


## **CAUTION**

General-purpose PCs can be used to view the web portal, but must:

1. Support a screen resolution of 1366 x 768 pixels or higher.
2. Be compatible with version 97 or higher of the Chrome web browser.

# Symbols

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Warning		Non-ionising electromagnetic radiation		Input voltage
	CAUTION		The CE mark and the registration number of the notified body indicate that the device complies with all essential requirements of the European Medical Device Regulation 93/42/EEC		Machine wash at 30° C
	Manufacturer's contact details		Separate collection for electrical and electronic equipment		Do not bleach
	UDI in Data Matrix (Unique Device ID)		IP classification		Do not tumble dry
	Refer to the user manual		Direct input power		Do not dry clean
	Serial number		Input current		Do not iron
	Medical device		Maximum power		Temperature
	Batch number				Humidity
	Classification Type BF Applied part				Ambient pressure

# Contents of the viQtor box

## Step 1: Check the contents of the box

Upon receipt, verify that the box contains:

1. User manual
2. The monitoring device (viQtor)
3. The armband (device accessory)
4. The charger
5. The mains adapter and power cable.

**⚠ CAUTION**  
If any of these items are missing upon arrival, contact Customer Service.

**⚠ CAUTION**  
Make sure you fully charge the device before use (page 32 step 2).

**⚠ CAUTION**  
The device does not require time to start up before being used.

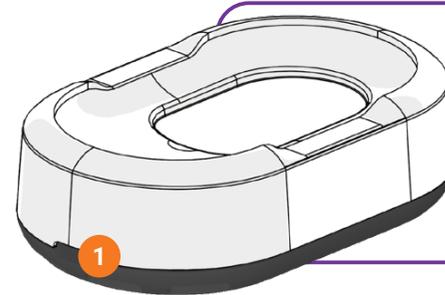


# Getting started



## The device - viQtor

1. Personal assistance button
2. LED



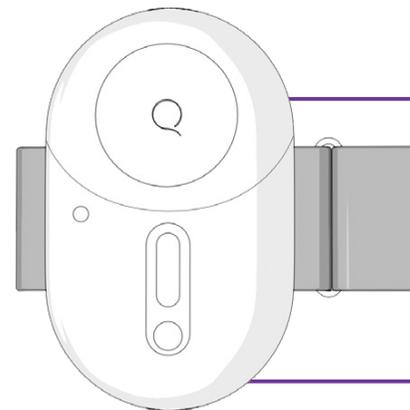
## Charger

1. USB-C input



## The charging cable and adapter

1. The power adapter
2. Power cable with USB-C connector

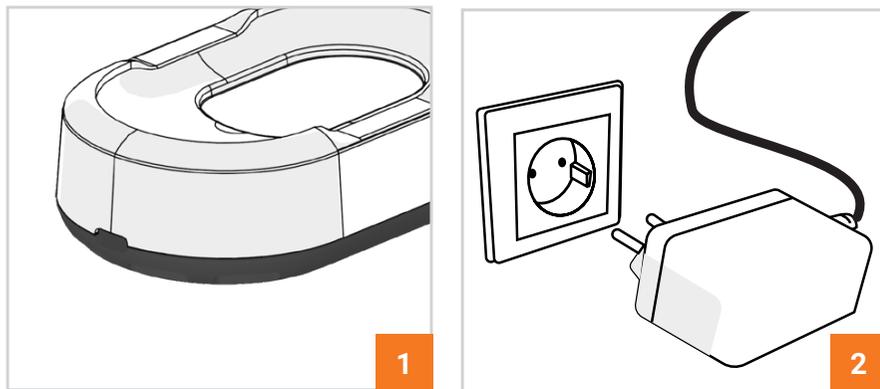


## Armband with device holder

# Getting started

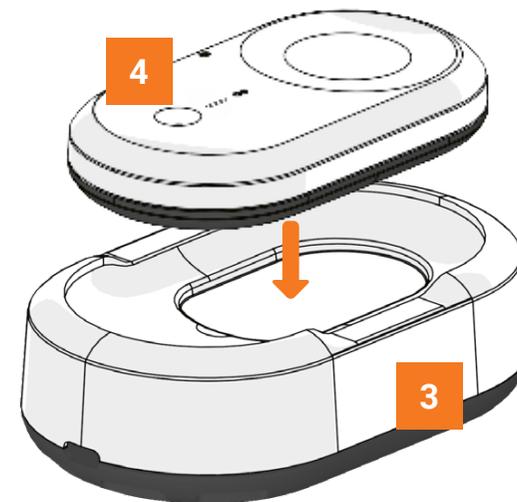
## Step 2: Installing the charger

1. Plug the power adapter cable into the back of the charger;
2. Plug the mains adapter into a standard socket (100-240V AC);
3. Place the device with the black side with LED sensors facing down on the charger;
4. While the device is charging, the LED flashes orange (if the battery is empty) or green (if the battery is more than 20% charged). The device is fully charged when the LED remains green.



## CAUTION

Make sure to place the device on the charger so that the raised edge on the back of the monitoring device falls into the cut-out on the charger. When positioned correctly, the device fits snugly onto the charger. The triangle on the back of viQtor is then on the side of the power cable and points to the power cable.



# Getting started

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## Step 3: Creating your account

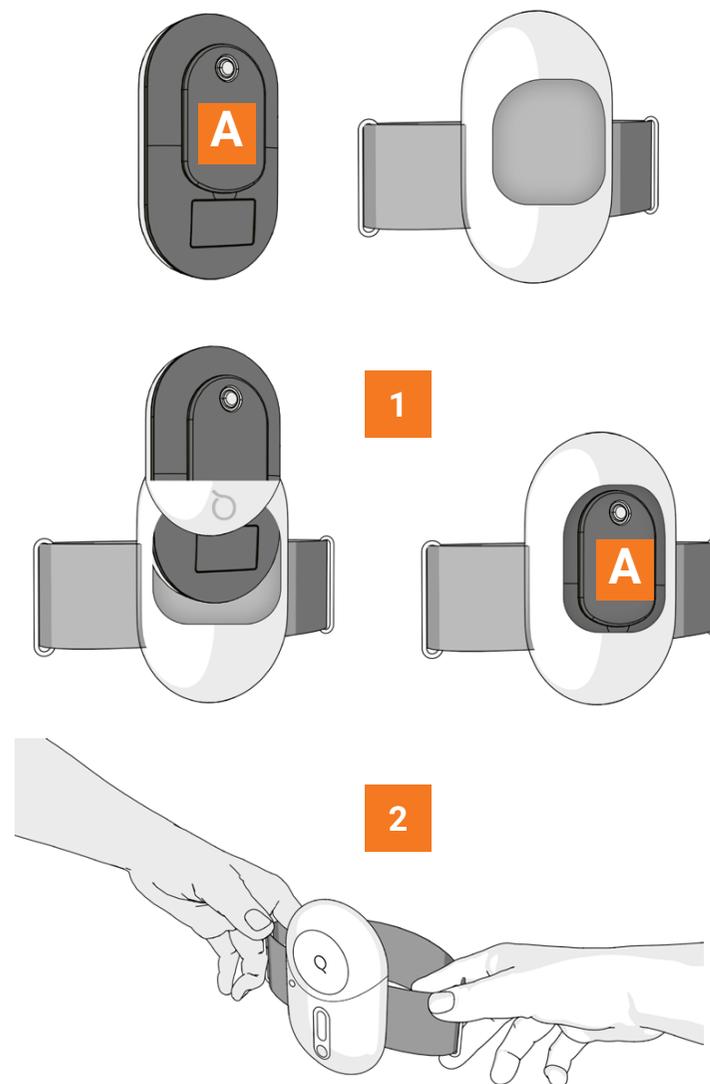
Ask your care giver or someone from the Social Care Circle to help you.

1. Contact the care organisation.
2. The care organisation creates the account.
3. Your care professional checks your data on the viQtor portal.

# Getting started

## Step 4: Inserting the device in the armband holder

1. Open the holder and slide the device into the armband holder. The arrow on the back of the device goes in first. In this way, the LED sensors (A) are visible through the opening of the holder
2. Pull the top (tab) of the holder over the device so that the device is fully seated in the holder. Turn the armband around and check whether the device's LED sensors are clearly visible through the opening of the holder.



# Getting started

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## Step 5: Place the armband with the device on the upper arm

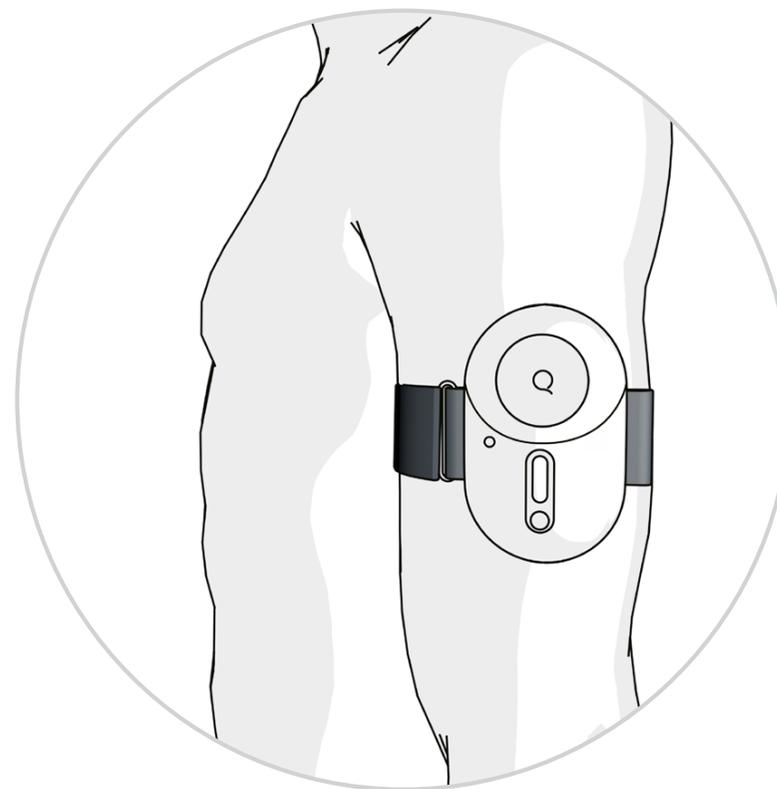
1. Thread the Velcro strap a little way through the buckle, but not too far, so that the armband has a wide circumference.
2. Move the armband with the device from the wrist to the upper arm. Pull the Velcro strap further through the buckle until it feels comfortable. Firmly press down the Velcro strap.

The armband is the correct size when it can be worn comfortably around the upper arm. The device and the armband do not move on the arm when the arm is moved.

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

## Step 6: Check your connection

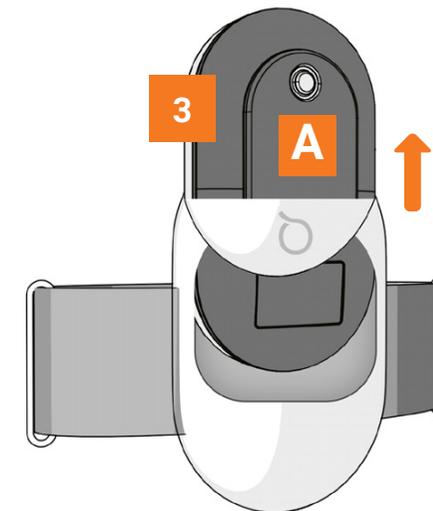
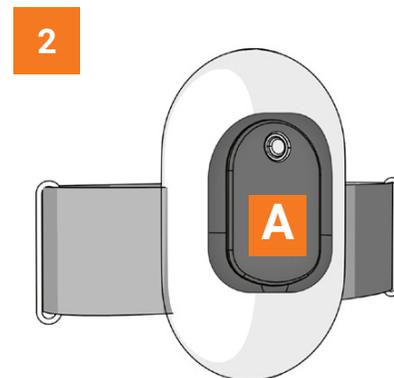
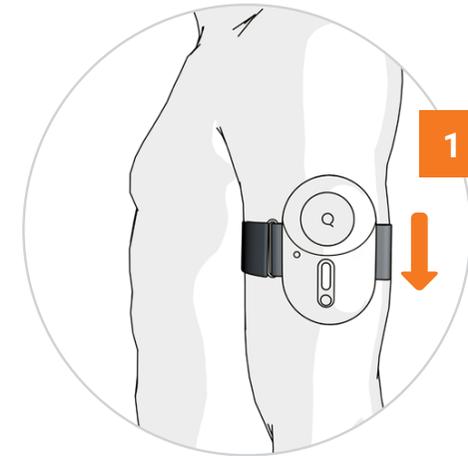
The healthcare professional will check via the app or the viQtor portal whether the device is working properly.



# Getting started

## Taking the device off and charging it

1. Loosen the Velcro strap and move it through the buckle so that it loosens.
2. Slide the armband with the device down the upper arm and over the wrist.
3. Pull the tab of the holder back over the device.
4. Slide the device out of the holder.
5. You can now charge the device as shown in step 2 on page 32.



# 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 will be green or orange. Green means that the battery is still sufficiently charged. Flashing green means that the device needs to be charged within 6 hours. Flashing orange means the battery is low. See section 'Battery Status Indications' on page 40 for more information.

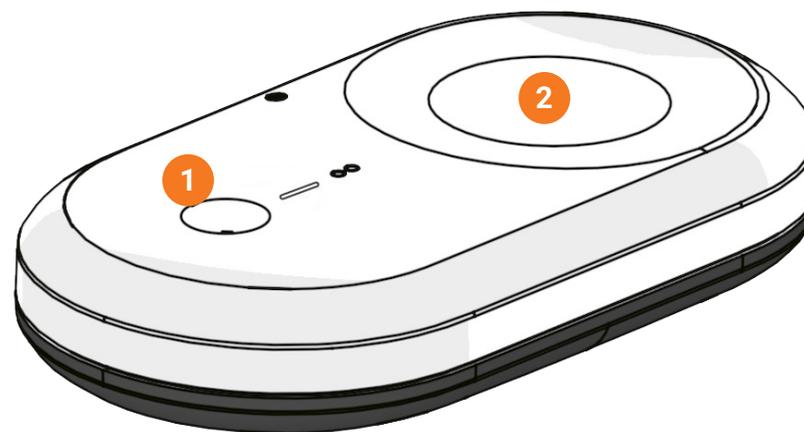
### Large button for activating and cancelling a help request. ②

Pressing the large button for 3 seconds immediately sends a help request to your Medical Service Centre.

In this case, the LED flashes red and the viQtor monitoring device vibrates and beeps for 40 seconds. This help request can be cancelled within 30 seconds by pressing the large button again for 3 seconds.

The red LED, the vibration function, and the beeper then go out.

If a fall is detected, the device automatically triggers the help request. Again, the LED will flash red and the device will vibrate and beep. You can also cancel the automatic help request in this case by pressing the large button for 3 seconds. The light, the vibration and the beeper will then go off and the help request is cancelled.



# Meaning of the viQtor signals (LEDs, vibration and audio)

## Main functions

SITUATION	ACTION	LED	VIBRATION	AUDIO
You want to manually activate an alert	Press large button for 3 seconds	LED flashes red for 40 seconds	Monitoring device vibrates for 40 seconds	Monitoring device beeps for 30 seconds (1x per second)
An alert for pulse rate or blood oxygen saturation has been automatically generated	None	None	None	None
A fall has been automatically detected and has generated an alert	None (unless you are OK and want to deactivate the alert)	LED flashes red for 40 seconds	Monitoring device vibrates for 40 seconds	Monitoring device beeps for 30 seconds (1x per second)
You want to cancel the alert (manually or automatically activated after a fall)	Press the big button again within 30 seconds before the beeping stops	LED flashes green for 15 seconds to confirm that the alert has been cancelled	Short vibrations to confirm that the alert has been cancelled	Alert stops beeping
Alert mode active - not cancelled	None the healthcare professional will contact you	LED flashes red continuously	Vibrates 2x per second for 15 seconds to confirm that help mode is active. Repeats every five minutes. Stops after 40 minutes	Alert beeps 5x per 2.5 seconds. Repeats every 5 minutes

## Meaning of the viQtor signals (LEDs, vibration and audio)

### Main functions

SITUATION	ACTION	LED	VIBRATION	AUDIO
The monitoring device has no communication with the viQtor portal during an alert	Call your healthcare professional	LED flashes purple for 15 seconds. 1x per minute for 5 minutes	Vibrates 4x per second for 15 seconds	High pitched beep 1x per second for 15 seconds
Battery is low	Soon place the monitoring device on the charger	LED will be orange for 2 hours	One short vibration every 5 minutes	3x 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
The viQtor monitoring device is turned off	This happens automatically when the battery is empty.	LED flashes white for 5 seconds	None	None
The viQtor monitoring device is turned on	This happens automatically when the battery is recharged or after a reset	LED flashes purple for 15 seconds	1x per second	1x 'welcome' beep
Software update in progress	None, starts and stops automatically	LED flashes purple until update is complete	None	None
Software update completed	None, starts and stops automatically	LED flashes purple for 15 seconds	1x per second	1x 'welcome' beep

## Meaning of the viQtor signals (LEDs, vibration and audio)

---

### Battery status

When the small button is pressed	
> 10%	Orange LED flashes (2 Hz)
> 20%	Green LED flashes (2 Hz)
> 50%	Green LED on

During charging	
> 0%	Orange LED flashes (0,5 Hz)
> 20%	Green LED flashes (0,5 Hz)
> 98%	Green LED on

# Cleaning and maintenance

---

## Charging

It is advised to charge the device at the same time every day. If you make a habit of charging it for at least 30 minutes every day, you will always have enough charge for use. See page 32 for charging instructions.

## Cleaning the device and charger

To avoid contamination, clean the device regularly with a damp, lint-free cloth (without any cleaning agent). If you also want to clean the charger, make sure you disconnect it from the power supply first by pulling the cable out of the charging station. You can then wipe the charging station with a damp, lint-free cloth. Do not forget to plug the cable back into the charging station.

If the monitoring device, the optical sensor on the bottom of the device or the charging station looks dirty and you cannot remove the dirt with a damp lint-free cloth alone, you can use a damp lint-free cloth with one of the following cleaning products:

- Soap solution
- Isopropyl alcohol (IPA 70%), also suitable for disinfection of the device
- Ethanol (96%), also suitable for disinfecting the device



## CAUTION

DO NOT use bleach (chlorine) or other aggressive cleaning agents. Avoid excessive amounts of liquid when cleaning the charger so that no liquid leaks into the device as this may damage the electronics.

# Cleaning and maintenance

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## Cleaning the armband

REMOVE the device from the armband before washing. Regularly wash the armband in the washing machine (e.g. once a week or when it looks dirty) at a maximum temperature of 30° with a mild detergent that does not contain bleach (chlorine) or fabric softener. Then hang the armband to dry on a clothesline.



### CAUTION

Do NOT dry the armband in a tumble dryer. Do NOT iron the armband. Do NOT place the device in a wet armband.

## Other serviceable components

The device and charger do not contain any user-serviceable components.

## End of use

The viQtor solution is given on loan to you. If you decide that you no longer wish to use the viQtor solution, you must return the monitoring device and its accessories to your care organisation or to smartQare.

Due to synchronization with the viQtor portal, the monitoring device may contain digital data that has not yet been transmitted. Ask your care organisation to disconnect the viQtor monitoring device from the viQtor portal. The data on the monitoring device is then deleted after synchronization

# Troubleshooting

Although the device has been manufactured with the greatest care, problems may occur. Below are some of the problems you may encounter and instructions on how to resolve them. If you encounter a problem not mentioned below, please contact customer service.

Problem	You can try the following
The device is not charging.	Make sure the charger power cable is properly connected to the power outlet and the charger itself. Make sure the monitoring device lies flat in the charger. The device has a unique shape and only fits properly in the charger one way. If it is placed correctly, the device will vibrate and beep once and the LED will be purple in color.
The web dashboard in the viQtor portal or the app displays a message indicating that the measurements are of poor quality.	Make sure the device and the armband are placed correctly on the upper arm. If necessary, you can perform a hard reset on the monitoring device by placing it on the charger and pressing and holding the (small) battery button for 15 seconds.
The device no longer works	Try charging the device first. If it is charged properly, see below
The device does not work even though it is fully charged	You can perform a hard reset on the monitoring device by placing it on the charger and pressing and holding the battery button for 15 seconds. If this also does not help, contact your care organisation or smartQare.

# Technical documentation

## Technical specifications: electronics

Specification	Device (viQtor)	Charger	Adapter
Weight	100 gram	N/A	N/A
Dimensions	94 x 55 x 21 mm	111.1 x 71.1 x 33.9 mm	N/A
IP classification	IP66	IP21	None
Input voltage	3.7 V	5V	100 - 240 Volt AC
Input frequency	N/A *	DC	50 - 60 Hz
Nominal usage	N/A	2A max.	0.6 A max.
Typical power	5 - 45 mA	N/A	N/A
Fuses	Internal, non-replaceable	Internal, non-replaceable	N/A
Operation	Continuous	Continuous	Continuous
IEC 60601-1 classification	Class II	Class II	N/A
Applied Part Type	BF	N/A	N/A
Communication	LTE/NB-IoT bands 3, 8 and 20	N/A	N/A
Wireless charging protocol	Wireless charging: inductive 127.7 kHz	Wireless charging: inductive 127.7 kHz	N/A
Effective radiated power	25.4 dBm	8W	N/A

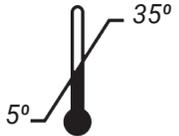
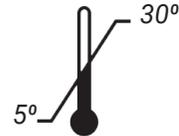
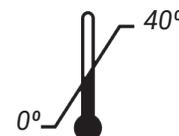
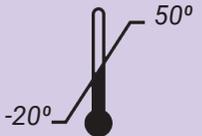
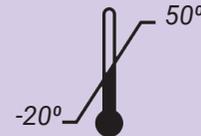
# Technical documentation

## Technical specifications: electronics

Specifications	Device (viQtor)	Charger	Adapter
Optical properties*  * for more info: <a href="mailto:support@smartqare.com">support@smartqare.com</a>	LED for SpO2 and pulse rate measurement:  Peak wavelengthse: 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	N/A	N/A
Battery	Capacity:1500 mAh Type: Li-Ion polymer Rated voltage 3.7V Non-replaceable	N/A	N/A
Normal lifespan	2 years	2 years	2 years

# Technical documentation

## Ambient conditions: electronics

Condition	Device (viQtor)	Charger	Adapter
Operating temperature	 <p>Between 5° and 35° Celsius</p>	 <p>Between 5° and 30° Celsius</p>	 <p>Between 0° and 40° Celsius</p>
Storage temperature	 <p>Between -20° and 50° Celsius</p>	 <p>Between -20° and 50° Celsius</p>	 <p>Between -20° and 50° Celsius</p>
Humidity	 <p>15 - 93%, non-condensing</p>	 <p>15 - 93%, non-condensing</p>	 <p>15 - 93%, non-condensing</p>
Ambient pressure	 <p>700 until 1060 hPa</p>	 <p>700 until 1060 hPa</p>	 <p>700 until 1060 hPa</p>
Maximum height	3000 m	3000 m	3000 m

# Technical documentation

## Biocompatibility

smartQare system component	Parts which are in long-term contact with user	Material	Biocompatibility
Device (viQtor)	Housing (outside)	M-ABS + TPE-E	Upon request available
	Protective cover sensors	M-ABS	Upon request available
	Metal cap of temperature sensor	Stainless steel	Upon request available
Armband	Fabrics	Polyester, polyamide, lycra, elastane	Upon request available
Charger	N/A	N/A	N/A
Adapter	N/A	N/A	N/A

# Technical documentation

## Measurement accuracy and range

Sensor/function	Range	Resolution	Accuracy
Oxygen saturation (SpO2)	0% to 100%	0.1%	Between 70%-100% $\leq 2\%$ relative to ARMS <sup>1,3</sup> . 0%-70% SpO2: undefined.
Skin temperature	20°C to 42.5 °C	0.1 °C	$\leq \pm 1$ °C RMSE <sup>2</sup>
Pulse rate	30 to 240 BPM	1 BPM	$\leq 3$ RMSE <sup>2,3</sup>
(Hard) fall detection	N/A	N/A	Sensitivity $\geq 95\%$ <sup>4</sup> Accuracy $\geq 95\%$ <sup>4</sup>
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	$\leq 1.5$ RMSE <sup>2</sup>
Location positioning <sup>5</sup>	N/A	N/A, location is shown on map	$\leq 20$ m in clear open field conditions
Wear detection <sup>6</sup>	N/A	N/A	Normal usage: 100% Heavy motion: 58% <sup>7</sup>

# Technical documentation

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## Measurement accuracy and range

*Explanation of footnotes of measurement accuracy and range on page 48:*

<sup>1</sup> Accuracy Root-Mean-Square (ARMS) is a statistical calculation of the difference between device measurements and reference measurements. About two-thirds of the device measurements fell within +/- ARMS of the reference measurements in a controlled study.

<sup>2</sup> RMSE indicates Root Mean Square Error;

<sup>3</sup> Without motion conditions;

<sup>4</sup> Hard fall conditions are continuous falls with a fall distance > 100 cm. Accuracy determined by a performance study in laboratory conditions;

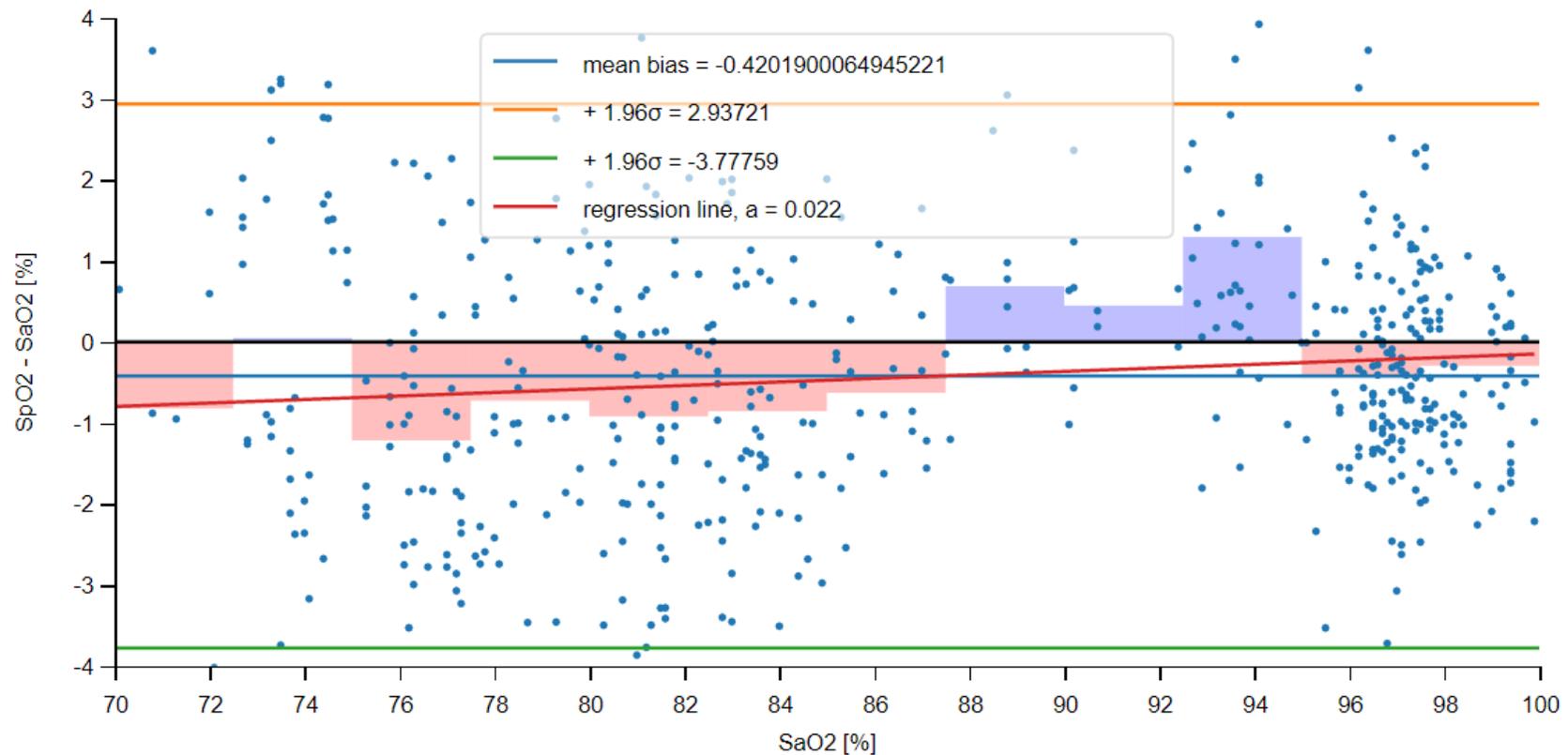
<sup>5</sup> Using Global Navigation Satellite System (GNSS);

<sup>6</sup> Detection whether the viQtor device is worn;

<sup>7</sup> The wearing detection will be less accurate in case of vigorous movement. Vigorous movement usually does not occur frequently for long periods of time and are corrected as soon as it stops.

# Technical documentation

The modified Bland Altman graphs below show the correlation of SpO2 and the reference Co-Oximeter (SaO2) in healthy adult subjects with an upper limit of 95% and a lower limit of 95%.



# Technical documentation

## Device active status

Device status	Active measurements/functions
The monitoring device is worn	All measurements and functions are active
The monitoring device is not worn	Only the large button for manual help requests is active
The monitoring device is charging	Only the large button for manual help requests is active
The monitoring device is in power saving mode	Only the large button for manual help requests is active
The monitoring device is completely off	No active functions. This is only the case if the battery is completely flat or the monitoring device has been deactivated by the care organisation
Attention request mode (monitoring device)	All measurements and functions are active, except to the help request button
Update mode	No active functions during update

# Regulatory Information

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## Data privacy and security

smartQare offers patients a secure web-based application (portal) and smartphone app. These offer secure electronic access to your registered data, to which only you and - with your permission - your healthcare professional has access.

smartQare makes every effort to take reasonable organisational, technical and administrative measures to protect personal data within the organisation. Unfortunately, no data transfer or storage system can ever be 100% safe. Even the best technical security system can be circumvented, especially if you do not protect your user ID and password for accessing the portal. If you have reason to believe that your interaction with us is no longer secure, let us know immediately.

## Electromagnetic Compatibility (EMC)

The device is designed for use in the electromagnetic environment as described in the following paragraphs. It is the patient or user's responsibility to ensure that it is used in such an environment.

The monitoring device requires special precautions regarding EMC in accordance with the EMC informati-

on in this section. EMC tests conducted in accordance with 60601-1-2 and 60601-1-11 are representative of 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 radio frequency 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

# 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
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 devices

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 disturbance (CISPR 11, <30 MHz) – device (viQtor)	Group 2 Class B
Radiated electromagnetic disturbances (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

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When returning the viQtor for repair, place all components in the original packaging.

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

smartQare or the reseller will repair or replace the device during the warranty period. Proof of damage and the original purchase receipt must be presented before repair or replacement can take place. This warranty supersedes all other local warranties as permitted under applicable law.

If the product is not operating satisfactorily, or if assistance or service is required, contact smartQare via one of the channels listed in the Contact section on page 59.

## **The warranty does not cover the following:**

- All parts are subject to normal wear and tear. This also applies to the armband and the smartQare rechargeable battery.
- Damage or defects resulting from improper use of or repairs to the device, or failure to store the device as described in this manual (see also the sections on 'Intended use' and 'Warnings and Precautions').

# Frequently Asked Questions

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## 1. Can I wear the monitoring device in the shower?

The monitoring device is splash proof. You can shower with it, but not swim.

## 2. If I press the big button, who sees my message?

The monitoring device sends the attention request to the Medical Service Centre. A staff member will contact you immediately. The person responsible of your care organisation will also be notified.

## 3. What happens if my pulse is too high?

The device will send a request for attention to your Medical Service Centre or care organisation. You will not notice this. If the measurement gives cause for concern, they will contact you.

## 4. What is the best place to place the charger?

The charger must be placed in a dry place near a wall socket. Never place the charger in a wet environment such as a bathroom or kitchen.

## 5. How often should I charge the device?

You are advised to charge the device for at least 30 minutes to 1 hour every day. It is best to charge

during the day when you have visitors. See pages 21 and 41.

## 6. How long does it take to charge the battery?

When the battery is completely empty, it takes about four and a half hours to fully charge it. For charging instructions see page 32.

## 7. How do I know the device is working properly?

You can check that the sensors on the back of the device are turned on (the lights are on). You can check the battery status by pressing the small button, and you or your informal caregiver can check in the app whether it is displaying the readings. See page 40.

## 8. How can I clean the device?

You can clean the device with a damp cloth, possibly with detergent. See pages 41, 42.

## 9. Can I turn the device on and off?

You cannot turn the device on and off manually. When the device battery is charged, it turns on automatically. You do not need to turn it on. The device

# Frequently Asked Questions

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will not turn off until the battery is completely exhausted.

## **10. What is the small button for?**

You can press the small button to check the battery status. See page 37.

## **11. Is my data kept safe?**

Your data is protected by the General Data Protection Regulation (GDPR). See pages 4 and 52.

## **12. What is the meaning of the LED?**

The LED can display different colours. For example, red is for a request for help, green indicates that everything is fine. See pages 31, 32, 37, 38, 39, 40, 43, 45.

## **13. Should I wear the device on the left or right arm?**

You can wear the device on either the right or left upper arm. See page 35.

## **14. Is the charger waterproof?**

No, only the monitoring device is splash proof. You can shower with it, but not swim.

# Contact

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## Manufacturer: smartQare BV



Kapteynstraat 1  
2201 BB Noordwijk  
The Netherlands

[www.smartqare.com](http://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.com](mailto:support@smartqare.com).

## Product information

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

**08720299572409**

Go to [www.smartqare.com](http://www.smartqare.com) for more information.

SQ1-100\_IFU\_wearable\_(ENG)\_v5.0

Date of issue: 20-NOV-2022

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

The viQtor solution is given on loan to you. If you decide that you no longer wish to use the viQtor solution, you must return the device and its accessories to your care organisation or smartQare. Contact smartQare BV for more detailed information.

## Copyright notice

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# Notes

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# Notes

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# Notes

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# smartQare

