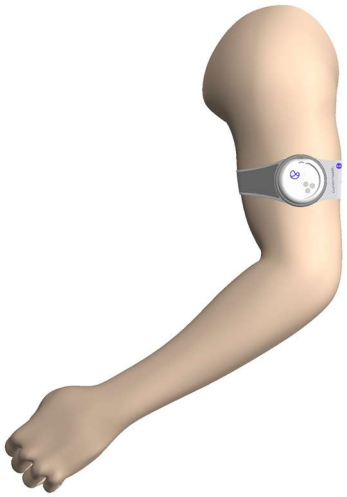
current health

# G2

# Instructions for Use



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CE
1639

www.currenthealth.com

200002/1

**WARNING: To properly use this medical device, read and comply with these instructions for use**

**WARNING: Current Health is intended for use by qualified medical personnel only**

*CAUTION: USA Federal Law restricts this device to sale by or on order of a physician.*



This device is subject to the EU Directive 2012/19/EU (WEEE). It is not registered for use in private households and may not be disposed of at municipal collection points for waste electrical and electronic equipment. Current Health Ltd has authorized a firm to dispose of this device in the proper manner. For more detailed information, please contact Current Health Ltd.

**Copyright Notice**

# Intended Use

The Current Wearable Health Monitoring System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals.

The Current Wearable Health Monitoring System is intended to provide visual and audible physiologic multi-parameter alarms. The Current Wearable Health Monitoring System is intended for temperature monitoring where monitoring skin temperature at the upper arm is clinically indicated.

The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters in adults:

- Pulse rate
- Oxygen saturation
- Skin Temperature
- Movement

The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring, in adults, of:

- Respiration rate
- Non-invasive blood pressure
- Lung function & spirometry
- Weight

The Current Wearable Health Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms.

The Current Wearable Health Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The Current Wearable Health Monitoring System is not a substitute for an ECG monitor.

The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.

# Documentation Features

## Warnings and Cautions

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

## Cross-References

Cross-references will specify the section or sub-section. For example, sub-section 2.1 or section 2.

## List of Symbols

| Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|
| | Warning/Caution | CE 1639 | The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC |
| | Manufacturer & Date of Manufacture | SN | Serial Number |
| LOT | Batch Code | | Separate Collection for Electric and Electronic Equipment |

| Symbol | Meaning |
|---|---|
|  | Catalog Number |
|  | Consult Instructions for Use |
|  | AC Current Input |
|  | Flammable if Damaged |
|  | IP Rating |
|  | Prescription Only |
|  | Non-ionizing electromagnetic radiation |

| Symbol | Meaning |
|---|---|
|  | Classification Type BF Applied Part |
|  | Fuse |
|  | Fragile |
|  | Batteries |
|  | Do not re-use Applies to the strap |
|  | Magnetic Resonance Unsafe |

## List of Abbreviations

| Abbreviation | Meaning |
|---|---|
| ECG | Electrocardiogram |
| EMC | Electromagnetic Compatibility |
| ICU | Intensive Care Unit |
| LED | Light Emitting Diode |
| RF | Radiofrequency |
| RPM | Respirations per Minute |
| SpO2 | Functional oxygen saturation |
| WEEE | Waste Electrical and Electronic Equipment |

# Safety Considerations

These Instructions for Use assume a working knowledge of vital signs monitoring. To support proper, safe, and accurate operation of equipment, read all operating instructions carefully before you use the monitor. Current Health should only be used by trained healthcare professionals.

**WARNING: To maintain patient safety, adhere to all WARNINGS and CAUTIONS listed in these Instructions for Use and on equipment labels**

**WARNING: No modification of the equipment is allowed. Modification of this equipment may cause interference with other devices, injury to patient and user including electric shock, burns or death**

**WARNING: A rapid recognition of alarms and an appropriate response are only possible if the user is in hearing range of the audible alarm signals. The user must stay within the hearing range of the audible alarm signal and adjust the volume according to the distance from acoustic alarm signal**

**WARNING: Ensure mobile device for receiving alarm signals has audio switched on and is at an appropriate volume**

**WARNING: Ensure mobile device for receiving alarm signals has WiFi or data connection**

# Site of Operation

Only use Current Health in areas that meet the environmental requirements outlined in the technical data section

**WARNING:**
**Do not operate the equipment in areas such as: magnetic resonance imaging (MRI) environments, aircraft, ambulance, home or hyperbaric chambers.**

**Do not operate the equipment in close proximity to equipment that emits microwave or other high-frequency emissions since they may interfere with the device's operation.**

**This equipment is neither approved nor certified for use in areas where oxygen concentrations are greater than 25% or where combustible or explosive gas mixtures are likely to occur.**

*CAUTION: To avoid short-circuiting or otherwise damaging the equipment, do not allow fluids to come in contact with the equipment. If fluids are accidentally spilled on the equipment, remove the affected unit from service as soon as possible and contact the manufacturer.*

*CAUTION: Read all cleaning instructions carefully before cleaning the equipment. Refer to the cleaning and disinfecting chapter of the instructions for use. Moisture may damage the circuits, compromise critical performance and/or present a safety risk.*

# Maintenance

Current Health equipment will be maintained by Current Health Service Staff only.

**WARNING: Risk of infection. Current Health technical staff can become infected with pathogenic germs. Disinfect and clean the equipment before returning the medical device for repair.**

**WARNING: Current-carrying components are located under the cover. Do not remove the cover. Maintenance measures must be performed by the manufacturer only.**

**WARNING: Repair of the device may only be carried out by the manufacturer otherwise the correct functioning of the device may be compromised.**

**WARNING: Risk of faulty components. Device failure is possible due to wear or material fatigue of the components. To maintain proper operation of all components, this equipment must undergo inspection at specified intervals.**

# Defibrillator Precautions

**WARNING: The wearable device and any other applied device parts should be removed before patient defibrillation**

# Medical Device Disposal

**WARNING: Risk of infection. The device and its components must be disinfected and cleaned before disposal**

**WARNING: The wearable device contains a lithium ion battery. Do not incinerate the device or place in a trash compactor. Do not puncture the battery.**

When disposing of the wearable device or charging dock, please return to Current Health and observe all applicable laws and regulations.

The return to Current Health will be arranged via the Current Health Support Center (see section 16).

This medical device is subject to the EU Directive 2012/19/EU (WEEE). It is not registered for use in private households, and may not be disposed of at municipal collection points for waste electrical and electronic equipment.

Current Health has authorized a firm to dispose of Current Health equipment in the proper manner. For more detailed information, please contact Current Health.

The strap is single use and should be disposed of in clinical waste after patient use.

# Cybersecurity

Current Health have taken significant steps to protect our system from cyberattacks, but the user has a crucial role in maintaining cybersecurity. The guidelines in this section must be followed.

Current Health's wearable device is connected to a network. No protected health information is stored within the wearable device, nor transmitted by the wearable device. Communications between the wearable device and the Current Health software platform are encrypted to an industry-standard. Moreover, the wearable device connects to a network over WPA2-PSK WiFi security.

Current Health's Patients App or Devices App can be installed on an iOS device running iOS version 13 or greater, or an Android device running Android version 8 (Oreo) or 9 (Pie). As Apple review every application before it is allowed on the Apple App Store, the iPhone is very resilient to cyberattacks. The Google Play store reviews applications for the Android platform. No protected health information is stored within the mobile device's local storage. All communications between the Patients App and Devices App and the Current Health software platform are encrypted to an industry-standard.

Current Health's platform is also accessible via the Google Chrome web browser. All communications between the Web Interface and the Current Health software platform are encrypted to an industry-standard.

The Homehub provided by Current Health for use in the home environment shall only be used by Current Health products and services. It cannot be used for, nor should it be used, for any other purpose, such as personal internet use.

## About password policies, password expiration and auto-logout

A combination of username and password are used to control access to the Current Health Patients App or Devices App.

It is the responsibility of the operating institution to apply the appropriate password policies e.g. password complexity, renewal intervals.

Follow these general recommendations on password strength in case your institution does not have a more specific policy:

- Use a minimum password length of 8 characters

- Include lowercase and uppercase alphabetic characters, numbers and symbols
- Generate passwords randomly where feasible

Follow this general recommendation for a password renewal interval in case your institution does not have a more specific policy:

- Passwords should be renewed after 90 days.

Users will be automatically logged out of the Patients App or Devices App if they are inactive for 15 minutes.

## About periodical software updates and patches

On iOS and Android, the Current Health Patients App and Devices App should be updated as soon as a new version becomes available. When a new version does become available, the Apple App Store in the case of iOS or the Google Play Store in the case of Android, will automatically update the app in-place.

When accessing the Current Health platform via the web interface, the user will always have access to the most up to date version.

## Dealing with a lost or stolen Current Health wearable device

In case a Current Health device is lost or stolen, please notify Current Health with the ID of the wearable device.

## General Guidelines for Security

1. It is recommended that any mobile device with the Current Health Patients App or Devices App installed also has a device passcode set

2. You should never disclose your Current Health username or password. No Current Health staff will ever ask you for these details

3. You should never write your Current Health username or password down

4. You should never provide an unauthorized user access to the Current Health Patients App or Devices App

5. You should never leave the Current Health Patients App or Devices App logged in and unattended. Please log out when you have finished using the system

6. You should never disclose protected health information within a support message to Current Health. This includes details like a patient's name or date of birth.

# Table of Contents

# 1 Introduction

Current Health allows wearable, multi-parameter physiologic monitoring in non-critical care environments within professional healthcare facilities, such as general medical-surgical units or skilled nursing facilities, and in the home.

## 1.1 System Hardware Components

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**WARNING: Use only recommended accessories supplied by Current Health**

The system consists of:

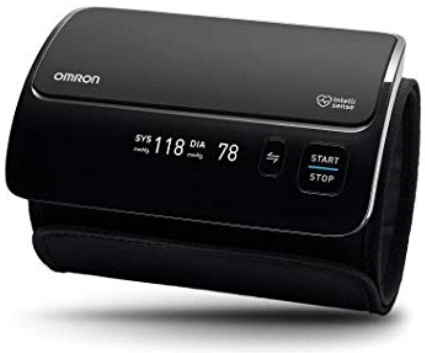
**Wearable Device Sensor**

(Class II, Type BF Applied Part)


**Single Use Strap**

**Charging Dock**


**iHealth Ease Blood Pressure Monitor (Hospital)**




**Omron Evolv Blood Pressure Monitor (Home)**

**iHealth View Blood Pressure Monitor (Home)**

**iHealth Neo Blood Pressure Monitor (Home)**

**VivaLnk Fever Scout Axillary Temperatur e Sensor**

**MIR Spirobank Smart Spirometer**

**Weighing Scales**


## 1.2 System Software Components

The system has three software applications:

**Patients App**
Available on:

- Apple iPhones and iPads running iOS 11 or greater
- Android tablets and smartphones running Android 8 (Oreo) or 9 (Pie)
- Any web-connected device running Google Chrome version 68.0.3440 or later

The Patients App provides access to real-time vital signs, vital sign trends and physiological alarms. It is explained in sections 5, 6 and 7.

Note that the Patients App is identical on both iOS and Android. As such, the processes explained below are the same across both platforms.

**Devices App**
Available on:

- Apple iPhones and iPads running iOS 11 or greater
- Android tablets and smartphones running Android 8 (Oreo) or 9 (Pie)

The Devices App is responsible for patient admission, discharge and transfer. It also receives technical alarms and allows monitoring of wearable device battery life.

**Patient-Facing App**
Available on:

- The provided Current Health Patient Tablet for home use

The Patient-Facing App provides an interface for the patient to use the integrated peripherals, communicate with their care team via video calling, and complete surveys

# 2 Wearable Device Setup & Management

**WARNING: The wearable device and its attachments pose a choking hazard. The wearable is not a toy and should not be chewed on or placed in the mouth.**

**WARNING: Use only the straps provided with the device to affix the device to the patient**

CAUTION: Do not apply the wearable device on open wounds, sores, or cuts

CAUTION: If redness appears during use, remove the device

It is expected that the Patient is able to set up the Wearable device, Homehub and Charging Dock themselves. They should also be able to charge the wearable device themselves, and will be provided with a Quick Start  Guide to help them accomplish these tasks.

## 2.1 The Wearable Device

The wearable device is worn on the upper arm of the patient using the supplied strap.

The wearable device is re-usable, while the strap is single use. Please review cleaning and disinfection instructions in section 17.

## 2.2 Fitting the device into the strap

An appropriate sized strap should be selected. The strap size can be determined visually by a tag on the strap. Straps are in three sizes:

- Up to 25cm – Small (S on Strap tabs)
- 25cm – 35.5cm – Medium (M on Strap tabs)
- 35.5cm – 56.5cm –Large (L on Strap tabs)


The strap provided with the device has a plastic ring into which the device sits. To fit the strap to the device, place the ring over the device and ensure the flat notch in the strap matches the flat surface on the top of the device.

When correctly positioned, the arrows on the device and on the strap align and point in the same direction.

Press down on the ring to secure the strap to the device.


## 2.3 Starting the Wearable Device

When the wearable device is first received new in the box, you should apply the charger for a few minutes (see section 4).

Thereafter, the wearable device is activated when it is applied to the skin.

## 2.4 Sensor Data Transmission

**WARNING: Removing the wearable device from WiFi range will prevent transmission of signal data and thus no vital signs nor alarm signals will be generated for the patient**

*CAUTION: If the device is removed from WiFi range, it will store signal data for a maximum of 17.5 hours. After 17.5 hours, no further signal data will be stored.*

The wearable device transmits physiologic signal data over standard IEEE 802.11 g/b/n 2.4GhZ WiFi to the Current Health software platform. Vital signs are computed by the software platform, rather than on the wearable device.

The wearable device will continuously sample the pulse oximeter between green/infra-red and red/infra-red.

If the wearable device is removed from WiFi network range, it will store sensor data internally for a maximum of 17.5 hours. After 17.5 hours, no further sensor data will be stored. When a WiFi network connection becomes available, the wearable device will transmit any internally stored data first, before transmitting real-time data.

It is important to note that while the wearable device is out of WiFi range, no vital signs or alarms will be generated.

**Note that as the wearable device transmits every 30 seconds, there is a short period of time between when sensor data is collected and it is processed by the platform into vital signs. This has an impact on the generation of alarms, as discussed in section 7, and on the time until vital signs are updated, discussed in the individual vital sign sections.**

## 2.5 **Homehub**

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**WARNING: Unplugging the Homehub during active use will prevent transmission of signal and thus generation of vital signs and alarms**

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*CAUTION: We recommend placing the Homehub in a main area of the house, such as the lounge or bedroom. This ensures maximum signal coverage*

Where existing home WiFi is not available, our Homehub can be used. The Homehub provides an IEEE 802.11 WiFi network for our products and services. Where signal coverage is poor, the Homehub can be connected to a domestic fixed-line internet connection.

# 3 Monitoring Wearable Device Battery Life

*CAUTION: The battery charge level displayed in the user interface is only accurate if the batteries are in normal working condition.*

The Devices App allows monitoring of device battery life for devices that are paired to a patient, and actively transmitting data. It also allows receipt of technical alarms, which is described in section 8.

To check on the battery life of a device, follow the below steps.

1. Log into the Devices App
2. Active patients will be shown on the display
3. Tapping into each patient will show the wearable devices which are paired to that patient, the battery level of each device, and when that device last transmitted data

# 4 Charging

**WARNING: Worn out or defective batteries can significantly reduce battery capacity or the operating time.**

**WARNING: To avoid electrical shock, inspect all cables before use. Never use cables that appear cracked, worn or damaged in any way.**

**WARNING: The Device Charging Dock must be powered by the supplied wall adapter**

**WARNING: Consider and prevent liquid spillages onto the Charging Dock. If the Charging Dock is immersed in liquid, or has liquid spilled on it, disconnect it and return for service**

**WARNING: Only Current Health approved peripherals should be connected to the Charging Dock**

CAUTION: Inspect the charging contacts and clean them of any debris before charging the wearable.

The wearable device lithium ion battery is charged using the supplied on-arm charging dock. The wearable device has a battery life of around 28 hours. Daily charging is required for between 15 and 30 minutes.

## 4.1 Charging a Single Device while on-arm

**WARNING: The Charging Dock contains magnets. On-arm charging is not recommended for patients fitted with pacemakers, or using other mechanical or electro-mechanical medical devices**

**WARNING: On-arm charging should NOT be used while the patient is bathing or taking a shower.**

**WARNING: On-arm charging should NOT be used whilst the patient is using a second mains power device.**

The Charging Dock is provided with the wearable device, and is responsible for charging the device through its Charging Head, powering the Current Health Patient Tablet (if used), and charging integrated peripherals (if used).

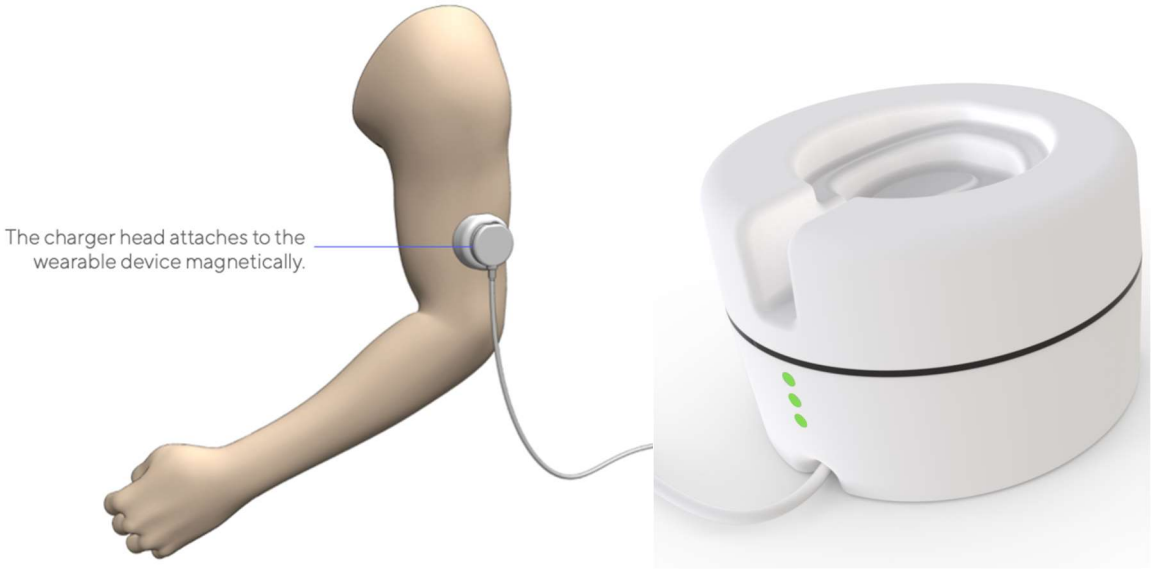

Before charging a wearable device, inspect the Charging Dock and Mains Power adapter for damage. If damage is identified, the Charging Dock or Mains Power adapter should not be used. Please contact the Support Center, per section 16.

Ensure the Charging Dock is plugged in with clear access to disconnect the plug if required.

To use the Device Charging Dock, connect the central power cable (the USB-C terminated cable), and plug the Mains Power adapter into a power outlet.

Remove the Charging Head from the Charging Dock. The Charging Dock will flash an orange LED.

Place the charging head onto the wearable device, matching the position of the charger electrodes with the metal pins on the surface of the wearable device. The Charging Head will click into place magnetically when in the correct position.




If the Charging Head is not correctly located, the Charging Dock will continue to flash its orange LED.

When the Charging Head is first located on the wearable device, the Charging Dock will show a solid single green LED before charging of the wearable device starts.

While charging, the three LEDs on the Charging Dock will flash green individually from bottom to top.

When the device is fully charged, all three LEDs will turn solid green as shown above.

When charging is complete, remove the Charging Head from the wearable device and place it back on the Charging Dock.

## 4.2 Charging a Single Device off-arm

When not in use, the device can be stored and charged on the Charging Dock, as shown below

When charging in this mode, the LEDs on the front of the Charging Dock behave identically to when charging on-arm. The LEDs will flash from bottom to top while charging, turning solid green when fully charged.

## 4.3 Fault detection in the Charging Dock

If the Charging Dock shows a flashing or solid red LED, there is an issue or fault with the Charging Dock, and it should be returned to the manufacturer for service.

# 5 Admission and Discharge

## 5.1 Admitting Patient to Current Health

**WARNING: Healthcare professionals should inspect the physical condition of all kit before assigning it to a patient.**

**WARNING: Visually check that the device has been placed securely against the skin. The strap should be snug and comfortable. You should be able to fit one finger under the strap.**

**WARNING: Inspect the strap on a regular basis and replace with a new strap if appropriate**

**WARNING: Excessive strap tightness may cause a pressure injury. Ensure the strap is set to the minimum level of tightness, such that the wearable device does not slip down the arm.**

The Admission process is a step-by-step process that includes mandatory and optional stages dependent on the local operating institution's configuration.

### 5.1.1 Admitting a patient

1. Open the Current Health app and login

2. Tap the Admit button

3. Enter the patient's identifier. Depending on your local operating institution's configuration, you may also be permitted to use the mobile device's camera to scan a machine-readable representation (usually a barcode or QR code) of the patient's identifier.

4. If a patient record is found that matches the identifier entered, these fields will be automatically populated and are displayed in order to confirm that the correct details have been found

5. If a patient record does not exist, complete the patient information form

6. Tap Next to confirm patient details

### 5.1.2 Entering demographic information for a patient (depends on configuration)

1. Choose the birth sex for the patient
2. Choose the patient's ethnicity from the dropdown
3. Enter the patient's height and weight
4. Tap Next to confirm the patient's demographic information

### 5.1.3 Update alarms for a patient

1. Select the relevant alarming profiles for the patient.
    a. Tap the checkbox next to the search field to select all profiles.

2. When an alarm is toggled on, a "Review" button will appear. This allows for an institution-wide alarm to be tailored to a particular patient

3. To tailor an alarm to a patient:
    a. Tap Review next to the alarm
    b. Use the plus and minus buttons to increase or decrease the relevant alarm threshold values
    c. If edited in error, tap "Reset to default values" to clear any changes to alarm thresholds
    d. When edited, the title will read "(modified)"
    e. Tap the Back arrow to confirm the tailored values

4. Verify the correct alarms are selected

a. Verify those that are marked as “(modified)” have been modified correctly

5. Tap Next to confirm alarm selection

### 5.1.4 Select the patient’s location

A patient can only be assigned to one location.

1. Tap the relevant location label to select it
2. Tap Next to confirm the patient’s location

### 5.1.5 Connecting the first wearable device to the patient

1. Bring the active wearable device near the mobile device until it is discovered
2. Tap Done to complete the pairing process

### 5.1.6 Connecting a Home Pack to the patient

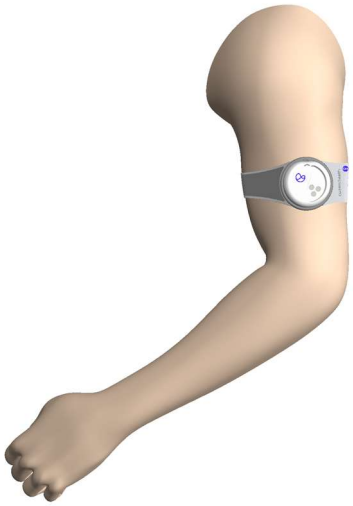
1. Tap Connect Home Pack
2. Pick up the Current Health tablet and turn it on
3. On the tablet screen, tap the “Scan QR Code” button
4. Use the tablet camera to scan the QR code shown on the mobile device
5. Once scanned and authenticated, the tablet will show a greeting including the patient’s name, and present the patient’s task list

### 5.1.7 Fitting the wearable to the patient

Correct fitting is critical to obtaining good-quality vital sign data. The wearable device must be in contact with the skin at all time. The wearable device must not be fitted in a way that allows the wearable device to lift away from the skin. The wearable device must keep a stable position during the patient’s normal activities

1. Select the location

a. Normally the wearable device is placed on the outer side of the upper left arm. It should be placed high enough above the elbow to minimize disturbance when the arm is bent.



b. The placement may be rotated towards the rear of the arm if this is helpful, but do not place the device to the inside of the arm. If the left arm is absent, is bandaged, has broken skin, a tattoo, or shows localized edema, the device may be worn on the right arm

c. Check the patient's skin, particularly the area where the sensors will be. Consider adjusting the location to avoid the following features:

   i. Particularly hairy areas
   ii. Moles or areas of raised skin
   iii. Deep wrinkles, areas of pitted skin or scar tissue
   iv. Tattoos or areas of strongly varying skin colour

2. Measure the patient's arm size, and use an appropriate size of strap for that patient.
3. Fit the device into the strap, ensuring the arrows are aligned and the ring sits into the notches on the device. Thread the strap through the eyelet on the other end of the strap and slide up the patient's arm.

4. Hold the wearable device in place on the Patient's arm with one hand

5. Hold the free end of the strap with the other hand, and pull it gently through the eyelet until the strap starts to stretch

6. Carefully release the stretch until the strap is neither tight nor slack - the neutral length. Repeat once or twice to establish a consistent result

7. From the neutral length, tighten the strap so that it is snug to the arm

## 5.2 Discharging Patient from Current Health

**WARNING: Unpairing a patient will remove them from the mobile application and central dashboard.**

A patient can be discharged from Current Health by using the Devices App and following the below steps.

### 5.2.1 Discharging a patient

1. Login to the Devices app

2. Search the list for the patient

3. Tap the patient entry

4. Tap Discharge Patient

# 6 Monitoring Live Vital Signs

The Patients App allows monitoring of live vital signs for a patient. A patient's vital signs are available on both the Dashboard and Patient Live Vitals screens.

The Dashboard provides one screen to review all vital signs for all patients. It groups patients into high, medium and low priority and will display them in priority order. This priority status is on the basis of alarm conditions that have been generated for the patient (described in section 7). Patients with no active alarm conditions are grouped under low priority.

Patients who are no longer being monitored e.g. wearable device has been removed but who have not been discharged from Current Health are grouped under the Unknown category.

To monitor live vital signs, follow the below steps.

1. Log into the Patients App

2. The Dashboard is the first view presented. It shows all patients, ordered by name with alarming patients at the top.

3. The list of patients on the dashboard can be filtered and re-ordered by tapping the filter icon in the top-right corner

    a. Available filter options are:
        i. Watching
        ii. Ongoing Alarm
        iii. Low Battery
        iv. Supplemental O2
        v. Location

    b. Available sort options are:
        i. Priority
        ii. Name
        iii. Date paired

4. Selecting a Patient takes you to the Vitals screen. Active Alarm Conditions are viewable by at the bottom of the screen, while the timeline presents all alarm conditions as well as user notes, acknowledgements, pauses and silences (see section 7).

# 7 Physiological Alarms

## 7.1 Alarming Profiles

**WARNING: The operator should ensure that the alarming profile selected is appropriate for the patient.**

**WARNING: For patients being monitored within the same care area, different alarming profiles can be configured per patient provided that the alarming profile set for the patient is appropriate.**

Physiological alarms can be configured to alert healthcare practitioners to particular deviations in the patient's vital signs.

Alarming profiles are set at a local institution level, but can be refined on an individual patient basis during the admission process.

An alarming profile contains multiple rules that can trigger an alarm. Each rule comprises one or more vital signs, an aggregation method (such as average), a comparator (such as greater than), a value and a time window. This allows alarms to be triggered based on rules such as if pulse rate is on average > 80 for 1 hour.

Multiple rules can be combined using AND or OR methods. The AND method requires all rules in the ruleset to have matched before the alarm is generated. The OR method allows for any of the rules in the ruleset to match before generating the alarm.

Rulesets also have a priority attached to them. These priorities are:

- Low
- Medium
- High

When an alarm is generated, the priority level of the ruleset will be applied to the patient. If multiple alarms are active simultaneously, the highest priority level will be applied to the patient.

The table below indicates factors for consideration when setting the priority of alarms:

| Potential result of failure to respond to cause of Alarm Condition | Onset of potential harm | | |
|---|---|---|---|
| | Immediate | Prompt | Delayed |
| Death or Irreversible Injury | High | High | Medium |
| Reversible Injury | High | Medium | Low |
| Minor Injury or Discomfort | Medium | Low | Low |

Where:

- Immediate = seconds to several minutes
- Prompt = several minutes to many minutes
- Delayed = many minutes to hours

User roles are set by your local operating institution for your user account on Current Health. Examples of user roles include “nurse”, “resident” and “attending”. Only your local operating institution can change your role. This allows alarms to be sent to the most appropriate group of users, and for alarm escalation if necessary. When an alarm is generated, it is sent to all On-Duty users for the selected role (see section 7.2).

The alarming profile selected for a patient is displayed on the Patients App for each patient.

## 7.2 On-Duty/Off-Duty

**WARNING: Operators must remember to mark themselves as On-Duty in order to receive alarm signals. In the event that no operators are on-duty, then the alarm shall not be sent.**

In order to receive alarms, you should mark yourself as On-Duty via the Patients App. When you no longer wish to receive alarms, you should mark yourself as Off-Duty via the Patients App.

To do this, follow the below steps:

1. Log into the Patients App

2. If you wish to go On-Duty, tap the Profile icon in the bottom-right corner, choose the locations you wish to go on-duty for, then tap Go On Duty

3. Tap Confirm

4. If you wish to go Off-Duty, tap the Profile icon in the bottom-right corner, then tap Go Off Duty

## 7.3 Alarm Condition Delay & Alarm Signal Delay

The Current Health wearable device transmits every 30 seconds. The vital sign calculation algorithms then utilize averaging, to smooth out inappropriate outliers. This leads to a short delay before the triggering event for an alarm is recognized. This is called the Alarm Condition Delay. The maximum Alarm Condition Delay is 33 seconds.

There is then a short delay between a triggering event being recognized and an alarm signal being sent to the user. This is called the Alarm Signal Delay. The maximum alarm signal delay is 2 seconds.

This means that the delay between a triggering event occurring and the user is notified can be 35 seconds.

The above timing assumes the wearable has connection to WiFi and the Current Health platform.

## 7.4 Receiving Alarm Signals

**WARNING: A rapid recognition of alarms and an appropriate response are only possible if the user is in hearing range of the audible alarm signals. The user must stay within the hearing range of the audible alarm signal and adjust the volume according to the distance from acoustic alarm signal.**

**WARNING: Ensure mobile device for receiving alarm signals has audio switched on and is at an appropriate volume.**

**WARNING: When operating in a noisy environment, the volume of the alarm signals must be adjusted to suit. Always set the volume of the alarm signal sufficiently high.**

Alarm signals are received by the Patients App, running on iOS or Android. When an alarm signal is received it will cause a visual and audible indication.

The visual signal will display the reason for the alarm as well the priority. The audible signal is priority encoded, that is the higher the priority the longer the audible signal and there is a difference in the composition of the tone.

When an alarm is received, the user can select the alarm signal and it will automatically open (after authenticating the user) to the alarm detail screen. No protected health information is divulged in the alarm signal, you must select it and then authenticate to see the patient the alarm signal has been generated for.

## 7.5 Reviewing Alarms

You can log into the Patient's App and review alarms.

Patients with alarms are displayed at the top of the dashboard. Active alarms are displayed on the patient card. After selecting a patient on the Dashboard, you can view all active alarms on the bottom of the screen. Selecting an alarm, displays the detail of that alarm.

The timeline allows you to review all prior alarms for a patient, as well as acknowledgements, snoozes, silences and notes (see sections 7.6 and 7.7). You can select any alarm on the timeline to view more detail about that alarm.

## 7.6 Acknowledging, Notifying, Pausing & Silencing

Once a user has received an alarm signal, there are four actions they can take.

**Acknowledge**
You can acknowledge that you have reviewed the alarm. Your name is added to the patient's timeline as having reviewed the alarm.

**Snooze**
You can acknowledge that you have reviewed the alarm and then pause any further reminder signal generation for a period of time. That period of time is selectable by a selection box. This then provides you time to review the cause of the alarm. If the patient subsequently triggers another alarm, this will still lead to alarm signals.

The snooze times available are configurable by your local operating institution.

Your name and the amount of time you have paused the alarm for will be added to the timeline (described in section 8.6) for other users to see.

**Silence**
You can acknowledge that you have reviewed the alarm and then silence any further reminder signal generation. The alarm will remain active until is silenced. You should only silence an alarm once the cause has been dealt with. Note that if the triggering event for the alarm occurs again, the alarm will be generated again.

Your name and the inactivated state will be added to the timeline.

**Notify Another User Role**
This function allows you to notify another user group of the alarm. You are given the option to select the role you wish to notify in a selection box. All On-Duty users within this user role group then receive alarm signals.

## 7.7 Adding Notes

You can add a textual note to the patient's timeline. This note is then shared with all other members of your operating institution with access to Current Health, when they view that patient's timeline.

To add a note, simply select Add Note on the interface.

## 7.8 Reminder Signals

After an alarm signal for an alarm is sent, reminder signals may be sent if the alarm is not acknowledged and then paused or silenced (see section 8.4).

Whether reminder signals are sent and the frequency with which they are sent will depend on your local operating institution. These are configured by the local operating institution. If you would like a reminder signal to be sent or to change the frequency with which they are sent, please discuss with your local operating institution.

# 8 Technical Alarms

## 8.1 Types of Technical Alarm

The below list of technical alarms is generated by Current Health.

| Type | Priority | Users who Receive | Suggested Action |
|---|---|---|---|
| **Degradation of Platform**<br>This occurs when the platform experiences an increase in latency or reduction in performance that may be noticeable to users | By local institution configuration. | By local institution configuration. | No further action required. Current Health will be working to resolve the issue and will be in touch if any action is required. |
| **Wearable Device Stops Transmitting***<br>This occurs when a wearable device, which is monitoring a patient, stops transmitting data to the platform for greater than **5 minutes** | By local institution configuration. | By local institution configuration. | Ensure the patient is still within WiFi network range, and that their device is on their arm. Check battery life as per section 3. If the device is unresponsive, discharge the patient from the device and then admit the patient to a new device as per section 5.1. |
| **Wearable Device Low Battery***<br>This occurs when a wearable device has a battery level supporting less than 6 hours use. A further technical alarm is sent when the battery level supports less than 2 hours use.<br><br>When a device has no remaining battery level it stops transmitting; please refer to the entries for Wearable Device Stops Transmitting, above. | By local institution configuration. | By local institution configuration. | Remove the device and discharge the patient. This device should then be charged as per section 4. Admit the patient to a new device as per section 5.1. |

* These descriptions assume default alarm settings, these settings may be configured by the local institution.

## 8.2 Receiving Alarm Signals

**WARNING: A rapid recognition of alarms and an appropriate response are only possible if the user is in hearing range of the audible alarm signals. The user must stay within the hearing range of the audible alarm signal and adjust the volume according to the distance from acoustic alarm signal**

**WARNING: Ensure mobile device for receiving alarm signals has audio switched on and is at an appropriate volume**

Technical alarm signals are received by the Devices App, running on iOS or Android. When a technical alarm signal is received it will cause a visual and audible indication.

The visual signal will display the reason for the alarm as well the priority. The audible signal is priority encoded, that is the higher the priority the longer the audible signal and there is a difference in the composition of the tone.

When a technical alarm is received, the user can select the alarm signal and it will automatically open (after authenticating the user) to the technical alarm detail screen.

## 8.3 Snoozing & Silencing

Once a user has received a technical alarm signal, there are two actions they can take.

**Snooze**
You can acknowledge that you have reviewed the alarm and then pause any further reminder signal generation for a period of time. That period of time is selectable by a selection box. This then provides you time to review the cause of the technical alarm.

Your name and the amount of time you have paused the technical alarm for will be added to the timeline.

**Silence**

You can acknowledge that you have reviewed the alarm and then silence any further reminder signal generation. This inactivates the alarm. The alarm will remain active until it is silenced. We recommend you only silence an alarm once you have dealt with the root cause of the technical alarm.

Your name and the fact that the alarm has been inactivated will be added to the timeline.

## 8.4 Reminder Alarm Signals

After an alarm signal for a technical alarm is sent, reminder signals may be sent if the alarm is not acknowledged and then paused or silenced (see section 8.3)

Whether these are sent and the frequency with which they are sent will depend on your local operating institution. These are configured by the local operating institution. If you would like a reminder signal to be sent or to change the frequency with which they are sent, please discuss with your local operating institution.

## 8.5 Review all Technical Alarms

The Devices App can be used to review all technical alarms. To access the technical alarms screen, follow the below steps.

1. Log into the Devices App

2. Select the Alarms tab on the bottom right hand corner

3. You can select any Technical Alarm to view more detail

# 9 Trends

Current Health allows the user to view trends for a patient's vital signs across a number of different periods of time. The trends are provided as

To access the Patient Trends screen, follow the below steps.

1. Select a Patient from the Dashboard
2. Select View Trends
3. You can change which vital sign you wish to view trends.
4. You can change the time period trends are displayed over
5. You can select an area of the graph to identify a vital sign at that time period

Where trends are viewed, averaging will be used. The amount of averaging is dependent on the period of time selected and the amount of data recorded for a patient.

# 10 Pulse Rate

## 10.1 Principle of Operation

Current Health monitors pulse rate via pulse oximetry from the upper arm. Technical specifications are included in section 18.4.1.

## 10.2 Averaging

Current Health utilizes averaging in order to smooth pulse rate data and prevent inappropriate and transient artifacts from affecting stability of results. The data update period is provided in the technical data in section 18.4.1.

The time that a pulse rate was calculated is displayed on the user interface next to each pulse rate.

## 10.3 Display Value, Outputs and Indicators

Pulse rate is presented as beats per minute (BPM). The time that pulse rate was last observed is presented next to each pulse rate observation.

# 11 Respiration Rate

**WARNING: The safety and effectiveness of the respiration measurement method in the detection of apnea has not been established. Do not rely solely on the device for detecting cessation of breathing**

**WARNING: The device does not monitor obstructive apnea. Patients at risk for respiratory crises should be observed closely**

**WARNING: Current Health is not intended for use on patients with extremely low (less than 6rpm) and extremely high (greater than 60rpm) respiration rates**

## 11.1Principle of Operation

Current Health monitors respiration rate based on chest movements and, in particular, the impact this has on the upper arm. This has been validated in multiple postures and in multiple body types. Technical specifications are included in section 18.4.3.

## 11.2Averaging

Current Health utilizes averaging in order to smooth pulse rate data and prevent inappropriate and transient artifacts from affecting stability of results. The data update period is provided in the technical data in section 18.4.3.

The time that a pulse rate was calculated is displayed on the user interface next to each respiratory rate.

## 11.3Display Values, Output and Indicators

Respiratory rate is presented as respirations per minute (RPM). The time that respiration rate was last observed is presented next to each respiration rate observation.

# 12 Pulse Oximetry (SpO2)

**WARNING: Movement, ambient light and low perfusion may affect SpO2 and pulse rate calculation and accuracy. Current Health is not intended for use in calculating accurate SpO2 during periods of high motion, high ambient light and low perfusion conditions.**

**WARNING: SpO2 measurements are particularly sensitive to the pulsations in the artery and the arteriole. Measurements may not be accurate if the patient is experiencing shock, hypothermia, anemia or has received certain medications that reduce the blood flow in the arteries.**

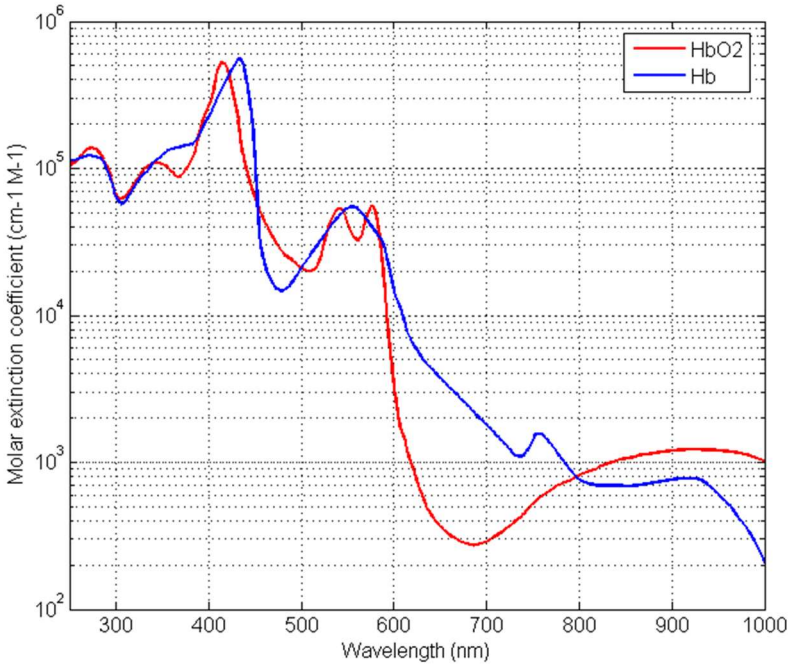
**WARNING: Current Health should not be used as an apnea monitor.**

**WARNING: The device should not be placed over a tattoo - doing so may prevent calculation of an accurate SpO2 or pulse rate.**

## 12.1Principle of Operation

**Current Health calculates functional oxygen saturation (SpO2) using pulse oximetry from the upper arm. Technical specifications are available in 18.4.2.**

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. $O_2$ is carried in the blood in two forms, either dissolved in plasma or combined with hemoglobin. The majority of $O_2$ is carried on hemoglobin. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infra-red light, as shown in the graph below.




*Extinction Spectra for HbO2 and Hb*

Current Health uses an optical sensor that shines both red and infra-red light at the skin of the upper arm to distinguish between oxygenated blood and deoxygenated blood. Signal data is obtained by the reflections of red and infra-red light back onto the sensor by the blood and other tissues. The maximum radiant power of the strongest light is rated at <15mW. The sensor converts the reflected light into an electronic signal, known as a photoplethysmograph.

The Current Health software platform receives the photoplethysmograph from the wearable and uses proprietary algorithms to calculate the patient's functional oxygen saturation (% SpO2) and pulse rate.

Note that Current Health is calibrated to measure and display functional oxygen saturation (SpO2), which is the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.

## 12.2Application Site & Frequency of Change

**WARNING: The strap contains polyester, polyamide and nylon. Do not use if the patient has a known allergy to any of the materials.**

**Some individuals may be sensitive to neoprene. If a rash develops, discontinue use.**

**WARNING: Do not apply the device or strap over an open wound/broken skin**

**WARNING: Inspect the application site of the wearable and the strap every twenty four hours to check the skin quality and correct optical alignment. Change the application site at least every 24 hours. Failure to change application site may result in minor irritation to the skin.**

The Current Health wearable device should be attached to the upper arm to intact skin only. The upper arm should be inspected every twenty four hours to check skin quality and ensure the sensor is close to the skin.

The strap should be attached no tighter than is required to stop the device from sliding down the arm.

The device should not be applied over a tattoo.

## 12.3Averaging

Current Health utilizes averaging in order to smooth oxygen saturation data and prevent inappropriate and transient artifacts from affecting stability of results. The data update period is provided in the technical data in section 18.4.2.

The time that a oxygen saturation was calculated is displayed on the user interface next to each oxygen saturation, as shown below.

## 12.4Display Values, Outputs and Indicators

SpO2 is presented as %. The time that SpO2 was last observed is presented next to each SpO2 observation.

# 13 Temperature

**WARNING: Do not use Current Health to monitor core temperature**

**WARNING: Ambient, environmental temperature changes may impact the temperature of the patient and thus temperature monitoring.**

## 13.1 Principle of Operation

Current Health monitors skin temperature in direct mode from a probe applied to the upper arm. This probe is an intrinsic part of the wearable device. Technical specifications are available in section 18.4.4.

## 13.2 Display Value, Outputs and Indicators

Temperature is presented in °C, or in °F as configured by the operating institution. The time that temperature was last observed is presented next to each temperature observation.

# 14 Motion Levels

**WARNING: Motion levels are provided for information purposes only. They should not be relied upon to inform patient care.**

Current Health monitors motion levels via a gyroscope and accelerometer. The patient's level of motion is represented as one of ten motion levels, from Level 1 to Level 10. They are then grouped into 4 motion classifications:

Level 1 to 2 – Very Still
Level 3 to 4 – Still
Level 5 to 6 – Minor Movement
Level 7 to 8 – Moderate Movement
Level 9 to 10 – Considerable Movement

Level 1 indicates the lowest level of motion, while Level 10 indicates the highest level of motion. These motion levels have been calculated based on 12,000 hours of real patient movement data.

# 15 Custom Scores

**WARNING: Custom scores are provided for information purposes only. They should not be relied upon to inform patient care.**

Where your local operating institution has enabled this, Current Health allows a Custom Score to be set for a particular patient. A Custom Score is a single aggregate integer number, which is calculated based on the level of one or more vital signs.

Custom Scores are calculated via Custom Scoring Profiles. These are set by your local operating institution. They cannot be set or changed by the user. If you would like to enable Custom Scores or add a Custom Scoring Profile, please speak to your local operating institution.

A Custom Scoring Profile generates a custom score by applying an integer score to one or more vital signs based on the level of that vital sign. Individual vital sign scores are then summed to generate the final Custom Score.

Note, that alarms are not and cannot be based on custom scores or changes in custom scores.

Custom Scoring Profiles, where enabled, are set during the Admission process to Current Health (described in section 5). During the Admission process, there is the option to select which Custom Scoring Profile should be enabled for a patient, as in the screen below:

Once a Custom Scoring Profile has been selected during the Admission process, it will then appear on the Patients App for that patient. It will be shown both on the Dashboard and on the Patient Live Vitals screen. The name of the Custom Scoring Profile used to calculate the Custom Score. The individual custom scores of each vital sign are also displayed on the Patient Live Vitals Screen.

# 16 Support Center

The Current Health Support Center is available through the Patients App and Devices App and allows users to contact Current Health via instant message.

To access the Support Center, select the Support button on the bottom menu.

# 17 Cleaning and Disinfecting

**WARNING: Do not autoclave or sterilize the wearable device or any part of the Current Health monitoring system**

**The Wearable Device, Charging Dock system, Home Hub and power supply are re-usable and may be used for more than one patient. The strap is single use and should be disposed of in clinical waste or according to local guidelines and regulations**.

The re-usable components must be decontaminated following each and every episode of use and prior to being sent for service or repair. This is to ensure the safety of both patients and staff.

The term decontamination refers to a process that removes or destroys contamination. Consequently, micro-organisms and other contaminants are prevented from reaching a susceptible site in sufficient numbers to initiate infection or any harmful response.

Standard infection control precautions should be adhered to as per your local operating institution's guidelines, policies and procedures. It is the responsibility of the user to ensure that correct decontamination has been carried out.

To clean the re-usable components they should be completely wiped with detergent wipes, paying attention to all surfaces.

If there is evidence of blood or other bodily fluids, then disinfection wipes should be used. Additional precautions should be taken, and personal protection equipment used, as per your local operating institution guidelines, policies and procedures.

During usage, users should regularly check the condition of the Current Health equipment and clean as necessary.

# 18 Technical Data

This section contains technical specifications for the physical and functional aspects of Current Health. These specifications apply to adult patients.

## 18.1 Electrical Safety

The Current Health Wearable Device and Charging Dock have been tested for electrical safety and meet IEC (ANSI/AAMI) 60601-1:2005 +AMD1:2012 and IEC (ANSI/AAMI) 60601-1-11:2015 for devices used in the home.

## 18.2 Electromagnetic Compatibility (EMC)

The Current Health Wearable Device and Charging Dock have been tested to and meet IEC/AAMI/ANSI 60601-1-2:2014, are FCC qualified as a portable device and comply with the Radio Equipment Directive (2014/53/EU).

**EMC Warnings & Pre-Cautions**

Portable RF communications equipment (including antenna cables, external antennas, wireless home network devices, mobile phones, and cordless phones) should be used no closer than 30cm (12 inches) to any part of the Current Health Wearable Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Current Health should be periodically tested for electrical safety.

## 18.3System Hardware Components

### 18.3.1 Wearable Device

| | |
|---|---|
| **Physical Attributes** | |
| Size (HxWxD) | 4.8cm x 4.9cm x 1.8cm |
| Weight | 32g |
| **Battery Specifications** | |
| Rating Voltage | 3.7 DC Nominal |
| Capacity (for a new battery) | 835mAh |
| Operating Time | 28 Hours |
| Charge Time | 30 Minutes |
| **Environmental Specifications** | |
| Temperature Range | Operating: 5°C (41°F) to 40C°C (104°F)<br>Storage: -20°C (-4°F) – 60°C (140°F) |
| Relative Humidity | <95% |
| Protection Against Ingress of Water | IP22 |
| **Storage** | |
| Data Storage: | 10 Hours of Internal Storage if the Wearable Device loses connection to the WiFi Network |
| **Network Specifications** | |
| Transmission Protocol | IEEE802.11 b/g/n |
| Frequency | 2.4Ghz |
| Security | WPA2-PSK |
| IP Addressing | DHCP or Static, v4 |

### 18.3.2 Charging Dock and Mains Power Adapter

| | |
|---|---|
| **Physical Attributes** | |
| Size (HxWxD) | 6.0cm x 9.0cm x 9.0cm |
| Weight | 227g |
| **Environmental Specifications** | |
| Temperature Range | Operating: 5°C (41°F) to 40C°C (104°F)<br>Storage: -20°C (-4°F) – 60°C (140°F) |
| Relative Humidity | <95% |
| Protection Against Ingress of Water | IP21 |
| **Mains Power Adapter** | |
| Company | FRIWO Gerätebau GmbH |
| Manufacturer Part Number | NEO018.0-I-X-05 |
| **Physical Attributes** | |
| Size (HxWxD) | 81cm x 53cm x 34 cm |
| Weight | 190g |

| Electrical Specifications | |
|---|---|
| Input Voltage | AC 100 - 240 V, 50/60Hz |
| Output Voltage | DC 5V +/- 5% |
| Maximum Output Current | DC 3000mA |
| **Environmental Specifications** | |
| Temperature Range | Operating: 0°C (32°F) to 50°C (122°F)<br>Storage: -40°C (-40°F) to 70°C (158°F) |
| Relative Humidity | <95% |
| Protection Against Ingress of Water | IP40 |

## 18.4Monitoring Specifications

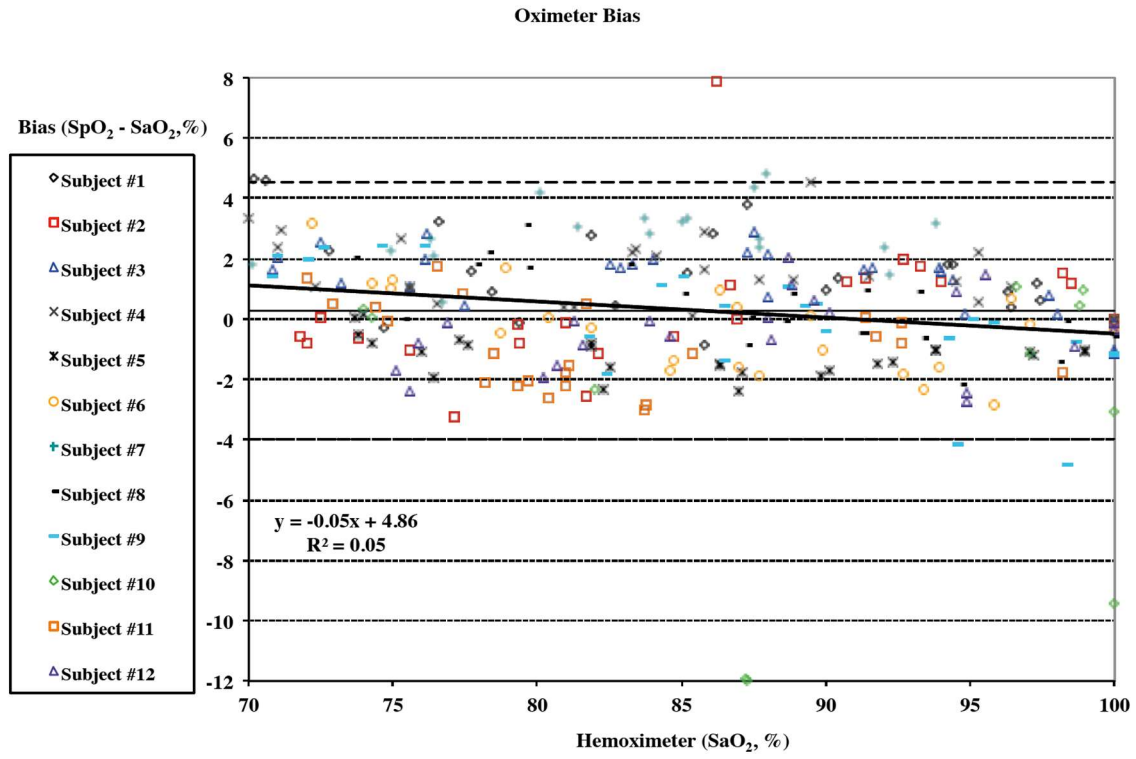
### 18.4.1 Pulse Rate

| | |
|---|---|
| Sensing Method | Pulse oximetry |
| Measurement Range | 30bpm to 240bpm |
| Resolution | 1bpm |
| Accuracy | ±3pm |
| Data Update Period | 28 seconds |

### 18.4.2 Pulse Oximetry (SpO2)

| | |
|---|---|
| Sensing Method | Pulse oximetry |
| Measurement Range | 0% to 100% |
| Resolution | 1% |
| Accuracy | 70 to 100%: ± 2 digits<br><br>70 to 80%: ± 2 digits<br>80 to 90%: ± 3 digits<br>90 to 100%: ± 2 digits |
| Data Update Period | 28 seconds |
| Nominal Wavelength | Red: 660nm<br>Infra-Red: 950nm<br>Green: 530nm |
| Power | Red: 14.1mW<br>Infra-Red: 11.7mW<br>Green: 6.5mW |

Note: Accuracy was measured in a controlled, induced hypoxia study in healthy adult volunteers. A graphical plot of data points captured in this study is provided below.




Note: Wavelength range can be especially useful to physicians, such as those performing photodynamic therapy.

Note: A functional tester cannot be utilized to assess the accuracy of Current Health SpO2 monitoring.

### 18.4.3 Respiratory Rate

| | |
|---|---|
| Sensing Method | Chest Movements |
| Measurement Range | 6rpm – 60rpm |
| Resolution | 1rpm |
| Accuracy | Supine Arm at Side: ± 1rpm<br>Supine Arm Above Head: ±2rpm<br>Seated at 90°: ±2rpm<br>Seated at 45°: ±1rpm<br>Standing: ±3rpm<br>Prone: ±2rpm<br>Lying on Side: ±1rpm |
| Data Update Period | 28 seconds |
| Apnea Detection | No |

### 18.4.4 Temperature

| | |
|---|---|
| Sensing Method | Thermistor |
| Measurement Range | -20.0°C to 50.0°C (-4°F to 122°F) |
| Resolution | 0.1°C |
| Response Time | 130 milliseconds |
| Accuracy | ± 0.1°C (0.18°F) |

## 18.5Alarm Specifications

| | |
|---|---|
| Alarm Tone Sound Pressure | High-Priority Alarms – 56dB to 76dB<br>Medium-Priority Alarms – 54dB to 72dB<br>Low-Priority Alarms – 41dB to 58dB |

## 18.6FCC

**WARNING: This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.**

**WARNING: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.**

**WARNING: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment**