vitalthings®
GUARDIAN M10

Installation and Service Manual

Guardian M10

English
Version 1.4

Table of Contents

1 Technical information

1.1 Version data

Date of issue	2024-05-08
Version	1.4
Supported software	1.x.y (x, y can be any number)

Version history

1.0 Initial version

1.1 Includes minor improvements to grammar and style

1.2 Includes an additional notice in Configuring connection type

1.3 Includes an updated system update process

1.4 Includes minor corrections after technical documentation assessment

1.2 Legal notices

Copyright

Disclaimers

The manufacturer, Vitalthings ("Manufacturer"), supplies this product with the expectation that users will obey all instructions and guidelines set forth in this manual. The Manufacturer's responsibility for the safety, reliability, and performance of this product is contingent upon the product being used as specified herein.

Any modifications, changes, or repairs to this product must be done by the Manufacturer or by personnel expressly authorized by the Manufacturer. Unauthorized alterations can compromise the safety, reliability, and performance of the product and can void any warranties or guarantees.

While this manual can give recommended maintenance guidelines, the Manufacturer does not assume responsibility for the execution of such maintenance. The responsibility for doing maintenance for the product in a safe and reliable condition rests solely with the individual or entity in possession of the device.

The Manufacturer disclaims all liability for any damages or losses, whether direct, indirect, incidental, or consequential, resulting from the use, misuse, or inability to use this product.

Users of this product should understand that all clinical conclusions, decisions, or actions based on the use of this product are the sole responsibility of the relevant medical specialist or user. The Manufacturer does not endorse or guarantee any specific clinical outcomes.

1.3 Contact and support

International contact	**Email:** contact@vitalthings.com
	Postal address: Vitalthings AS Dybdahls veg 5 7051 Trondheim NORWAY
International support	**Email:** support@vitalthings.com
	Telephone: +47 40 20 53 00

1.4 About this manual

This manual contains the information needed to safely identify, install and service the Guardian M10 patient monitoring system.

Read carefully before use

Read this manual carefully before starting the installation or service of Guardian M10. All personnel involved in the maintenance and repair of the system must be familiarised with its contents.

This manual does not replace medical or professional training.

Keep this manual in a safe location near the system, where it can be accessed as necessary.

Warnings, precautions and notices

There are two safety text types and one note text type in this manual. Familiarise yourself with them.

⚠ **WARNING**
Warnings are used in cases where, should you not perform your actions according to the instructions, serious incidents can occur.

⚠ **Precaution**
Precautions are used in cases where, should you not take into account the instructions, undesirable side effects such as patient deterioration, loss of data, or reduced device performance can occur.

ⓘ Notice: Notices are used in cases where additional or referential information is provided.

1.5 Indications for use

Adult subjects where respiratory rate monitoring is requested.

1.6 Contraindications for use

Guardian M10 is not meant to be used in any situation where hyperacute respiratory events can occur.

For medical devices approved by the Guardian M10 manufacturer for use together with Guardian M10, refer to their manufacturers' instructions for contraindications.

1.7 Safety information

General safety guidelines

> ⚠ **WARNING**
> This manual must be read and understood before installing or using the equipment.

> ⚠ **WARNING**
> Manufacturer’s guidelines for installation and service must be strictly followed. Improper installation and/or service can compromise device performance, or cause overheating of the device and its surroundings.

> ⚠ **WARNING**
> Unauthorized modifications or repairs can cause danger and void the product's warranty.

> ⚠ **WARNING**
> Only qualified healthcare professionals trained to use the device are allowed to use the device.

> ⚠ **WARNING**
> Upon initial receipt and before each use, inspect each component for damage. Do not use any component if damage is apparent.

> ⚠ **WARNING**
> Do not install the device in an environment with high electromagnetic interference (EMI).

Power and electrical safety

> ⚠ **WARNING**
> Modification of the device is prohibited.
> Do not attempt to repair the device yourself as it can lead to electric shock.

> ⚠ **WARNING**
> The device must only be connected to power supplies approved for the application. These are the approved power supplies:
> - VT58000 Trolley - Battery Dock for the mobile configuration
> - VT50031 Sensor Unit USB-C Power Supply for the stationary configuration
>
> Incorrect power connection can lead to electric shock.

Electromagnetic compatibility

> ⚠ **WARNING**
> Do not use in the presence of magnetic resonance imaging (MRI) devices.

WARNING
The use of other medical electrical equipment in the immediate proximity of this device can influence the accuracy of the measurements.

Precaution
Use of accessories and cables other than specified or provided by the manufacturer of this equipment can result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.

Storage

Precaution
Storing parts in environments that are outside the limits given in the technical specification can reduce the lifetime of the equipment or cause it to malfunction.

1.8 Compliance with standards

The Vitalthings Guardian M10 product family complies with the regulatory requirements of the EU regulation 2017/745 that is applicable for medical devices. The product family is tested to meet all applicable requirements in relevant EU Directives, EU regulations and European or international standards. Any changes to accessories, peripheral units or any other part of the system must be approved by the manufacturer. Ignoring this advice can compromise the regulatory approvals obtained for this product.

This product complies with these standards:

Standard	Description
EN 60601-1:2006+A1+A12+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2013+A2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8:2007+A1+A11+A2:2021	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 62304:2006+A1:2015	Medical device software - Software life cycle processes

Standard	Description
EN 62366-1:2015+A1:2020	Medical devices - Application of usability engineering to medical devices
EN 80601-2-49:2019	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
ETSI EN 302 065-1:2016	Short Range Devices (SRD) using Ultra Wide Band technology (UWB) - Harmonized Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU - Part 1: Requirements for Generic UWB applications
EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice

1.9 Transport, handling and storage

Every part of Guardian M10 is designed and packaged to ensure safety during transport, ease of handling, and appropriate storage. Adhere to the guidelines provided in this section to maintain the integrity and functionality of the system.

Transport and delivery

The parts are:

- Securely packaged and cushioned to prevent any damage during transit.
- Transported in separate packages to ensure maximum protection.
- Supplied in distinct packages, each labelled appropriately.

Handling

- Upon receiving the system parts, make sure to handle each package with care, avoiding any sharp impacts or drops.
- When unpacking the parts, place them on a clean and flat surface.
- Follow the unpacking and inspection on page 22 guidelines to ensure all parts are accounted for and there are no visible damages.

Storage

For detailed storage conditions, see Technical specifications on page 68. General storage recommendations include:

- Store the device and its components in a climate-controlled environment, away from direct sunlight.
- If any special storage conditions are required, they will be indicated on the packaging.

Package dimensions and weight

The package dimensions and weight for each part are provided on the packaging labels. Make sure you have adequate space for storage based on this information.

For further reference on transport and storage conditions, see Unpacking and inspection on page 22 and Technical specifications on page 68.

1.10 Terminology

Name (abbreviation)	Definition
active alarm	An alarm is active when its underlying alarm condition is active.
active monitoring session	The instance from the start of monitoring until the end of monitoring.
administrative user	User with authority to access the ***Administrative*** and ***Maintenance*** tabs in *Device management view*, and therefore adjust the default system settings or do maintenance tasks.
alarm acknowledged	The user can acknowledge active alarms. Acknowledgement time lasts for five minutes. During this time, alarm sounds are not generated for the active alarms that are already acknowledged by the user. New active alarms will still generate alarm sounds. After the five-minute period has gone, alarm sounds will be generated for any alarms that are active.
alarm condition	A situation or a state where the alarm system has found that a potential or actual hazardous situation exists and attention from the user is necessary. When an alarm condition is active, an alarm is active.
alarm limit	A limit associated with an alarm condition. When the actual measured value is more than the upper alarm limit or less than the lower alarm limit, an alarm becomes active.
alarm message	A message that shows at the bottom of *Main view* or *Patient management view* when an alarm becomes active. The message contains details of the alarm, such as time and date of its occurrence.

Name (abbreviation)	Definition
alarm paused	When alarms are paused, no visual or auditory alarm signals will be generated except for the messages in the alarm messages area. Alarms can be paused for two minutes each time; after two minutes, alarm signals will be generated again. Alarms can be paused for a defined period if alarm signals are not necessary. For example, when a doctor comes to a patient's bed to examine the patient's condition and it is not necessary to see or hear alarm signals, they can pause alarms.
alarm signal	A visual or audible indication of an alarm condition.
alarm triggering event	General term for any measurement that can lead to an alarm condition.
annunciation delay	A defined time period that the alarm limit has to be breached continuously before an alarm becomes active. For example, when the alarm limit for a high respiration rate is defined as "more than 30 rpm" with an annunciation delay of 40 seconds, there has to be a consecutive measurement of a respiration rate that is more than 30 rpm for 40 seconds before the alarm becomes active. Any measurements below this will restart the timer.
application programming interface (API)	The defined format for information exchange between Guardian M10 and a remotely connected system.
avoid zone	A measurement zone of the sensor unit where the system cannot get reliable readings from the patient, but persons and moving objects within this zone can have a negative effect on the monitoring of the patient in the optimal zone.
backup battery	The internal batteries of Guardian M10 (one inside the display unit and the other inside the sensor unit) that give power for a limited amount of time in case there is no other power source.
barcode scanner	An optional device that can be used to input patient's ID if enabled.
Bluetooth (BLE)	A short-range wireless technology standard that is used for exchanging data between devices over short distances.
bootup mode	A state where the system has just been turned on, and it is booting up. The Vitalthings logo is shown on screen.
cleaning mode	State of the display unit where the screen is locked and can be cleaned.

Name (abbreviation)	Definition
default view	View into which the display unit automatically goes back from other views if the user does not touch the screen for a set period of time. The default view is *Main view* if there is an active session, and *Patient management view* if there is no active session.
Device management view	View on the display unit that contains device settings, system information, maintenance tools, and the user manual.
display unit	The tablet used as a graphical user interface for Guardian M10 which is used to operate the system.
event log	Log containing the last alarm or system related events, such as patient registration, alarm limit adjustment, alarm acknowledgements, or changes to system settings. Shows the logged events from the last 48 hours of the current monitoring session. Available to all users, and opened from *Main view*.
Guardian M10/the system	Reference to the entire configurable device, when it is not necessary to differentiate between the stationary configuration or the mobile configuration.
hot-swap	Battery can be changed without the system loosing power during the time period the battery is disconnected from the system. An alarm will sound if a new battery is not inserted within 5 minutes.
hardware (HW)	The part of a device that is installed and cannot be altered without replacement or physical modification. For example, the printed circuit board.
idle mode	A state where there is no active monitoring session.
inactive alarm	Alarm is inactive when its underlying alarm condition is no longer active.
instant start	Option in *Patient management view* to start a monitoring session with an unregistered patient. Instant start can be used to start a monitoring session when there is no patient name or ID immediately available.

Name (abbreviation)	Definition
latching alarm	A case where the visual alarm signal of an alarm remains even if the clinical or technical event triggering the alarm has resolved itself. For example, a situation where the respiration rate of a patient falls under the alarm limit for a low respiration rate alarm. The alarm becomes active, but after a while, the patient's respiration rate returns to a normal range, so the alarm is now inactive. The visual signal of the alarm then remains until it is acknowledged by the user to let them know that an event has occurred.
limited zone	A measurement zone of the sensor unit where the system can still sense persons and moving objects, but with lower accuracy and frequency compared to optimal zone.
Main view	The live monitoring view of the display unit where the majority of functions are located or accessed from. This is the main view of the display unit.
mobile configuration	A configuration of Guardian M10 where the display unit and the sensor unit are installed on a trolley which can be moved around. This configuration is marketed as Vitalthings Guardian M10 Mobile.
optimal zone	The zone directly in front of the sensor unit where measurements are obtained in the clearest and most reliable manner. The intended position of the patient during monitoring.
optional pulse oximeter	Nonin WristOx$_2$® Model 3150 Pulse Oximeter BLE with 8000S Series reusable soft sensors measure pulse rate and oxygen saturation.
oxygen sat. (oxygen saturation)	Measure of how much haemoglobin is bound to oxygen, compared to how much haemoglobin is unbound to oxygen. Number is given in percentage.
patient	A living being (person) undergoing a medical or surgical procedure.
patient ID	Unique identifier of the patient, such as a social security number.
Patient management view	A view for registering or discharging patients. Default view when there is no active session.
physiological alarm	Alarm for an alarm condition that is related to a patient's vitals.
plethysmograph (pleth.)	A graphical illustration of blood perfusion through the optional pulse oximeter.

Name (abbreviation)	Definition
pop-up message	A blue text box that shows on screen to indicate additional information, something that is preventing correct system operation, or action that is necessary before the user can continue.
privacy mode	Mode of the display unit in which the *Main view* is replaced after a certain time of inactivity by another view that hides patient-specific data.
pulse oximetry	A light-based measurement of oxygen saturation and pulse rate by a device.
pulse rate	The number of times the heart beats per minute.
quick response (QR) code	A two-dimensional barcode that is presented on the screen to be scanned by a barcode reader to obtain device ID if necessary.
remotely connected system	An external system, which can communicate with Guardian M10 through the API.
respiration rate (RR)	The frequency of respiration given in respirations per minute (rpm).
respiration waveform	A graphical representation of the respiratory movement.
sensor unit	The unit responsible for contactless monitoring.
service technician	The intended reader of the Installation and Service Manual. Person responsible for installation, service and maintenance procedures of Guardian M10.
silent alarm	A configurable option where, if activated, alarms will only generate visual alarm signals for a pre-defined time period before an audio signal is started. Silent alarm configuration is by default set for a period of two minutes.
slider	Control in display unit user interface for selecting a value or range from a fixed set of options.
SpO_2	Technical abbreviation of oxygen saturation.
standby mode	A state where there is an active monitoring session, but monitoring, alarm generation, and operation of the unit are temporarily paused by the user. Standby mode can be activated when the user enters the monitoring zones, or when the patient leaves the optimal zone.

Name (abbreviation)	Definition
stationary configuration	A configuration of Guardian M10 where both the display unit and the sensor unit are installed on the wall. This configuration is marketed as Vitalthings Guardian M10 Stationary.
suspended mode	A state where there is an active monitoring session but the measuring of a patient's respiration rate is suspended by the system due to sensor unit movement. A technical alarm is also generated.
software (SW)	Programs running on the device responsible for different tasks and functions.
system log	Log containing the last alarm or system related events, such as patient registration, alarm limit adjustment, alarm acknowledgements, or changes to system settings. Contains a maximum of 604 800 log entries. Available to administrative users and service technicians, and opened from *Device management view.*
technical alarm	Alarm for an alarm condition that occurs in the equipment or the alarm system.
touchscreen	A type of display unit screen, allowing touch-controlled input.
Trend view	View (in the display unit) for reviewing the history of the monitoring data collected from the current patient.
trolley battery	The primary power source for the mobile configuration. The battery has capacity for 14 hours of regular use. The battery can be hot-swapped on the trolley without interrupting operation. The battery is charged at a battery charging station placed in a convenient location.
user	An operator of the system who can do all the daily tasks and adjustments to settings, but does not have administrative access.

2 Introduction to Guardian M10

Guardian M10 is a patient monitoring system designed for continuous and contactless monitoring of respiration rate. The system is intended to be used at healthcare facilities, and can notify healthcare personnel when a patient's respiration rate is above or below configurable alarm limits. As an addition, an optional pulse oximeter can be connected for monitoring of pulse rate and oxygen saturation. The system is operated from a touch display which graphically presents the numerical measurements and trends. The system can be configured to communicate with a remotely connected system. Guardian M10 is available in two device configurations: stationary configuration and mobile configuration.

This chapter gives information about the device configurations and their components.

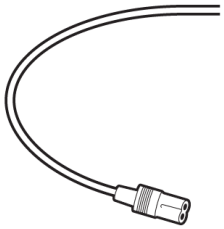
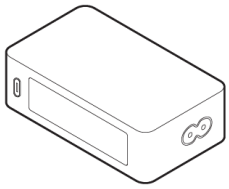
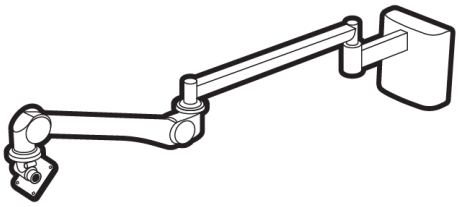
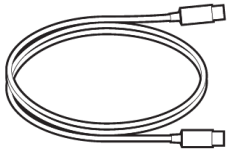
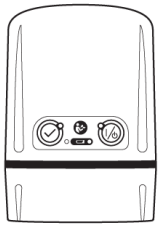
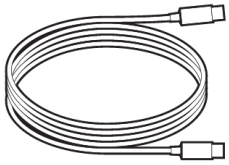
2.1 General description

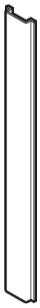
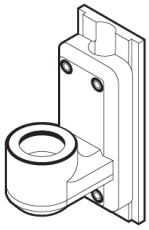
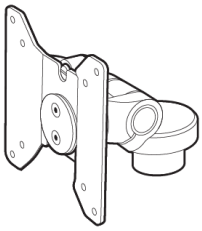
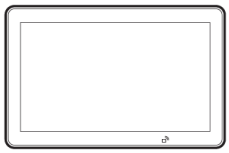
Guardian M10 has two device configurations:

- Stationary configuration, where the sensor unit is installed on an adjustable arm over the patient’s bed. The stationary configuration is connected to the mains power supply, and it is intended to be installed at the same location over a long time.
- Mobile configuration, where the sensor unit is installed on a trolley that is placed next to the bed. The mobile configuration is battery operated, and it can be transported to a location where monitoring is necessary.

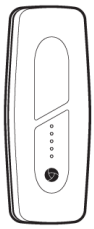
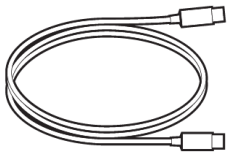
Both configurations of the system have the same indications for use on page 6.

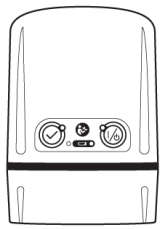
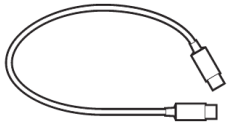
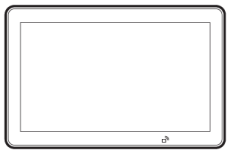
Stationary configuration

Callout	Picture	Part (part number)	Description
A		Power chord IEC 60320 C7	The chord connects the system to main power. Provided by the installer.
B		Sensor Unit USB-C Power Supply (VT50031)	The power supply gives power to the system.
C		Sensor Unit Wall Mount Arm (VT50033)	The sensor unit is installed on the wall mount arm. It can be adjusted and moved.
D		USB-C Cable - 2.2 m (VT60001)	The 2.2 metre USB-C cable connects the sensor unit to the power supply.
E		Guardian M10 (sensor unit) (VT50024)	The sensor unit measures the respiration rate of the designated patient.
F		USB-C Cable - 4.0 m (VT25029)	The 4.0 metre USB-C cable connects the display unit to the sensor unit.

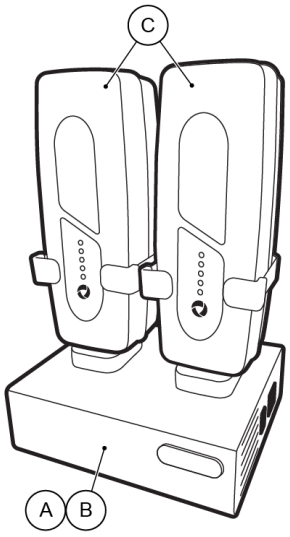
Callout	Picture	Part (part number)	Description
G		Display Unit Wall Mount - Track - 946 cm (VT50037)	The track holds the track mount bracket and houses the display unit cables.
H		Display Unit Wall Mount - Track Mount Bracket (VT50038)	The track mount bracket attaches to the track and holds the display unit bracket.
I		Display Unit Wall Mount - Display Unit Bracket (VT50039)	The display unit bracket attaches to the track mount bracket.
J		Display Unit (VT50028)	The display unit shows all measurement results. It controls all operation of the system, including alarm handling, patient registration, and connecting the optional pulse oximeter.

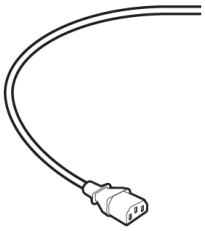
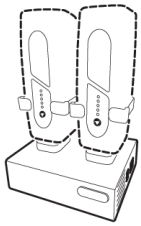
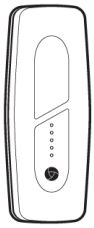
Mobile configuration

Callout	Picture	Part	Description
A		Trolley - Base (VT50017)	The trolley is used as the base for the mobile configuration. The sensor unit, display unit and docking station are installed onto it.
B		Trolley - Battery Dock (VT58000)	The docking station houses the trolley battery.
C		Trolley Battery - C200 (VT58001)	The trolley battery is the main power supply for the mobile configuration.
D		USB-C Cable - 1.4 m (VT60000)	The 1.4 metre USB-C cable connects the trolley battery docking station and the sensor unit.

Callout	Picture	Part	Description
E		Guardian M10 (sensor unit) (VT50024)	The sensor unit measures the respiration rate of the designated patient.
F		USB-C Cable - 0.5 m (VT25028)	The 0.5 metre USB-C cable connects the sensor unit and the display unit.
G		Display Unit (VT50028)	The display unit shows all measurement results. It controls all operation of the system, including alarm handling, patient registration, and connecting the optional pulse oximeter.

In addition to the mobile configuration, there is at least one battery charging station and a spare battery.



Callout	Picture	Part	Description
A		Power chord IEC 60320 C13	The chord connects the charging station to main power. Provided by the installer.
B		Trolley Battery Charging Station - Dual (VT58002)	The charging station recharges the batteries.
C		Trolley Battery - C200 (VT58001)	The trolley battery is the main power supply for the mobile configuration.

2.2 Compatibility statements

The Guardian M10 system consists of a display unit and a sensor unit. The system can be used by itself, but without a pulse oximeter, it does not support oxygen saturation or pulse rate measurements.

Nonin WristOx$_2$® Model 3150 Pulse Oximeter BLE with 8000S Series reusable soft sensors are required for the system to support oxygen saturation and pulse rate measurements. You must order the pulse oximeter from the Guardian M10 manufacturer or distributor to prevent accidentally ordering an incompatible pulse oximeter.

3 Installing the physical components

This chapter gives information about the installation of the physical components of the Guardian M10 patient monitoring system, including the procedures required before and after installing the configurations.

3.1 Unpacking and inspection

Check the sales package upon delivery. After unpacking, always inspect the delivered units and parts to make sure they are correct and undamaged.

3.1.1 Contents of the sales packages

Each package contains a single part. See the tables below for all packages and the configurations they belong to.

Stationary configuration

Package	Contents (part number)	A manufacturer's manual is included
Guardian M10 (sensor unit)	VT50024	No
Display Unit	VT50028	Yes
Sensor Unit USB-C Power Supply	VT50031	No
Sensor Unit Wall Mount Arm	VT50033	Yes
Display Unit Wall Mount - Track - 946 cm	VT50037	Yes
Display Unit Wall Mount - Track Mount Bracket	VT50038	Yes
Display Unit Wall Mount - Display Unit Bracket	VT50039	Yes
USB-C Cable - 2.2 m	VT60001	No
USB-C Cable - 4.0 m	VT25029	No

Mobile configuration

Package	Contents (part number)	A manufacturer's manual is included
Guardian M10 (sensor unit)	VT50024	No
Display Unit	VT50028	Yes
IP22 Label & Instructions	VT50034	Yes
Trolley - Base	VT50017	Yes
Trolley - Battery Dock	VT58000	No
Trolley Battery - C200	VT58001	Yes
Trolley Battery Charging Station - Dual	VT58002	Yes
USB-C Cable - 1.4 m	VT60000	No
USB-C Cable - 0.5 m	VT25028	No

Accessories

Package	Contents (part numbers)	Comes with a separate manual
Nonin WristOx$_2$® Model 3150 Pulse Oximeter BLE with 8000S Series reusable soft sensors	VT57000, VT57001, VT57002, VT57003, VT57004, VT57005, VT57006 (Models for different finger sizes)	Yes

3.1.2 Unpacking and inspecting the units

Make sure you are in a clean, well-lit, and clutter-free area before unpacking. Use appropriate tools, such as scissors or a box cutter, to open the packaging carefully. Make sure the tool is directed away from the body and the contents inside to prevent accidental damage.

Unpacking

1. Gently place the package on a flat surface.
2. Remove any tapes or seals using an appropriate tool.
3. Open the box or package and carefully remove each item, placing them on a flat surface.

4. Make sure to check all sides or compartments of the package to ensure no items are overlooked.

Disposal of the packaging materials

Flatten cardboard boxes for recycling or reuse. Recycle plastic materials, such as bubble wrap or plastic bags, in appropriate recycling bins, or reuse them if possible. Place polystyrene or foam inserts in general waste bins unless there's a specific recycling option available.

Disposal of the accompanying documents

For sensitive documents like invoices or bill of lading, it is recommended to shred them to maintain privacy and prevent any unauthorized use. For non-sensitive documents, you can either keep them for future reference or recycle them.

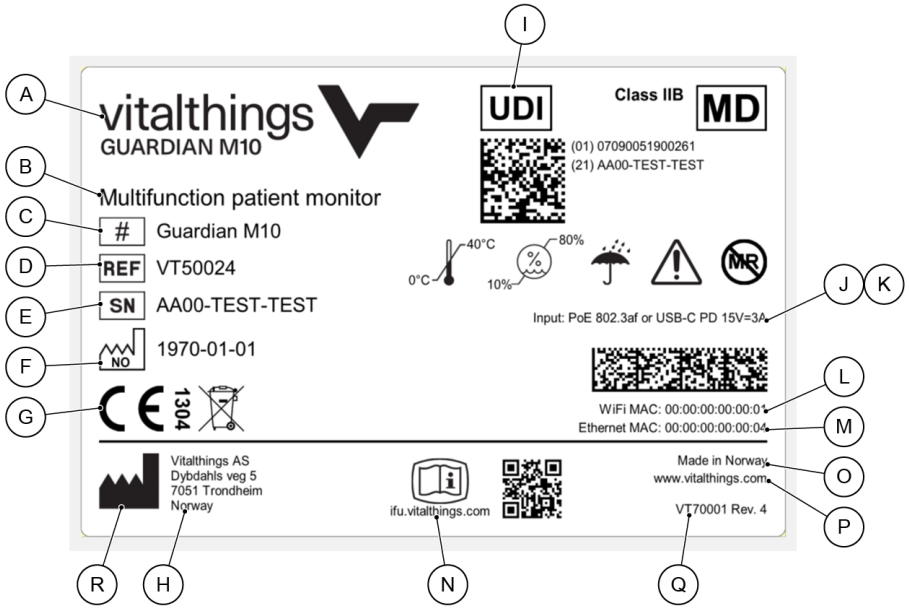
Checking the contents against the package list

- Each package should include a list of contents or an inventory slip.
- Lay out all the unpacked items and cross-check them against the provided list, and items of the sales package as specified in this manual. Ensure all items are accounted for.
- In case of any missing items, contact the supplier or manufacturer immediately.

Examining for shipping damage or broken seals

1. Inspect each item for any visible signs of damage, such as cracks, dents, or broken parts.
2. Check the seals of all devices and components. Broken or tampered seals can indicate potential damage or unauthorized access.
3. If you discover any signs of shipping damage or broken seals, document the damage with photographs and contact the supplier or manufacturer for guidance.

3.1.3 Product identification



The product label identifies Guardian M10.

Callout	Field	Content	Additional information
A	Product name	Vitalthings Guardian M10	
B	Type of product	Multifunction patient monitor	
C	Model (#)	Guardian M10	
D	Part number	VT50024	
E	Serial number	AA00-TEST-TEST	Each device has a unique serial number.
F	Manufacturing date	YYYY-MM-DD	ISO8601 format
G	Compliance marking	CE	
H	Manufacturer	Vitalthings AS Dybdahls veg 5 7051 Trondheim Norway	
I	UDI	GS1 DataMatrix containing fields: 01 UDI-DI (GTIN) 21 Serial number	Each device has a unique serial number. The combination of the part number and the revision defines the device.
J	Power over ethernet (PoE)	802.3af	The implemented PoE standard
K	USB-C PD	15V-3A	The implemented USB-C PD power delivery
L	Wi-Fi MAC address	MAC (Media Access Control) / hardware address for the Wi-Fi station interface	
M	Ethernet MAC address	MAC (Media Access Control) / hardware address for the Ethernet interface	

Callout	Field	Content	Additional information
N	Instructions for use	URL & QR code with link to online representation	
O	Country of origin	Made in Norway	
P	Manufacturer homepage	www.vitalthings.com	
Q	Label part number and revision	VT70001	
R	Symbols	See the symbols table below	

The serial number is unique over the complete range of Vitalthings products. Test results from manufacturing are stored and can be referenced by serial number.

Symbols

Symbol	Title	Description	Reference
CE 1304	CE mark with Notified Body number	Indicates that the manufacturer of the product affirms its compliance with the relevant EU legislation. If stipulated in any EU product legislation, assessment by a Notified Body or manufacturer according to a certified production quality system may be required. Where relevant, after the CE mark a registration number of the notified body involved in conformity assessment is added.	(EU) 2017/745
	WEEE	Indicates that separate collection for waste electric and electronic equipment (WEEE) is required.	IEC 60417 Ref. No.: 6414
#	Model number	Identifies the model number or type number of a product.	IEC 60417 Ref. No.: 6050
REF	Catalogue number	Identifies the manufacturer's catalogue number.	ISO 7000 Ref. No.: 2493
SN	Serial number	Identifies the manufacturer's serial number.	ISO 7000 Ref. No.: 2498

Symbol	Title	Description	Reference
	Country of manufacture	Identifies the country of manufacture of the product. The two-letter ISO 3166-1 country code within the symbol indicates the product's country of manufacture. The manufacturing date is placed next to this symbol.	IEC 60417 Ref. No.: 6049
	Manufacturer	Identifies the manufacturer of a product.	ISO 7000 Ref. No.: 3082
	Medical device	Indicates that the item is a medical device.	ISO 15223-1 Ref No.: 5.7.7
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.	ISO 15223-1 Ref No.: 5.7.10
	Electronic instructions for use	Indicates on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.	ISO 7000 Ref. No.: 3500
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed. To indicate that the current situation needs operator awareness or operator action in order to prevent undesirable consequences.	ISO 7000 Ref. No.: 0434B
	Keep away from rain	Indicates that the equipment must be kept away from rain and in dry conditions.	ISO 7000 Ref. No.: 0626
	Temperature limit	Indicates the maximum and minimum temperature limits at which the item must be stored, transported or used.	ISO 7000 Ref. No.: 0632
	Humidity limitation	Indicates the acceptable upper and lower limits of relative humidity for transport and storage.	ISO 7000 Ref. No.: 2620
	MR Unsafe	Indicates that the medical device should not enter or be placed in the MRI scanner room.	ASTM F2503 “MR Unsafe”

3.2 Installing the stationary configuration

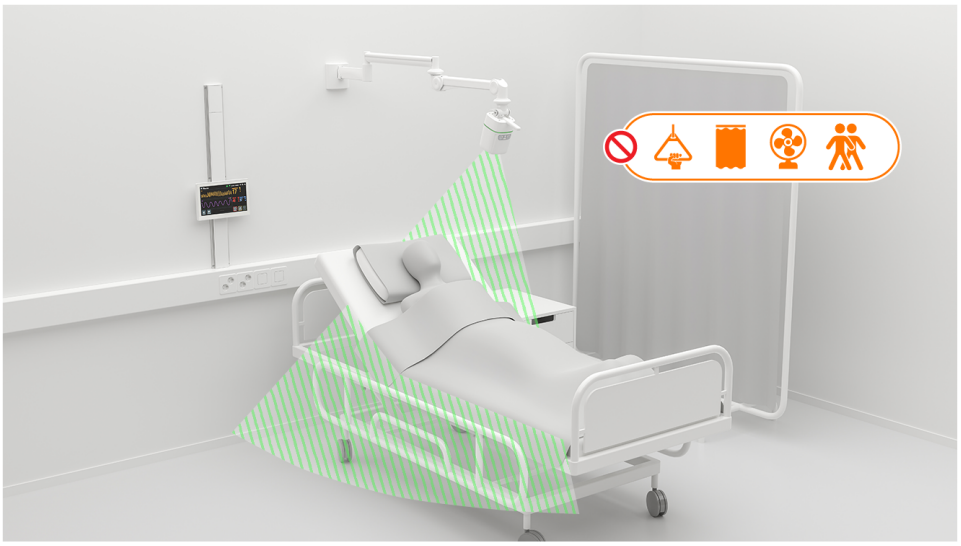
Installing the stationary configuration covers the assembly, positioning and connection of the physical components.

3.2.1 Positioning the components

> ⚠ **Precaution**
> Do not install or use the system closer than one metre from a Wi-Fi access point.
> Device can negatively affect/be negatively affected by Wi-Fi radio signals in close proximity to the sensor unit.

Ensuring the correct positioning of the system components is crucial for optimal patient monitoring and minimizing potential disturbances. Follow the guidelines below for the correct placements of the sensor unit and the display unit when installing the stationary configuration.

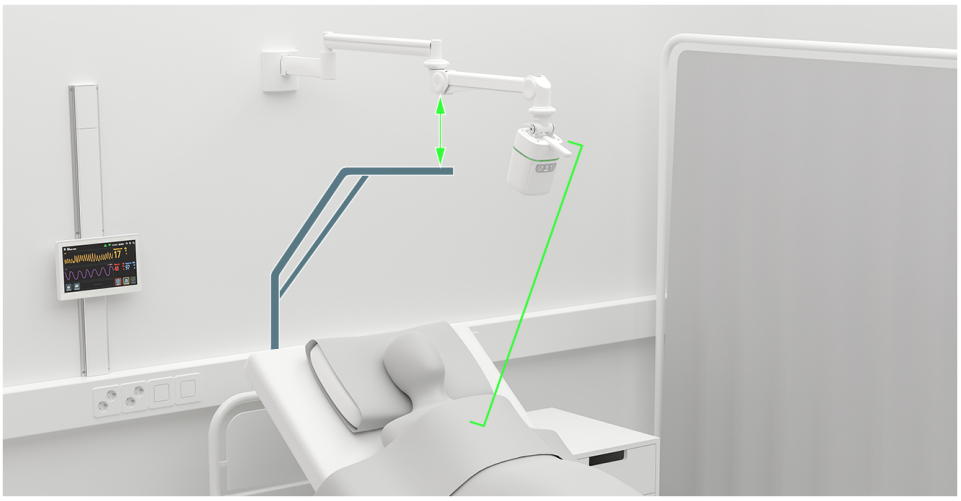
Positioning the sensor unit



The sensor unit should be positioned so that patient's chest stays within the optimal zone even if they move around in bed, sit up or lie down. This ensures the highest accuracy in readings.

Take precautions to minimize the potential for disturbances from other individuals or objects, in all the monitoring zones. For a comprehensive understanding of these zones and any features to take into consideration when positioning the sensor unit, see "Instructions for Use", and the following sections:

- "Monitoring zones"
- "Checking that the sensor unit is correctly positioned"
- "Checking that no objects conflict with the functioning of the system"



When placing the wall mount arm of the sensor unit, make sure that the distance between the patient's chest and the sensor unit can be adjusted within the range of 0.5 to 2.0 metres. Make sure that the installation position of the wall mount arm does not interfere with any standard equipment which may not be present in the room at the time of installation, such as the bed trapeze.

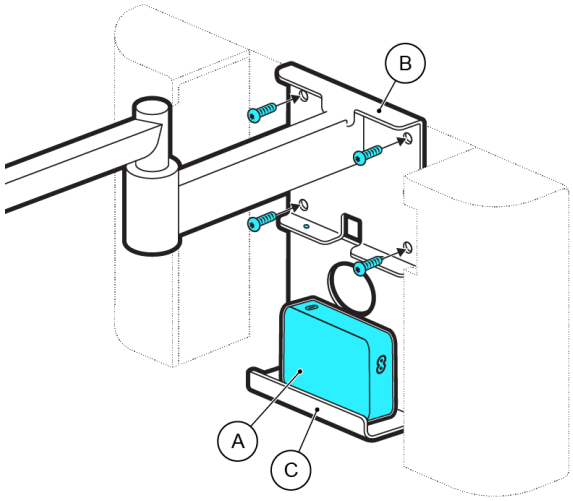
Positioning the display unit

The display unit track should be placed so that the display itself can be adjusted to a comfortable and ergonomic working height for the healthcare personnel, and its placement will not cause the display or the person using it to enter the optimal zone. The placement of the display unit should not interfere with any bed adjustments either, or prevent moving the bed to and from the room.

3.2.2 Installing the sensor unit

Install the sensor unit as the first part of the physical component installation.

Installing the power supply and wall mount arm



Callout	Part (part number)
A	Power supply (VT50031)
B	Wall mount arm (VT50033)

After you have found a suitable location for the stationary configuration, follow the instructions provided in the manufacturer's manual to complete these next steps:

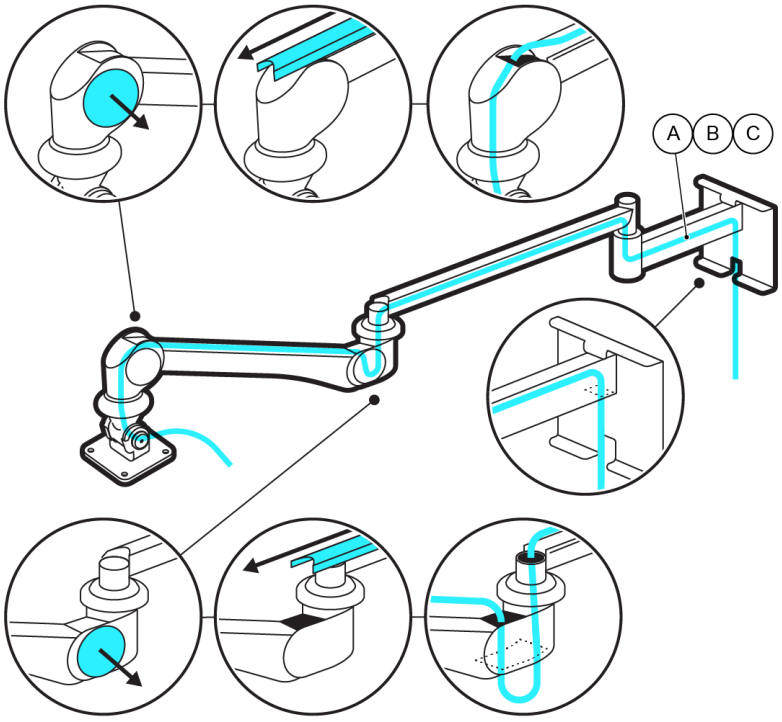
1. Attach the bracket (C) where the power supply is held to the wall mount arm bracket (B).
2. Attach the wall mount arm to the wall.
3. Place the power supply (A) on its bracket.

Note that the covers hiding the power supply should not be placed back over the base of the wall mount arm, as the cables will be connected at a later installation stage.

Routing the cables inside the wall mount arm

> Notice: If you are uncertain about any part of the routing process, or if the system seems to not operate correctly after routing, consult with a professional technician or refer back to the manufacturer's guidelines.

The cables can be routed already upon delivery, in which case they must still be checked to make sure they have not been affected by the transport.



Callout	Part (part number)
A	The 2.2 metre USB-C cable (VT60001)
B	The 4.0 metre USB-C cable (VT25029)
C	Installer provided network cable (Optional)

Cables have been routed pre-delivery

- Make sure that the cables are securely and neatly routed inside the wall mount arm: they should be free of any noticeable kinks, bends or potential pinch points.
- Identify the connection points where the cables exit the wall mount arm to help integration with other parts.

Cables must be routed on site

Make sure you have a screwdriver ready at hand before you begin. If necessary, you can take the wall mount arm off from the wall to make routing easier.

1. Remove the plastic cover on the upper part of the arm.
2. Use a screwdriver and remove the plastic covers that surround the bendable joints on the lower part of the arm.
3. Slide out the plastic cover from the lower part of the arm.
4. Route the cables, starting from behind the VESA mount. Make sure the cables exit behind the VESA mount with sufficient length so they can be easily connected to the sensor unit.
5. Make sure the cables cannot slip, sag or get pinched when the position of the wall mount arm is adjusted, but so that they are not too tight either.
6. Reinstall all plastic covers.

Cables must be changed due to wear and tear

1. Disconnect the old cables.
2. Follow the installation procedure for “Cables must be routed on site” to remove the plastic covers.
3. Remove the broken cable or cables.
4. Follow the installation procedure for “Cables must be routed on site” to route the replacement cables.

With both the pre-routed and/or on-site routed cables, test the wall mount arm’s movement. The movement should be smooth and the cables should not be pulled tight or pinched even if the wall mount arm is adjusted. This must be the case even after the cables are connected to the respective parts. Correct routing is essential to prevent potential hazards and maintain the correct functioning of the system.

Installing the sensor unit to the wall mount arm

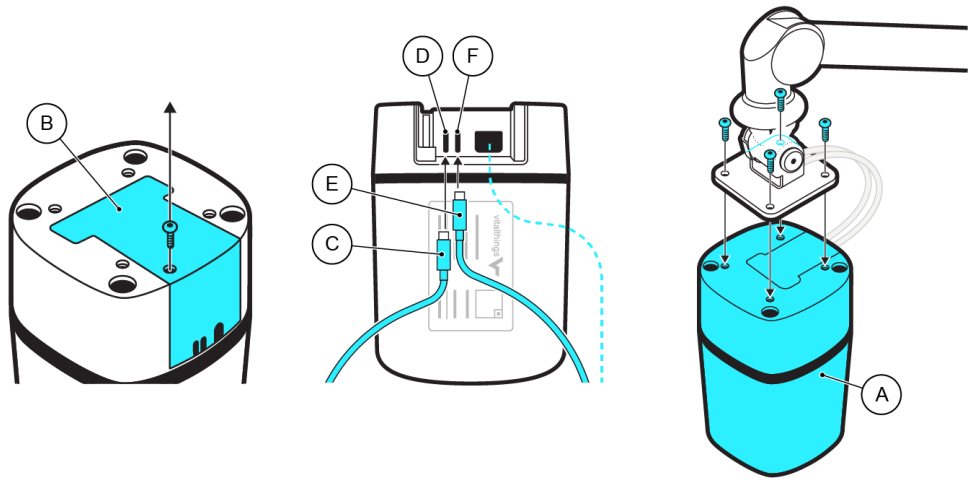
ⓘ Notice: Always refer to the manufacturer's guidelines specific to your sensor unit and wall mount arm when installing the components. If at any stage you are uncertain or encounter issues, seek guidance from the manufacturer or a professional technician.

Notice: The wall mount arm has an adjustable spring for balancing a load. See the manufacturer's manual for further details and adjustment procedures.

Once the wall mount arm is in place, install the sensor unit to the VESA mount at the end of the wall mount arm. Proper installation ensures stability, safety, and optimal device performance.

Before you begin, make sure that:

- You have all the necessary tools and components ready at hand. This includes screws and screwdrivers.
- Make sure that the wall mount arm is securely fixed to the wall and it can withstand the weight of the sensor unit.
- Make sure that the sensor unit's mounting points match with the attachment points on the wall mount arm.



Callout	Part (part number)
A	Sensor unit (VT50024)

1. Remove the back cover (B) on the sensor unit.
2. Connect the 4.0 metre USB-C cable (C) to the display connector (D) and the 2.2 metre USB-C cable (E) to the power connector (F) on the sensor unit. Additionally, if you use Ethernet as a connection option, connect the Ethernet cable to the designated port on the sensor unit at this stage as well.
3. Put the back cover back on the sensor unit.
4. Hold the sensor unit close to the wall mount arm, and align the mounting points of the sensor unit with the attachment points on the VESA mount.
5. Use the designated screws to secure the sensor unit onto the wall mount arm. Make sure screws are tightened appropriately, but avoid over-tightening, which might damage the sensor unit.
6. Make sure that, when connected, the cables attached to the sensor unit are not tangled or strained due to the installation process.
7. Gently test the stability of the sensor unit by applying slight pressure. It should feel firm and not wobble or move. If needed, adjust the wall mount arm spring for balancing the load according to the manufacturer's manual.

8. Adjust the wall mount arm to various positions to confirm that this does not strain or dislocate the sensor unit.

3.2.3 Installing the display unit

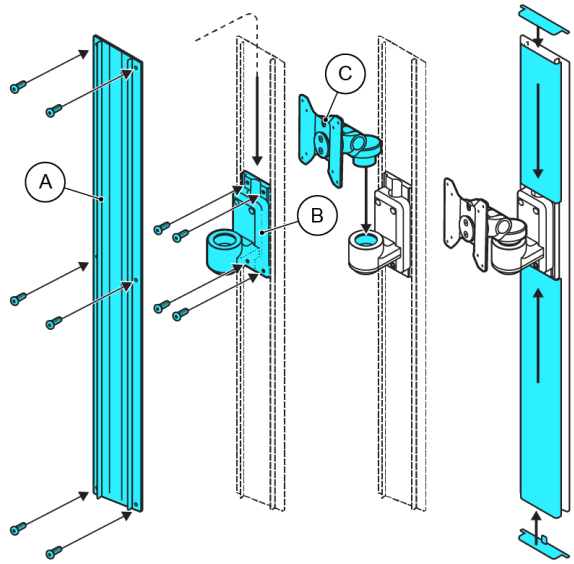
After the sensor unit is in place, install the display unit.

Installing the track and display unit bracket

> Notice: The track mount and display unit brackets are parts that come with their own manuals. Follow the instructions carefully. In case of conflicting information on how to install the part, follow the manufacturer's instructions.

Before you begin, make sure you have all the necessary tools ready, the wall type assessed, and the height decided:

- Tools required: a drill, wall anchors, screws, a level, a pencil, and a measuring tape.
- Wall assessment: determine that the type of wall (for example, drywall, plaster, brick or concrete) you are working with is compatible with the bracket's requirements.
- Height: determine the appropriate height for the display unit, considering ergonomics and the ease of view for healthcare personnel. The track must be located in relation to the wall mount arm's base so that the 4.0 metre USB-C cable from the sensor unit can be connected to the display unit. The cable channel in the track can be used to route the cable.



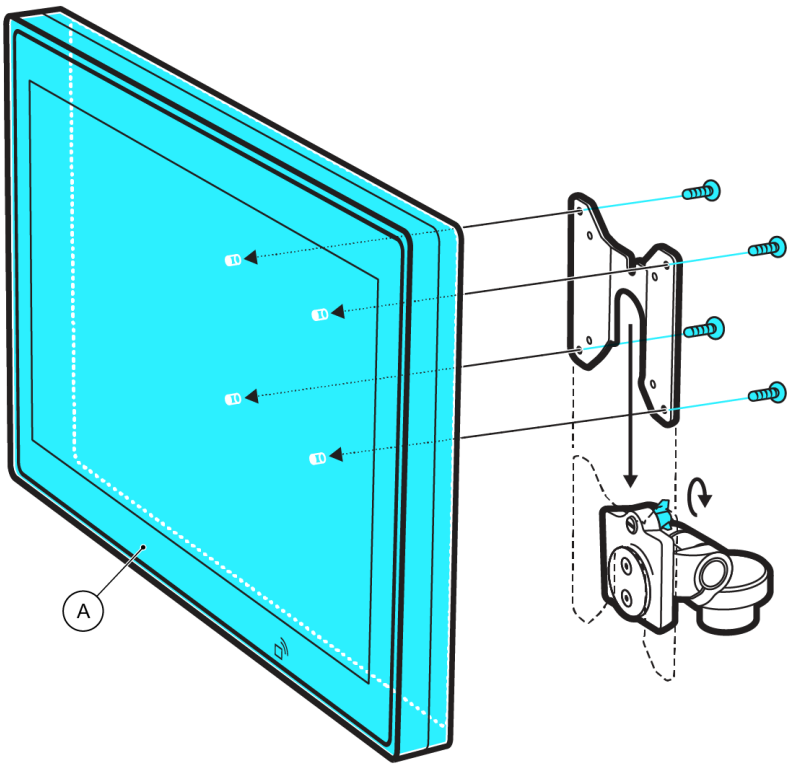
Callout	Part (part number)
A	Track (VT50037)
B	Track mount bracket (VT50038)
C	Display unit bracket (VT50039)

1. Hold the track (A) against the wall at the desired position, ensuring that it is level.
2. Use a pencil to mark the wall through the track's mounting holes to indicate where to drill.
3. Make holes at the marked spots. Make sure they are the right depth and width, following the manufacturer's specifications.
4. If the wall type requires it, insert wall anchors into the drilled holes.
5. Position the track over the holes and use the appropriate screws to secure it. Check for firmness.
6. Remove the track’s plastic covers.
7. Install the track mount bracket (B) at the height where the display unit should be located according to the manufacturer’s instructions.
8. Install the display unit bracket (C) into the track mount bracket according to the manufacturer’s instructions.

Install the track’s plastic covers after the cable to the display unit has been routed at a later installation stage.

Installing the display unit to the display unit bracket

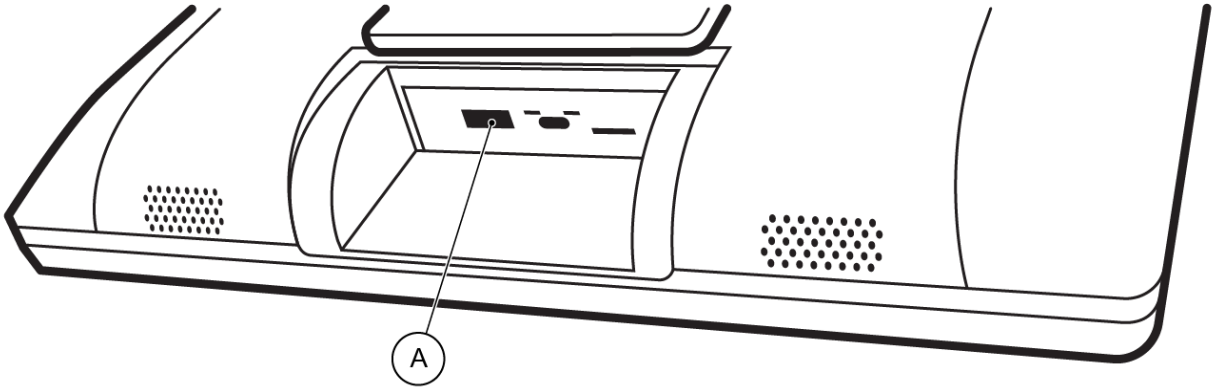
Before you begin, make sure that the display unit bracket is secure and it does not wobble or become loose, and any cables or power sources are disconnected from the display unit.



Callout	Part (part number)
A	Display unit (VT50028)

1. Detach the VESA mount from the display unit bracket by rotating and pulling the small handle on the back of the mount plate.
2. Carefully align the mounting points on the back of the display unit with the VESA mount of the display unit bracket.
3. Use screws to fasten the display unit to the VESA mount.
4. Place the display unit with the VESA mount back onto the display unit bracket. Turn slightly until the mount plate slots into a locked position.
5. Gently test the display unit's stability by lightly pushing it. It should not wobble or move.

3.2.4 Connecting a barcode scanner (Optional)

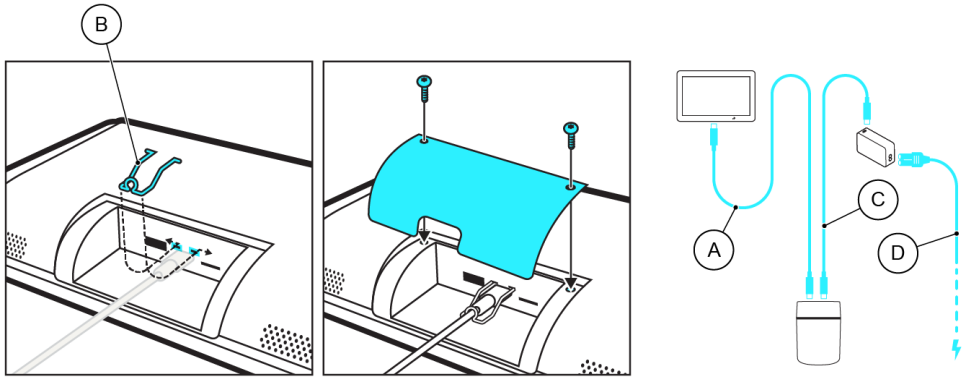


You can connect any barcode scanner equipped with a USB interface to the unit (A). Once connected, the scanner can serve as an alternative to manual keyboard entry, allowing you to scan barcodes to input data directly into a field.

After connecting the scanner, make sure that the scanner operates as expected by scanning an example barcode and confirming that the corresponding information is shown on the display unit.

3.2.5 Connecting the cables of the stationary configuration

Notice: Always refer to the specific guidelines provided when connecting cables. If any issues arise or you are unsure about a particular connection, consult the manufacturer’s manuals and instructions, or contact the manufacturer's support team.



1. Connect the 4.0 metre USB-C cable (A) from the sensor unit to the display unit. Apply the strain relief (B) on the back of the display unit so the cable cannot be unintentionally disconnected.
2. Connect the 2.2 metre USB-C cable (C) from the sensor unit to the power supply.
3. If you use Ethernet as a connection option and you connected the Ethernet cable as part of installing the sensor unit to the wall mount arm on page 31, connect the Ethernet cable from the sensor unit to the nearest available Ethernet port at this stage.
4. Connect a power chord (D) from the power supply to main power.
5. Confirm that each cable is firmly connected to its respective and appropriate port. Misconnection can lead to malfunctions.
6. Turn on the system and confirm that there are no technical alarms or issues.

Check the functionality of the system and the condition of the cables regularly.

3.2.6 Performing initial checks on the stationary configuration

Do the following checks after you have installed all the physical components.

Stability check

Apply slight pressure to the display unit and the sensor unit to check their stability. The units should remain steady, without any signs of wobbling or shifting. The sensor unit should not sway or move after its position is adjusted.

Functionality test

Turn on the system to check that the system self-test is successful. For information on turning on the system and the confirmation of a successful or an unsuccessful self-test, see Running a system self-test on page 57.

Speaker test

In *Main view*, tap the volume icon to open the adjustment pop-up, and then tap the ***Test display unit speaker*** button. If there is no sound, the test is unsuccessful, and you must not take the unit to use. Contact the manufacturer for correct recovery procedure.

Positioning and adjustments

If needed, adjust the display unit's height. Make sure that adjustments do not compromise the stability of the unit, and it stays where it is after adjustment.

3.3 Installing the mobile configuration

Installing the mobile configuration covers the assembly, positioning and connection of the physical components.

3.3.1 Positioning the components

The position of the mobile configuration is adjusted by the user before each monitoring session, so its positioning is not crucial at the installation stage.

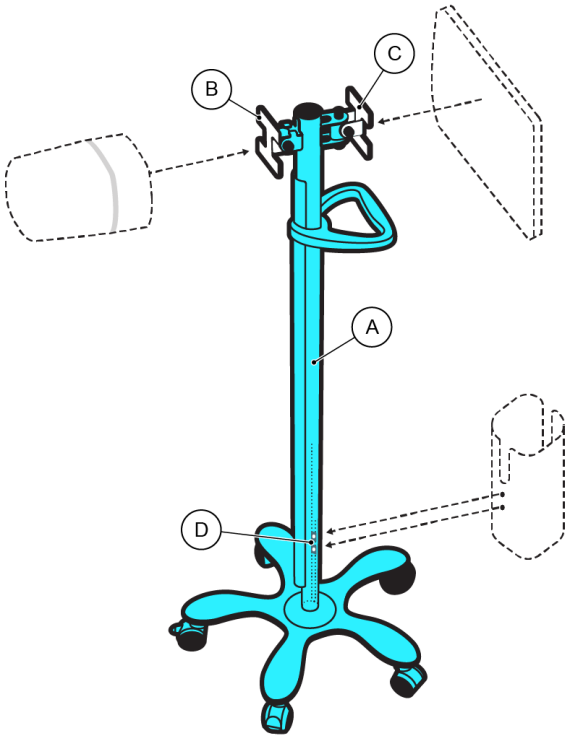
Positioning the sensor unit

The sensor unit is attached to the trolley, so it is moved alongside the trolley, and does not require specific adjustment at installation stage.

Positioning the display unit

The display unit is attached to the trolley, so it is moved alongside the trolley, and does not require specific adjustment.

3.3.2 Assembling the trolley



Callout	Part (part number)
A	Trolley (VT50017)

Follow the instructions provided in the manufacturer's manual to assemble the trolley with a bracket for the sensor unit (B), a bracket for the display unit (C), and mounting points for the docking station (D). Note that the display unit bracket and the docking station should be on the same side.

The trolley handle should not be installed before the cables have been routed at a later installation stage. If the instructions include the installation of a basket, do not install it, as the space is required for the installation of the docking station.

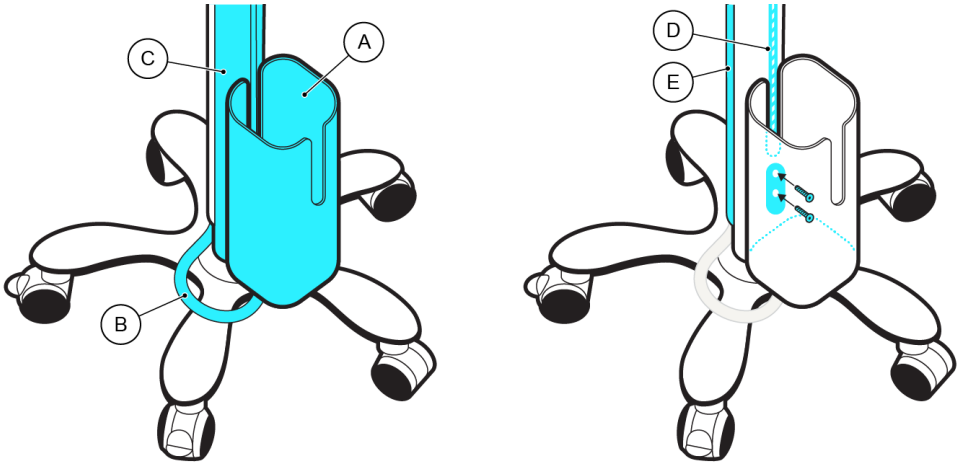
3.3.3 Installing the battery components

The mobile configuration requires a docking station, and a separate charging station.

Installing the docking station to the trolley

> Notice: Make sure that the final assembly mirrors the intended look as described in the visual aids. Should there be any discrepancies in appearance or functionality, recheck all steps. If uncertainties remain, consult the manufacturer's guidelines or contact a professional technician.

Before you begin, make sure you have the designated screws and a screwdriver ready at hand.

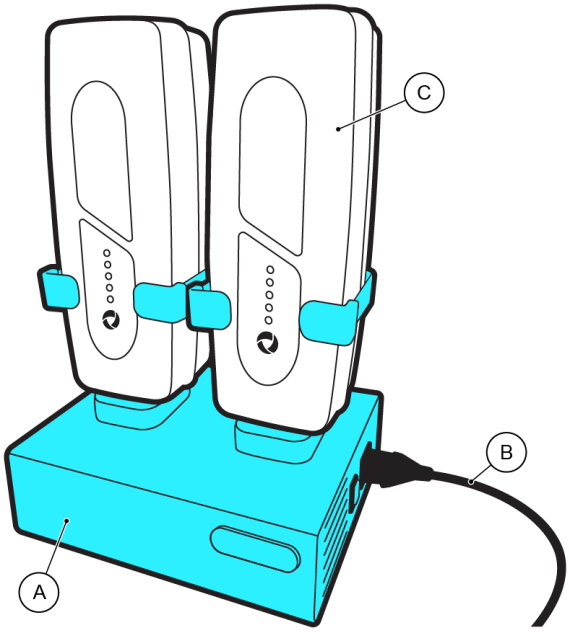


Callout	Part (part number)
A	Docking station (VT58000)
B	The 1.4 metre USB-C cable (VT60000)

1. Connect the 1.4 metre USB-C cable under the bottom cover of the docking station. The bottom cover must be removed and reinstalled as part of this installation step. Use the included strain relief to secure the cable.
2. Align the docking station with the trolley pole tracks: position it at the bottom of the trolley pole (C) to ensure the stability of the trolley.
3. Use the designated screws and mounting plate to fasten the docking station to the clamps in the trolley pole tracks (D).
4. Route the 1.4 metre USB-C cable through the channel on the trolley pole (E) to the top.
5. Gently test the stability of the docking station by applying light pressure. It should be firm, without wobbling or looseness.

To confirm that you have successfully installed the docking station, insert a battery into the docking station and make sure it fits properly.

Installing the charging station

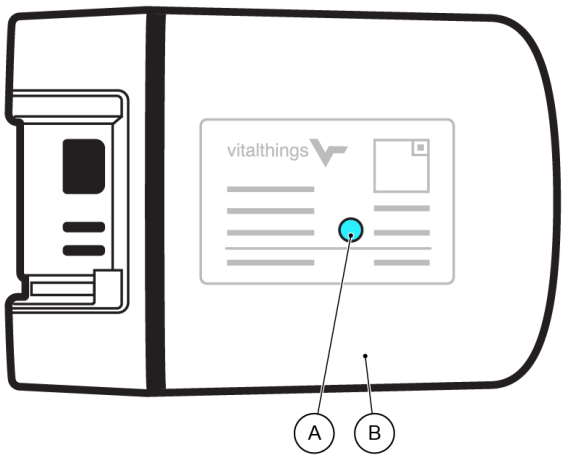


Callout	Part (part number)
A	Charging station (VT58002)
B	Installer provided power chord IEC 60320 C13
C	Trolley battery (VT58001)

Follow the charging station specific manual from the manufacturer for instructions and details on the correct safety and procedure.

After the installation is complete, place the accompanying batteries to the charging station. The batteries must be charged to full capacity in the charging station before their first use to switch off storage mode and ensure correct operation.

3.3.4 Placing the IP22 label



Follow the instructions provided with the label to place the IP22 label (A) on the sensor unit (B).

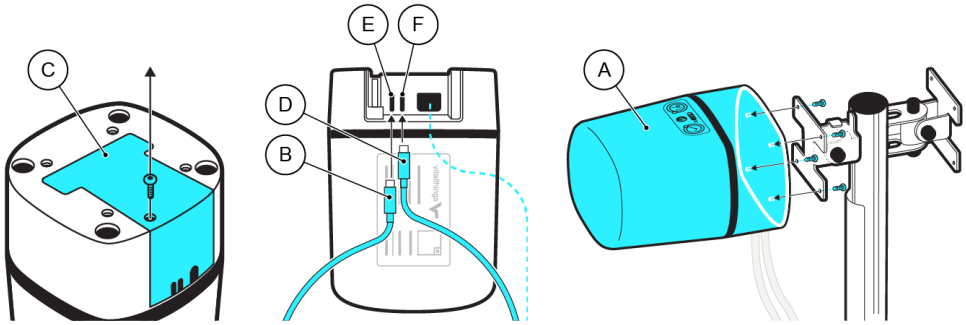
3.3.5 Installing the sensor unit to the trolley

> Notice: Always refer to the manufacturer's guidelines specific to your sensor unit and trolley when mounting the components. If at any stage you are uncertain or encounter issues, seek guidance from the manufacturer or a professional technician.

Once the trolley has been assembled, install the sensor unit onto the VESA mount. Proper mounting ensures stability, safety, and optimal device performance.

Before you begin, make sure that:

- You have all the necessary tools and components ready at hand. This includes screws and screwdrivers.
- The trolley's VESA mount is stable and it can support the weight of the sensor unit.
- The sensor unit's mounting points align with the attachment points on the trolley’s VESA mount.



Callout	Part (part number)
A	Sensor unit (VT50024)

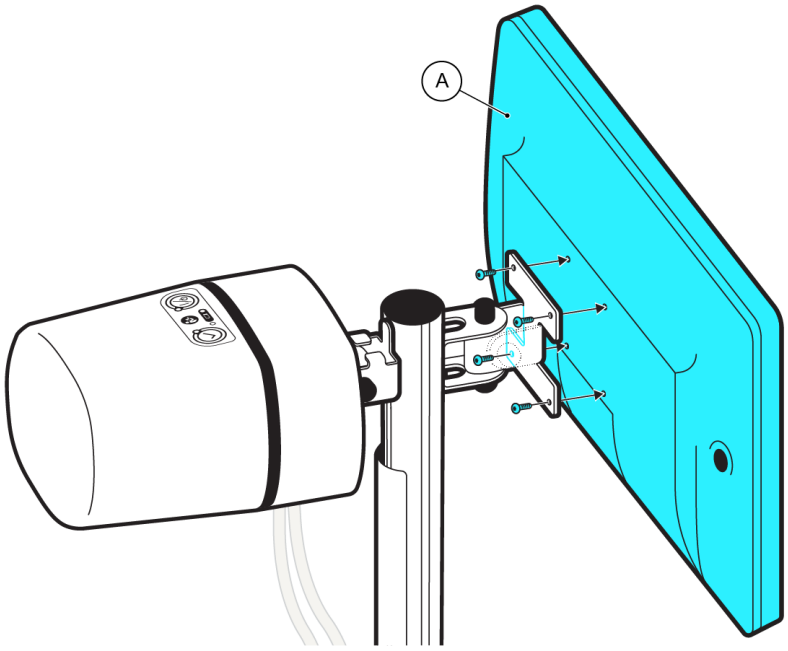
Callout	Part (part number)
B	The 0.5 metre USB-C cable (VT25028)

1. Remove the back cover (C) on the sensor unit.
2. Connect the 0.5 metre USB-C cable (B) to the display connector (E) and the 1.4 metre USB-C cable (D) to the power connector (F) on the sensor unit.
3. Put the back cover back on the sensor unit.
4. Hold the sensor unit close to the trolley, and align the mounting points of the sensor unit with the attachment points on the VESA mount.
5. Use the designated screws to secure the sensor unit onto the VESA mount. Make sure screws are tightened appropriately, but avoid over-tightening, which might damage the unit.
6. Gently test the stability of the sensor unit by applying slight pressure. It should feel steady and not wobble or move.
7. Adjust the angle of the sensor unit to confirm that this does not strain or dislocate the cables.

3.3.6 Installing the display unit to the trolley

> Notice: Always refer to the manufacturer's guidelines specific to your display unit and trolley when installing the components. If at any stage you are uncertain or encounter issues, seek guidance from the manufacturer or a professional technician.

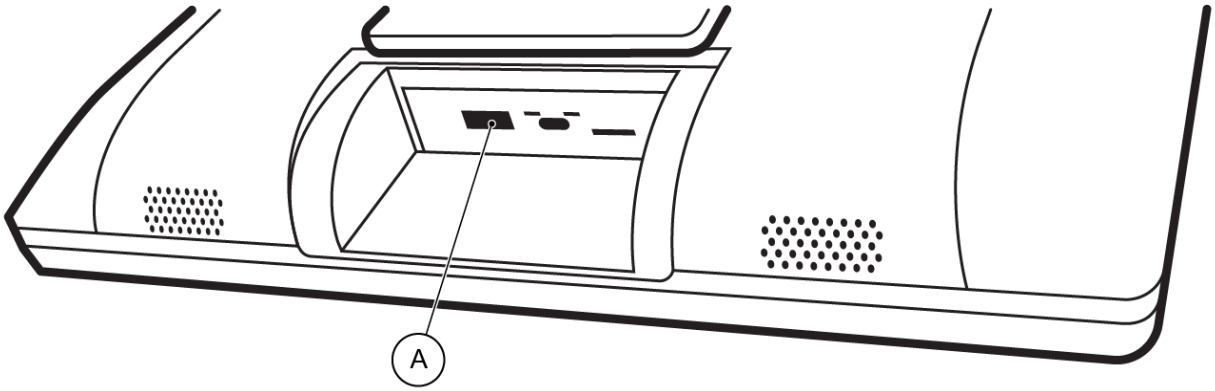
Before you begin, make sure you have the designated screws and a screwdriver ready at hand.



Callout	Part (part number)
A	Display unit (VT50028)

1. Carefully align the mounting points on the back of the display unit with the VESA mount of the trolley. Note that the display unit position is on the opposite side of the trolley pole from the sensor unit.
2. Use the designated screws to fasten the display to the VESA mount. Make sure screws are tightened appropriately, but avoid over-tightening, which might damage the unit.
3. Gently test the display unit's stability by lightly pushing it. It should not wobble or move.

3.3.7 Connecting a barcode scanner (Optional)

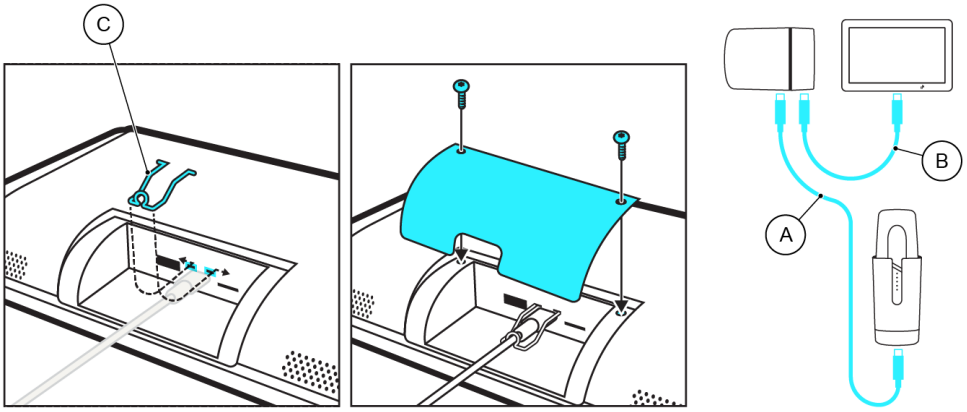


You can connect any barcode scanner equipped with a USB interface to the unit (A). Once connected, the scanner can serve as an alternative to manual keyboard entry, allowing you to scan barcodes to input data directly into a field.

After connecting the scanner, make sure that the scanner operates as expected by scanning an example barcode and confirming that the corresponding information is shown on the display unit.

3.3.8 Connecting the cables of the mobile configuration

ⓘ Notice: Always refer to the specific guidelines provided when connecting cables. If any issues arise or you are unsure about a particular connection, consult the manufacturer’s manuals and instructions, or contact the manufacturer's support team.



1. Make sure that the 1.4 metre USB-C cable (A) routed from the docking station to the sensor unit has remained in place and connected.
2. Connect the 0.5 metre USB-C cable (B) from the sensor unit to the display unit. Apply the strain relief (C) on the back of the display unit so the cable cannot be unintentionally disconnected.
3. Secure any dangling cable ends with cable ties or Velcro straps to prevent them from hanging loosely. The sensor unit has clamps to ensure the cables stay in place.
4. Turn on the system and confirm that there are no technical alarms or issues.

After you have connected and secured the cables, adjust the sensor and display unit angles to simulate typical usage. Monitor for any cables that may snag or become strained during movement, and adjust as necessary. Check the functionality of the system and the condition of the cables regularly.

3.3.9 Performing initial checks on the mobile configuration

Do the following checks after you have installed all the physical components.

Stability check

Apply slight pressure to the display unit to check its stability. The unit should remain steady, without any signs of wobbling or shifting.

Functionality test

Turn on the system to check that the system self-test is successful. For information on turning on the system and the confirmation of a successful or an unsuccessful self-test, see Running a system self-test on page 57.

Speaker test

In *Main view*, tap the volume icon to open the adjustment pop-up, and then tap the ***Test display unit speaker*** button. If there is no sound, the test is unsuccessful, and you must not take the unit to use. Contact the manufacturer for correct recovery procedure.

Backup battery check

If the technical alarm "*Internal backup batteries low*" is present after turning on the system, the backup battery must be charged by placing a fully charged trolley battery in the docking station. After 2 hours of charging, replace the trolley battery with another fully charged battery from the charging station to ensure optimal conditions before the next monitoring session.

If no such alarm is present after turning on the device, no further action is required.

Remember to turn off both the display unit and the sensor unit after this check.

Positioning and adjustments

If needed, adjust the display unit's angle to optimize viewing for healthcare personnel. Make sure that adjustments do not compromise the stability of the unit.

Turn off the system

After performing all initial checks, the system must be turned off. Both the display unit and the sensor unit must be turned off individually by keeping their respective on/off buttons pressed for 10 seconds.

4 Configuring the software

The Guardian M10 software is installed and tested during production. Upon purchasing, the settings in the system are factory settings. Before the units are taken into use, a service technician must review and configure these settings.

4.1 Configuring system settings

> Notice: Adjustments made under administrative settings during an ongoing patient monitoring session will take effect first when the next session is started.

The user can adjust certain system settings during normal operation, but an administrative user is required to adjust the default system settings. This section covers all the default settings a service technician must go through before the system is taken into use. To confirm that the settings configured at this stage are optimal to the intended users, consult the hospital staff on their preferences about the default settings.

Session settings adjusted during an active session are restored to the default settings, as determined by an administrative user, when the system is shut down or a new session is started. If an administrative user changes any default settings after the device is taken into use, these will be the new default settings for the device, and they will take effect the next time a session is started.

4.2 Guidelines on using the system with additional medical devices and other systems

Read the following guidelines for external systems and additional medical devices before proceeding with their configuration.

External systems

Guardian M10 can be connected through the API to external systems. Please refer to the documentation of such remotely connected systems for further details.

Additional medical devices

A pulse oximeter can be connected via Bluetooth to Guardian M10 to provide measurement data on the patient's pulse rate and oxygen saturation.

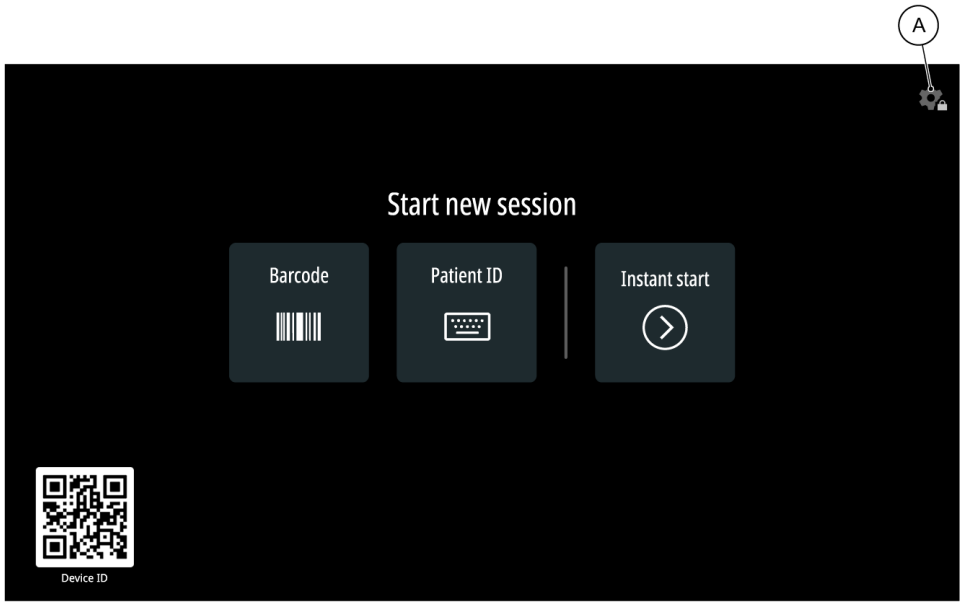
Familiarise yourself with any safety precautions or system requirements of the additional medical devices before configuring any related Guardian M10 settings. Users of Guardian M10 should be aware of any connected medical devices before they take units into use.

When a pulse oximeter is connected, Guardian M10 provides a larger set of physiological and technical alarms (see "Instructions for Use", section "Alarms" for details).

4.3 Logging in

> Notice: The administrative PIN is reserved for service technicians and administrative users only, and should otherwise be kept as private information.

Confirm that the physical components have been installed successfully and the following view is displayed after you turn on the system:



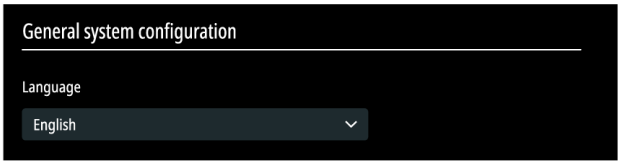
1. Tap the ***Device management view*** icon (A).
2. Enter the ***Administrative*** tab.
3. Enter the default PIN 0460 to unlock the tab and log in.

You can now view and adjust the default system settings.

4.4 Configuring general system settings

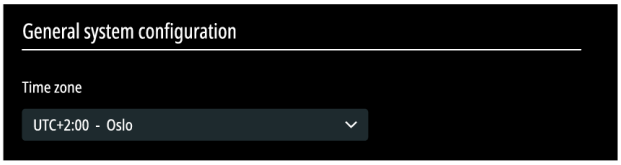
Access general system settings from *Device management view* > ***Administrative*** > ***General system configuration***. These refer to the basic settings, such as display language and sensor unit monitoring distance.

4.4.1 Selecting the language



Select the preferred system language from the drop-down list. The language selected here applies to the entire system.

4.4.2 Selecting the time zone



Select the time zone manually from the drop-down list.

For manual or automatic time and date selection, see Setting the date and time on page 49.

4.4.3 Configuring the sensor unit monitoring distance

Set the preferred maximum distance between the sensor unit and the patient. The distance should be set so that the patient's chest area is always within this distance as measured from the back of the sensor, even if they move in the bed, lie down or sit up.

Keep in mind that the monitoring distances may affect the ways in which the sensor unit can be positioned in any given environment. Do not set a distance that cannot be adhered to, for example: the maximum distance must not be so long that it continuously registers nearby patients, objects or people. For details on the monitoring zones affected by the maximum monitoring distance and what you should take into account, see "Instructions for Use", section "Monitoring zones".

4.5 Configuring connection settings

Access connection settings from *Device management view* > ***Administrative*** > ***Connection settings***.

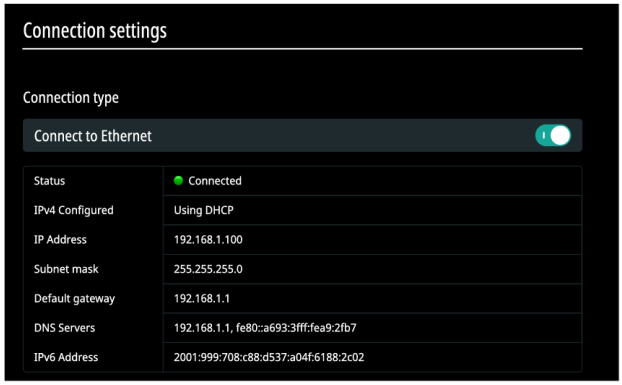
Guardian M10 can communicate with a remotely connected system through the API. For information about what functionality and data are made available through the API, please refer to the instructions or manuals of the remotely connected system.

4.5.1 Configuring connection type

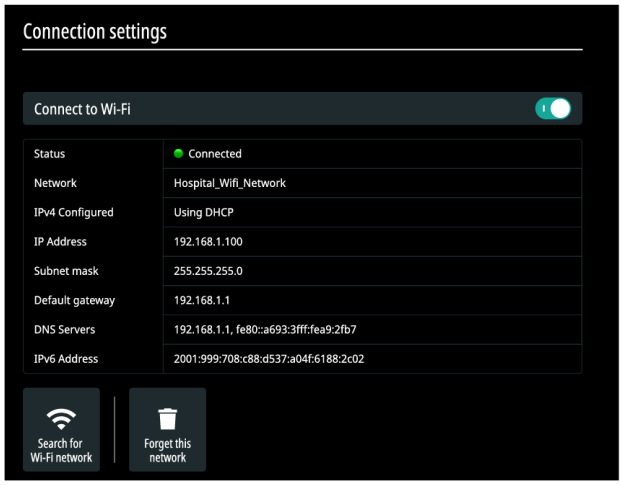
Notice: The Guardian M10 system does not require an internet connection in normal operation.

Notice: If you choose the Ethernet connection, you can still enable and configure the Wi-Fi as well, so it can be used as a backup if the Ethernet connection fails.

Notice: Enterprise authentication (IEEE 802.1X) is not supported in the current system version.



If Ethernet is available and required, the Ethernet connection option can be enabled from ***Connection settings***.

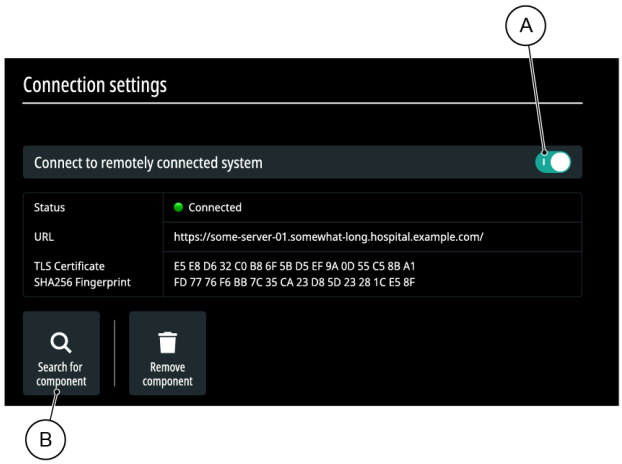


If Wi-Fi is available and required, the Wi-Fi option can be enabled from ***Connection settings***. Tap the ***Search for Wi-Fi network*** button. An adjustment window opens where you can select the network you wish to connect to from the list of available networks.

If you want to change the Wi-Fi network later, tap the ***Forget this network*** button and then search for a Wi-Fi network again.

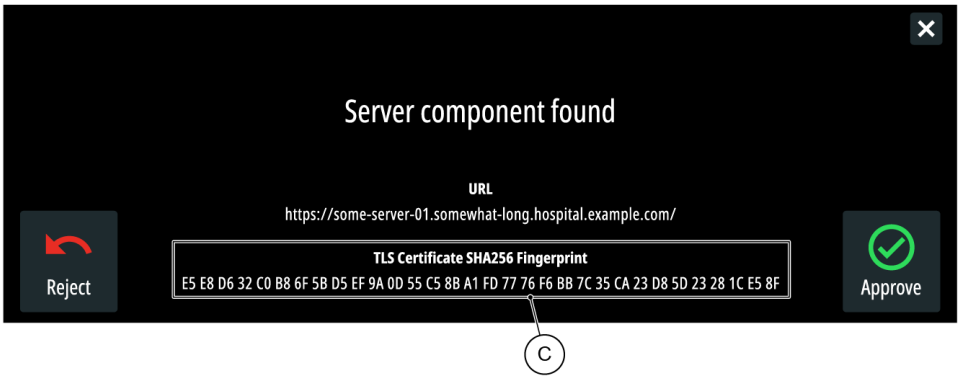
4.5.2 Configuring a connection to a remotely connected system

Notice: The spaces between hexadecimal digits in the SHA256 fingerprints are sometimes replaced by colons.



Use the toggle (A) to enable or disable a connection with a remotely connected system.

If you enable the connection, use the search tool (B) to find the correct provisioning of the connection to the server component.



If a server component is found, a pop-up window is displayed. Check that the displayed SHA256 fingerprint (C) of the server certificate corresponds to the one provided by the manufacturer of the server component. Approve the server component if it is correct.

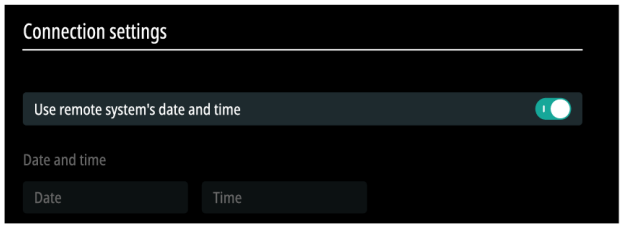
In case a server component is not found, or the two SHA256 fingerprints do not match:

- Check Ethernet cable and/or Wi-Fi signal.
- Confirm that you are connected to the correct network.
- Contact IT staff.

If you want to remove the server component, tap the ***Remove component*** button.

4.5.3 Setting the date and time

Notice: If the unit has been in storage for a long while, always check that the system time is still accurate when the unit is powered on.



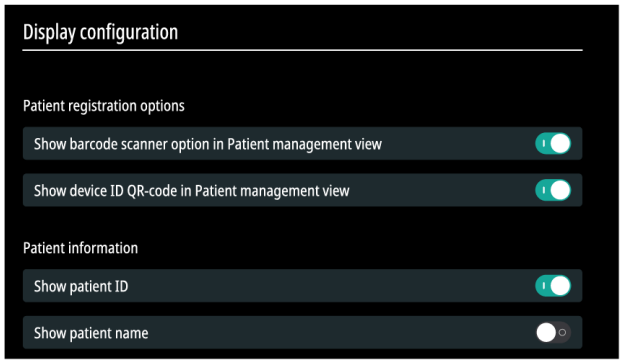
If you've established a connection to a remotely connected system, you can enable the ***Use remote system's date and time*** option to automatically update the date and time.

If a remotely connected system is not available, set the date and time manually.

4.6 Configuring display settings

Display settings can be adjusted to change the way information is displayed on the screen.

4.6.1 Configuring settings for displaying patient information



Enable ***Show barcode scanner option in Patient management view*** if your organization wants to use a barcode scanner to register a patient.

Enable ***Show device ID QR code in Patient management view*** if your organization wants to obtain device ID from *Patient management view* with a QR code scanner.

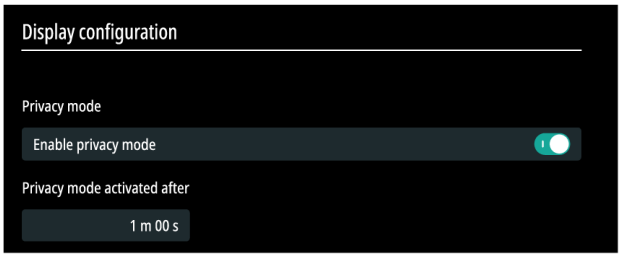
Disable ***Show patient ID*** to hide the patient ID on the display unit.

Disable ***Show patient name*** to hide the patient's name on the display unit.

4.6.2 Configuring privacy mode

Notice: Privacy mode is always deactivated when alarms become active, regardless of PIN configuration.

Privacy mode hides sensitive information and reduces light pollution during the night.



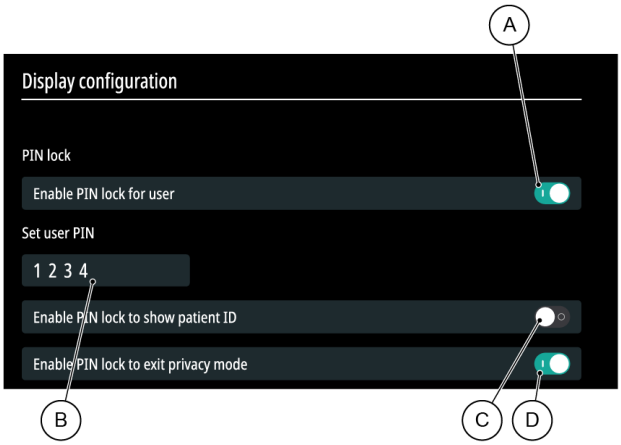
Privacy mode is on by default, but you can disable it by tapping the toggle on the ***Enable privacy mode*** selection.

If you leave the privacy mode enabled, set the preferred time after which privacy mode is automatically activated if the screen is not touched. Tapping the screen will then deactivate privacy mode, unless you have enabled the PIN lock on page 50.

4.6.3 Configuring the user PIN

> Notice: The user PIN is configurable. It can be shared with the hospital staff intended to use the system. The user PIN must not be confused with the administrative PIN, which cannot be changed, and should only be shared with administrative users and service technicians.

To prevent non-personnel from seeing the patient's information, define a user PIN code that must be entered before privacy mode is exited, or patient information can be viewed on screen.



Enable the PIN lock (A). You can adjust the other PIN lock settings only if this option is enabled. Set the user PIN (B), and adjust the toggles to determine if the PIN code must be entered to show the patient ID in *Main view* (C), and/or to exit privacy mode (D).

4.7 Configuring alarm settings

Precaution
If the same or similar equipment is used within a single area (for example, in a post-operative care unit), the alarm settings of such equipment should be taken into consideration when configuring the default alarm settings.

The system comes with a default set of alarm settings. If required by your organization, these settings can be changed by the service technician at the installation stage, or by the administrative user after the system is taken into use. As a service technician, you should consult the hospital personnel who is intended to use the system on the ideal default settings for the alarms.

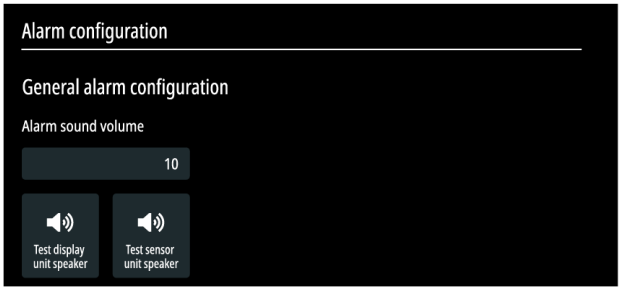
If any changes are made by a user during a monitoring session, the default alarm settings will be restored when a new session is started, or the system is restarted.

4.7.1 Adjusting and testing the default alarm sound level

Notice: Adjusting the volume only has an effect on the volume of the display unit. The volume of the sensor unit cannot be adjusted.

Users can adjust the sound level for a single session, but the default sound level defined here is restored whenever a new monitoring session starts.

Note that if you try to set the sound to a level that is lower than the system default, a pop-up message is shown to caution against low volumes that can be missed by the user.

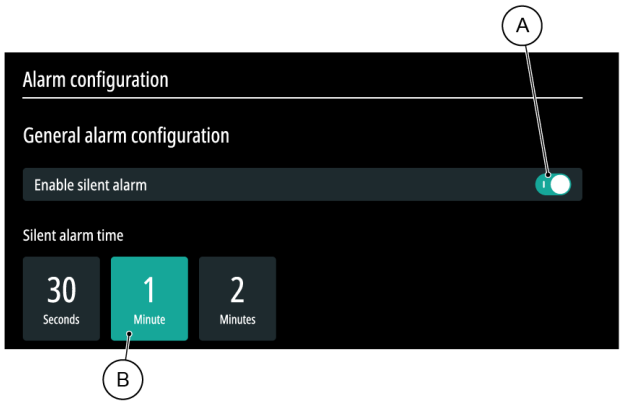


Tap the ***Alarm sound volume*** selection to open the adjustment window. Drag the slider to the desired sound level, or tap the ***Use default value*** button to set it to the manufacturer's default level.

You can tap the ***Test display unit speaker*** button to test the sound on the display unit, and the ***Test sensor unit speaker*** button to test the sound on the sensor unit.

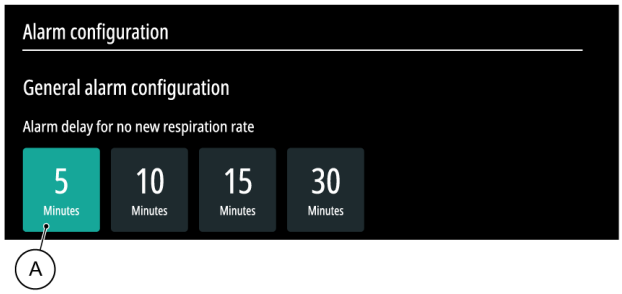
4.7.2 Configuring silent alarm

Silent alarm is a configurable option where, if activated, alarms will only generate visual alarm signals for a pre-defined time period before alarm sounds are generated. For more information, see "Instructions for Use", section "Silent alarms".



Choose whether silent alarm is enabled with the toggle (A). If enabled, set the preferred time period (B) before alarm sounds are generated.

4.7.3 Adjusting the alarm delay for no new respiration rate



If the system, over a period of time, does not obtain new respiration rate measurements, a technical alarm becomes active. The time duration before generating the alarm for no new respiration rate is configurable, and by default set to five minutes.

Tap one of the options (A) to set a new default value if necessary.

4.7.4 Adjusting the default alarm limits for physiological alarms

> ⚠ **Precaution**
> Do not set the alarm limits to extreme values that can render the alarm system useless.

If necessary, the default alarm limits for all physiological alarms can be adjusted. The alarm limits are restored to the settings defined here whenever a new monitoring session starts.

See the table below for the limits that are restored if you tap the ***Use default*** button.

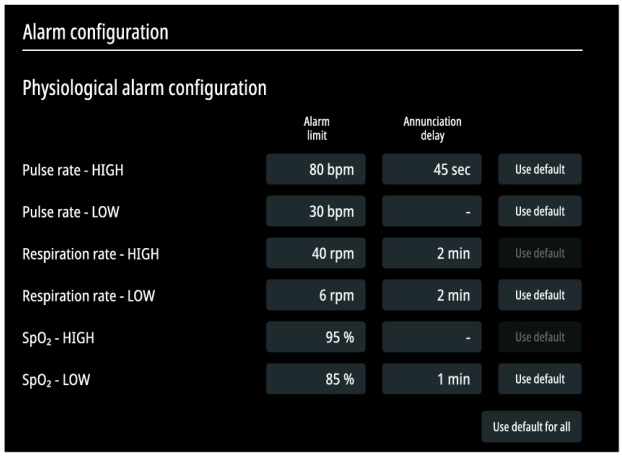
Vital	Default for lower limit	Default for upper limit
Respiration rate [rpm]	< 8	> 30
Pulse rate [bpm]	< 40	> 130

Vital	Default for lower limit	Default for upper limit
Oxygen saturation (SpO_2) [%]	< 85	Off by default*

*The default upper limit for oxygen saturation is off by default. When you adjust this default upper limit to some value other than “100”, for example, “95”, the new value will be the upper limit used for SpO_2 high alarm.

4.7.5 Activating/deactivating the annunciation delays

The annunciation delay is a defined time period that the alarm limit has to be breached continuously before an alarm becomes active. For example, when the high alarm limit for respiration rate is defined as 30 respirations per minute (rpm) with an annunciation delay of 40 seconds, there has to be a consecutive measurement of respiration rate that is faster than 30 rpm for 40 seconds before the alarm becomes active. Any measurements below or at 30 rpm will restart the 40-second timer.



Tap each field in the ***Annunciation delay*** column to open an adjustment window and enter the desired delay, or leave the fields empty if you do not want any annunciation delays to be in use. By default, annunciation delays are not in use, and the value in the column is “-”.

4.8 Verifying system performance

After all the configuration steps are completed, verify that the system is operating as intended by turning the system off and on again.

If the system self-test is cleared in bootup mode, there are no active technical alarms, and the previously configured settings in *Device management view* are all correct, the software configuration is complete.

4.9 Registering the device

After you have successfully installed the system and completed the configuration of the software, register the device when it is taken into use. Follow the instructions provided by the QR code or link below:

register.vitalthings.com/

5 Maintenance

> ⚠ **WARNING**
> Confirm that the unit is not in use before you begin maintenance.

This chapter gives information about the inspection and maintenance tasks and frequencies. Performing regular maintenance and inspections is crucial to keeping the system in working order.

Always follow the correct safety precautions when performing maintenance.

5.1 Maintenance schedule

Procedure	Interval	Instructions
Inspecting the system for physical wear	Before each use, or every month if in storage	Inspect the parts and components for signs of physical damage or wear.
Updating the system	As required	See Updating the system on page 55
Running a system self-test	Every month	See Running a system self-test on page 57
Changing the sensor unit backup battery	Every 36 months	See Changing the backup battery on page 56

5.2 Performing maintenance

This section covers the procedures for updating the system, changing the backup battery, and running a system self-test.

5.2.1 Updating the system

System updates are initiated from *Device management view*.

Update frequency

Whenever improvements become available, the manufacturer will publish an update. In general, these updates will mitigate bugs or weaknesses to reduce risks.

Your organization is responsible for keeping up to date with the latest published updates.

Update process

> ⓘ Notice: When the system is in an active monitoring session it will not be possible to initiate the update process.

1. In *Device management view* > ***Maintenance*** > ***General system setup***, tap ***Start system update*** button to initiate the update process.

2. Enable an internet connection over Wi-Fi by entering the network name (SSID) and password, and tap ***Confirm*** button.

The system will now enter update mode. If the Wi-Fi connection is successfully established and a system update is available, the update will automatically be downloaded and installed. The system will restart after the installation is completed. The whole process takes approximately 15 minutes.

The system update is successful if the system turns on after restart and no technical alarm related to incompatible software versions is shown.

If connecting to internet is unsuccessful, a system update fails after being initiated, or no system update is found within 30 minutes, the update process will be canceled. When the update process is canceled, Wi-Fi will be disabled and an error message will be shown. Update mode can be manually exited by tapping the ***x*** icon.

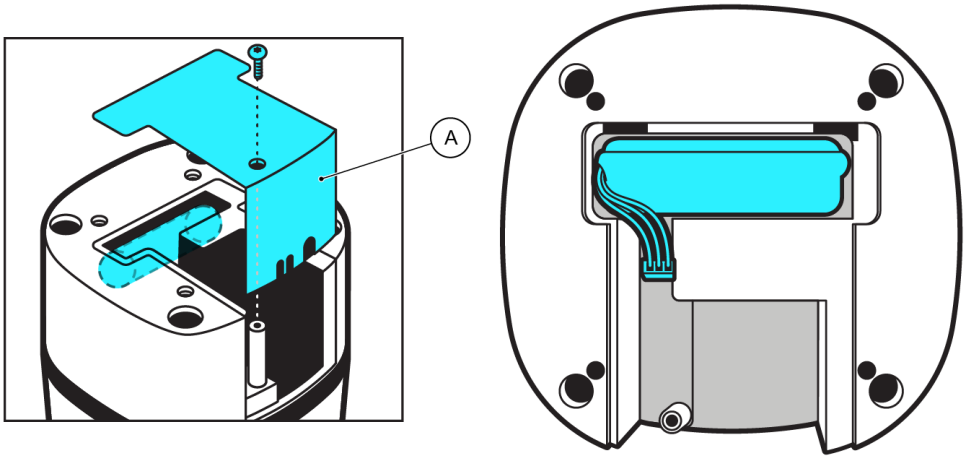
Version control

Information about the current software and hardware versions is found in *Device management view* > ***System information***.

5.2.2 Changing the backup battery

> ⚠ **WARNING**
> Disconnect the power source of the sensor unit before you begin.

The sensor unit backup battery maintains the continuous function of the system in case of power interruptions. It is located inside the sensor unit.



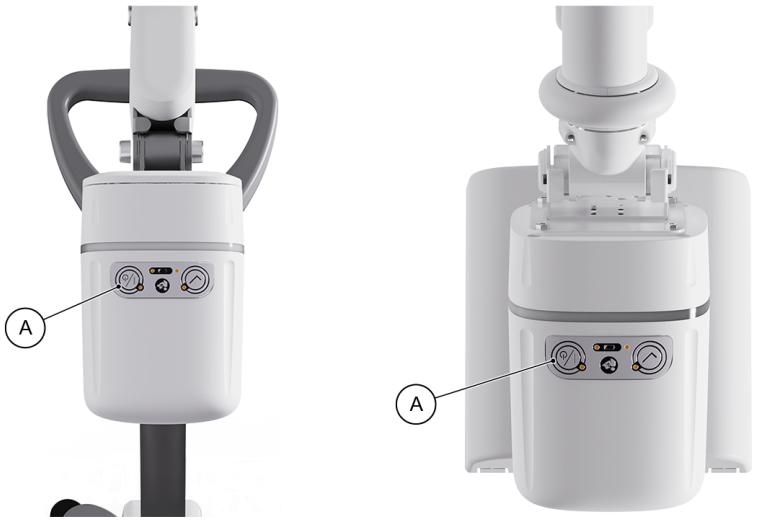
1. Make sure that the sensor unit is powered off and disconnected from its power source.
2. Remove the sensor unit from its current position.
3. Remove the back cover (A) on the sensor unit.
4. Disconnect and remove the current backup battery.
5. Make sure that the new backup battery is found from the Replacement parts list on page 66. Do not use any other battery.
6. Insert and connect the new battery. Pay attention to the orientation of the connector plug.
7. Put the back cover back on the sensor unit.
8. Reattach the sensor unit to its previous position.

Once you've changed the battery and successfully reattached the sensor unit to its correct position, you can reconnect the power source.

Turn on the system to confirm that it is functioning correctly and the new battery is providing power effectively.

5.2.3 Running a system self-test

Making sure that the system functions optimally is vital for accurate monitoring and patient safety. The system's built-in self-test feature provides a quick and efficient way to verify that all components are functioning as intended. This self-test runs automatically every time the sensor unit is restarted.



No specific actions are required to initiate the system self-test. Turn the sensor unit off by keeping the on/off button (A) pressed, and then on again with the same button, and the self-test runs automatically.

If the test is **successful**, no additional notifications appear on the display. All components should function as intended.

If the test is **unsuccessful** and the system detects malfunctions or issues, a technical alarm becomes active. In this case:

- Do not use the system until the issue is resolved.
- Mark down any error messages or codes displayed during the unsuccessful test.
- See "Instructions for Use" for a list of technical alarms and their recommended actions, or Troubleshooting on page 64 for further instructions.

Regularly running the system self-test, even if initiated unintentionally through a restart, is a proactive measure to ensure the system's accuracy and reliability. Always attend to any alarms immediately and seek professional assistance if you are unsure about the nature of the problem or its resolution.

5.3 Returning the system to operation

After you have performed any maintenance on the system, confirm that the system is operating as intended before you return it to normal operation. See Performing initial checks on the stationary configuration on page 36 for procedures to be done on the stationary configuration, and Performing

initial checks on the mobile configuration on page 43 for procedures to be done on the mobile configuration.

6 Repair

Guardian M10 is designed to require minimal maintenance and repair. Only regular service required by the system is any performance testing that is mandated by your institution.

In case there is a failure with any of the system components that leads to downtime and disruption to patient monitoring, this chapter gives information about basic repair guidelines. If the information here is not sufficient to resolve the issues you are facing or you are unsure of the correct way to proceed, contact your local representative.

See “Instructions for Use” for details on the usual operation of the system.

Safety precautions

> ⚠ **WARNING**
> Before you begin any service or repair, confirm that the system is turned off and, if applicable, disconnected from the power source.

> ⚠ **Precaution**
> All installation operations, changes, and repairs must be done by authorized personnel only.

> ⚠ **Precaution**
> Service and repair the system only in a well-lit, clean, and dry environment.

> ⚠ **Precaution**
> Wear appropriate personal protective equipment (PPE) such as gloves, safety goggles or masks.

6.1 Repair policy

Users must report any sings of malfunction or visual damage to the designated service technicians, who can then assess and address the issue. If service technicians cannot resolve the issue based on the guidelines set in this manual, they must contact the distributor or manufacturer for further instructions on how to proceed.

General guidelines

- User responsibility: All users are responsible for regularly inspecting the units for visual damage or potential malfunctions before, during, and after use.
- Training: All users should undergo training to familiarise themselves with this policy and the proper use of Guardian M10.
- Third-party repairs: Repairs or maintenance should only be conducted by authorized personnel. Unauthorized third-party repairs may void the unit's warranty and compromise its safety.
- Replacement parts: To ensure compatibility and the continued accuracy of the system, only use approved parts and components for replacements.

If any questions about replacement and spare parts or repairs remain, contact your local representative.

6.2 Performing repairs

Before proceeding with further repair actions, keep in mind that certain actions, like a factory reset, will erase all user data and settings.

6.2.1 Preliminary diagnosis

When you assess the unit for repair or service needs, look for signs of visual damage or unit malfunction.

Visual damage

Visual damage refers to any noticeable marks, cracks, dents, discoloration, or other physical imperfections on the units that were not present at the time of purchase or after standard use. If the device is reported and brought in for repairs with signs of visual damage, proceed to Replacing components on page 60.

Unit malfunction

Unit malfunction refers to the sensor unit or display unit not functioning as intended. This may manifest as erratic readings, blank screens, non-responsive buttons, or any other unexpected behaviour. If the device is reported and brought in for repairs with signs of unit malfunction, proceed to Running a factory reset on page 60. If the malfunction on the display unit is such that this is not an option, however, restart the system by keeping the power buttons on the display unit and the sensor unit pressed, and then turn them on again. If the problem still persists, contact the manufacturer.

6.2.2 Replacing components

In general, components of the Guardian M10 system are only replaced when:

- A technical alarm indicates that a replacement is needed. For a full list of technical alarms and their descriptions, see “Instructions for Use”.
- There is visual damage on the part that may affect the correct operation of the system.
- A troubleshooting scenario indicates that a replacement is needed (see Trobleshooting on page 64).

In both cases, the old part is sent to the manufacturer, and a new part is sent back. For a list of replaceable parts and their order numbers, see Replacement parts list on page 66. For instructions on how to remove and replace a part, refer to the corresponding installation section in Installing the physical components on page 22.

6.2.3 Running a factory reset

⚠ **Precaution**
A factory reset will restore the system to its original settings and erase data and configurations.

⚠ **Precaution**
Perform a factory reset only under the following circumstances:

- You observe signs of system malfunction.
- A troubleshooting scenario suggests that a reset is necessary. See Troubleshooting on page 64 for more details.

1. Access *Device management view* > ***Maintenance*** > ***System reset***.
2. Tap the ***Launch factory reset*** button.
3. The system will restart and restore the original factory settings.

If the system does not pass the self-test after running a factory reset, there can be a hardware or a significant software issue. In such instances, the unit must be removed from use or replaced. Please review the unit's warranty details or contact the manufacturer for further guidance on replacement procedures.

6.3 Returning the system to operation

After you have performed any repairs on the system, confirm that the system is operating as intended before you return it to normal operation. See Performing initial checks on the stationary configuration on page 36 for procedures to be done on stationary configurations, and Performing initial checks on the mobile configuration on page 43 for procedures to be done on mobile configurations.

7 Recycling and disposal

Proper recycling and disposal of medical equipment and its components are of paramount importance, not only for environmental protection but also to ensure the safety of individuals and compliance with regulations. The following sections outline the recommended procedures and practices for recycling, discarding, and returning the system components of Guardian M10.

7.1 Recycling or discarding system components

Notice: Before discarding Guardian M10 (sensor unit) it is recommended to run a factory reset to make sure that the patient data from the latest sessions is properly erased from the system. For instructions on how to run a factory reset, see Running a factory reset on page 60.

Efforts to recycle should always be prioritised, given the potential environmental impacts of waste. See this following list for recommended recycling or disposal methods for each component type:

- E-waste: send to certified e-waste recycling facilities that handle electronic waste.
- Metal waste: send to facilities that specialise in reclaiming metals.
- Package waste: recycle according to your local recycling guidelines.

Parts of the stationary configuration

Part (part number)	Method of recycling or disposal
Guardian M10 (sensor unit) (VT50024)	Recycle as e-waste.
Sensor Unit - Backup battery (VT25006)	Recycle as e-waste.
Display Unit (VT50028)	Recycle as e-waste.
Sensor Unit USB-C Power Supply (VT50031)	Recycle as e-waste.
Sensor Unit Wall Mount Arm (VT50033)	Remove the cables, and recycle as metal waste. Recycle the cables as e-waste.
Display Unit Wall Mount - Track - 946 cm (VT50037)	Remove the cables, and recycle as metal waste. Recycle the cables as e-waste.
Display Unit Wall Mount - Track Mount Bracket (VT50038)	Recycle as metal waste.
Display Unit Wall Mount - Display Unit Bracket (VT50039)	Recycle as metal waste.
USB-C Cable - 4.0 m (VT25029)	Recycle as e-waste.
USB-C Cable - 2.2 m (VT60001)	Recycle as e-waste.

Parts of the mobile configuration

Part (part number)	Method of recycling or disposal
Guardian M10 (sensor unit) (VT50024)	Recycle as e-waste.
Sensor Unit - Backup battery (VT25006)	Recycle as e-waste.
Display Unit (VT50028)	Recycle as e-waste.
Trolley - Base (VT50017)	Remove the cables, and recycle as metal waste. Recycle the cables as e-waste.
Trolley - Battery Dock (VT58000)	Recycle as e-waste.
Trolley Battery - C200 (VT58001)	Recycle as e-waste.
Trolley Battery Charging Station - Dual (VT58002)	Recycle as e-waste.
USB-C Cable - 0.5 m (VT25028)	Recycle as e-waste.
USB-C Cable - 1.4 m (VT60000)	Recycle as e-waste.

7.2 Return procedure

Contact the manufacturer's customer service or designated department to express your intent to return components. Obtain a Return Merchandise Authorization (RMA) form.

Fill in the required details in the RMA form, including the RMA Authorization Number and the reason for the return. Use the original packaging material, if possible. Ensure all components are clean and safely packaged to prevent damage during transit. Use the shipping method recommended by the manufacturer.

8 Troubleshooting

This chapter gives an overview of the commonly identified problems and their solutions. If you encounter a problem or a trouble scenario related to the use of Guardian M10 that is not covered in the lists, please see Contact and support on page 6 for correct contact and support information. You can also access the system log on page 64 to look for events that might have occurred during the time of the reported issue.

Sensor unit

Problem	Solution
The sensor unit does not work properly, and I cannot find a solution from the “Installation and Service Manual”.	Contact manufacturer.

Display unit

Problem	Solution
The display unit does not work properly, and I cannot find a solution from the “Installation and Service Manual”.	Contact manufacturer.

System

Problem	Solution
System self-test fails.	Run a factory reset. For instructions, see Running a factory reset on page 60.

Nonin WristOx$_2$® Model 3150 Pulse Oximeter BLE with 8000S Series reusable soft sensors

Problem	Solution
The pulse oximeter does not work properly, and I cannot find a solution from the “Installation and Service Manual”.	For detailed specifications of the pulse oximeter, see the manufacturer’s manuals, or visit their website. If you still cannot find a solution, contact the manufacturer of Guardian M10.

8.1 Viewing the system log

To open the system log, access *Device management view* > ***Maintenance*** > ***General system setup***. Alarm and system related events are stored in the log across different monitoring sessions. The log

holds a maximum of 604 800 log entries, after which each new event will overwrite the oldest event in the log. Note that shutting down the system or the system experiencing a complete power loss does not erase or reset the system log.

You can access the system log as part of troubleshooting to look for frequent alarms or events that might have occurred before, during, or after reported problems.

9 Replacement parts list

System replacement parts

Part number	Part
VT50024	Guardian M10 (sensor unit)
VT50028	Display Unit
VT25006	Sensor Unit - Backup Battery

Stationary configuration replacement parts

Part number	Part
VT50031	Sensor Unit USB-C Power Supply
VT50033	Sensor Unit Wall Mount Arm
VT50037	Display Unit Wall Mount - Track - 946 cm
VT50038	Display Unit Wall Mount - Track Mount Bracket
VT50039	Display Unit Wall Mount - Display Unit Bracket
VT25029	USB-C Cable - 4.0 m
VT60001	USB-C Cable - 2.2 m

Mobile configuration replacement parts

Part number	Part
VT50017	Trolley - Base
VT58000	Trolley - Battery Dock
VT58001	Trolley Battery - C200
VT58002	Trolley Battery Charging Station - Dual
VT25028	USB-C Cable - 0.5 m

Part number	Part
VT60000	USB-C Cable - 1.4 m

10 Technical specifications

See the subchapters that follow for technical specifications of the Guardian M10 components.

10.1 Sensor unit

Manufacturer	Vitalthings AS, Dybdahls veg 5, 7051 Trondheim, Norway
Model designation	VT50024 Guardian M10 (sensor unit)
Mode of operation	Measures respiration rate and body movements contactlessly by the use of Ultra Wideband Radar (UWB) technology.
Range and accuracy of respiration measurement	2-60 rpm, +/-1.2 rpm
Device dimensions	116x116x170 mm
Power connection USB-C-PD	15VDC, max 3A
Power consumption POE	44-57VDC, max 12.95W
Power consumption	Nominal 4.5W
MDR Classification	Class 2B
Medical electrical equipment classification	Class 2B
Equipment type / Applied part classification	Multifunction patient monitor, no patient applied part.
Ingress protection classification	IP22 when installed as a mobile configuration. No classification when installed as a stationary configuration.
Noise level	Silent
Mass	0.65 kg
Transport packaging dimensions	150x150x220 mm
Transport packaging weight	0.85 kg

Transport and storage conditions	0-40 °C, 10%-80% relative humidity.
Operating conditions	0-40 °C, 10%-80% relative humidity.
Installation location	Professional healthcare locations. One must comply with the installation procedure given in the “Installation and Service Manual”.
Minimum qualifications for service personnel	Service personnel must be formally trained to repair/do maintenance for the product.
Expected service life	5 years (for Guardian M10 including the display unit)
Shelf life	Not specified

This device has been subjected to EMC tests according to EN 60601-1-2:2015+A1:2021, showing compliance with the following limits and levels:

Emission

Description	Basic document	Limit level
Radiated emissions	CISPR 11	Class A, group 1

Immunity

Description	Basic document	Test level	
ESD immunity	EN 61000-4-2	Contact Air	+/- 8 kV +/- 2, 4, 8, 15 kV
Radiated immunity	EN 61000-4-3	80-2700 MHz 1 kHz (80% AM)	3 V/m
Enclosure port. Immunity to RF wireless communications equipment	EN 61000-4-3	380-390MHz 430-470MHz 704-787MHz 800-960MHz 1700-1990MHz 2400-2570MHz 5100-5800MHz	Table 9, EN 60601-1-2:2015+A1:2021.
EFT/Burst immunity	EN 61000-4-4	Ethernet port	+/- 1 kV (100kHz)

Description	Basic document	Test level	
Conducted immunity	EN 61000-4-6	0.15-80 MHz 1 kHz (80% AM) Ethernet port ISM + Amateur radio bands 1 kHz (80% AM) Ethernet port	3V 6V
Proximity magnetic fields	EN 61000-4-39	30 kHz, CW 134,2 kHz, PM 2,1 kHz 13,56 MHz, PM 50 kHz	8 A/m 65 A/m 7,5 A/m
Power frequency magnetic field	EN 61000-4-8	50 Hz	30 A/m

10.2 Display unit

Model	Advantech HIT-VLT-512-11ACF
Display maximum resolution	1920x1180 pixels
Touchscreen	Projected capacitive
USB 3.0	One port
Audio	Speaker 2Wx2
WLAN	802.11 a/b/g/n/ac
Bluetooth	BT 4.1
OS	WIN 10IoT
Mounting	VESA 75x75
Dimensions	296x190x33.4 mm
Net weight	1.5 kg
Input power	USB-C-PD 15V max 2.25A
Operating temperature	0-35 °C

IP rating	IP65
Vibration	1G
EMC & Safety	CE, FCC, CCC, EN 60601-1, ITE 62368

10.3 Optional pulse oximeter

For detailed specifications of Nonin WristOx2® Model 3150 Pulse Oximeter BLE with 8000S Series reusable soft sensors, see the manufacturer's manuals, or visit their website at https://www.nonin.com/

11 Appendices

11.1 Warranty information

Warranty

Vitalthings Guardian M10 ("the Product") is covered by a limited warranty provided by Vitalthings AS. This warranty guarantees that the Product will be free from manufacturing defects in materials and workmanship for a period of one (1) year from the original date of purchase.

Warranty Terms and exclusions

- The warranty is only valid for the original purchaser and is non-transferable.
- The warranty is not valid for Products with missing or altered serial numbers.
- The warranty is only valid if the Product is used in accordance with the instructions and recommendations set forth in the “Instructions for Use” and the “Installation and Service Manual”, and for its intended purpose.
- Any alterations, modifications, misuse, or use of the Product for other purposes than intended will void the warranty.
- The warranty does not cover damage caused by third-party accessories or consumables.
- The warranty does not cover cosmetic damages, superficial scratches, normal wear and tear, or damage resulting from accidents, negligence, or exposure to extreme environmental conditions.

Limitations

- Vitalthings’ obligation under the warranty is strictly limited to replacement or repair of the Product, at Vitalthings’ sole discretion. Under no circumstance shall Vitalthings be liable or responsible for any special, incidental, statutory, punitive, consequential, exemplary or any other indirect damages of any kind, arising from or related to the use or inability to use the Product.
- Vitalthings AS reserves the right to replace the defective Product or part with a product or part of equal or greater value if the original product or part is no longer available.
- Repairs or replacements will not extend the original warranty period.
- All warranty claims must be made within the warranty period. Any claims made after the expiration of the warranty period will not be honoured.
- The warranty covers only the main device and not any consumables or accessories, unless specifically stated otherwise.

Claims under the Warranty

In the event that you find a defect or experience a malfunction in the Product during the warranty period, please take the steps that follow:

1. Contact our customer support team.
2. Provide proof of purchase, such as a receipt or an invoice, and details of the defect.
3. Our team will guide you through the return process, if necessary.
4. Upon receipt and inspection, and after having verified that the Product is defect, we will either repair or replace the defective Product or its defective parts, and send you an operational Product.

Disclaimer

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED, ORAL, WRITTEN OR STATUTORY, INCLUDING BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.