vitalthings®
GUARDIAN M10

Instructions for Use

Guardian M10

English
Version 1.3

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1 Technical information

1.1 Version data

Date of issue	2024-05-08
Version	1.3
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 minor correction in technical specifications for the display

1.3 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 document

This document contains the information needed to safely identify and operate the Guardian M10 patient monitoring system.

Read carefully before use

Read this document carefully before using Guardian M10. All personnel operating the system must be familiarised with its contents.

This document does not replace medical or professional training.

Keep this document 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 document. 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 About the device

The system is meant to be used by trained medical personnel in healthcare facilities.

The system is intended for patients in resting states. Only one patient can be monitored at a time.

The system can be used continuously over several days. Monitoring can be interrupted **momentarily** by high motion situations or the patient leaving the monitoring area.

The system can be connected with these medical devices to give additional data:

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

These are the intended clinical benefits:

- Patient safety will be improved with respiration rate measurement that is more accurate than current standard level of care.
- Continuous measurements of respiration rate will detect deterioration of patients in hospital wards earlier.
- Continuous measurement will generate better trend data which improves patient safety.
- Continuous monitoring will be perceived as safer for patients as a “step down” approach from ICU to hospital ward transfers.
- Continuous respiration rate monitoring will detect clinically relevant events that are overlooked with current standard level of care today.

1.6 Indications for use

Adult subjects where respiratory rate monitoring is requested.

1.7 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.

1.8 Use environment

ⓘ Notice: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guardian M10 is meant for use in a professional healthcare environment.

1.9 Safety information

General safety guidelines

⚠ **WARNING**
Guardian M10 cannot be used as an apnea monitor.

⚠ **WARNING**
People within a two-metre radius of the sensor unit can affect measurements.

WARNING
The device is only for use on one patient at a time.
More than one object within the observation area can have a negative effect on monitoring, such as:
- Affecting measurements or giving false positives and preventing the detection of patient deterioration.
- Giving a larger number of technical alarms and increasing alarm fatigue.

WARNING
Do not use on patients with conditions causing prolonged high-motion situations (for example, the patient cannot maintain one resting position and twists and turns continuously) or patients leaving the monitoring area. Patient deterioration may not be detected.

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

WARNING
Upon initial receipt and before each use, examine each component for damage. Do not use damaged components.
Damaged components can compromise the device performance.

Precaution
The system must be installed and verified for use by qualified personnel before any clinical use. Incorrect installation can compromise device performance.
See “Installation and Service Manual” for detailed installation instructions.

Notice: If serious incidents occur in relation to the device, report them to the manufacturer and the competent authority.

Power and electrical safety

WARNING
Modification of the device is prohibited.
Do not try 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**
The use of other medical electrical equipment emitting RF (for example, mobile X-ray machines) in the immediate proximity (less than one metre) of this device can influence the accuracy of the measurements.

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

⚠ **WARNING**
Use of accessories and cables other than those specified or supplied by the manufacturer of this equipment could cause increased electromagnetic emission or decreased electromagnetic immunity of this equipment and cause improper operation.

Environmental factors

⚠ **Precaution**
Environmental factors from:

- third persons in the close proximity of the device or between the device and the patient
- a large number of persons in the measurement room
- excessive patient movement, including leaving the measurement area for several long periods
- significant electromagnetic disturbance
- patient using the system arm as bed trapeze

can cause:

- reduced device performance
- loss of alarms
- loss of data
- damage to mechanical arm.

ⓘ Notice: Electromagnetic disturbances can cause reduced performance of the device, where the system is unable to obtain respiration rate measurements and/or there is a loss of pulse rate and oxygen saturation measurements.

User setup errors

⚠ **Precaution**
Inadequate setup such as:

- mandatory software updates not performed
- alarm settings turned off or alarm limits set too close
- wrong patient registered
- information not detected

can cause risk of:

- registration of a wrong patient
- relevant clinical data missing from patient records
- loss of alarms or information, or unnecessary alarms or causing unnecessary disturbance to the patient
- system not performing as intended.

User errors

⚠ **Precaution**
User errors from:

- unqualified users or users trained with unsuitable training material
- connection to the wrong auxiliary system or device
- sub-optimal sensor setting or sensor moved during operations
- unintended or wrongly set alarm settings
- using the wrong “Instructions for Use”
- misunderstanding information
- alarm fatigue, alarm misunderstood, misinterpreted or lost
- tilting or dropping the system to the floor
- using unspecified cleaning agents
- registration of wrong patient or using on patient with contraindications

can cause risk of:

- inadequate setup of the system
- missed, misleading or no auditory alarms
- loss of data and missed alarms from auxiliary equipment
- respiratory depression or other deterioration not detected
- wrong treatment decision
- finger trapping or toe crushing
- device damage
- unnecessary disturbance to the patient.

Unauthorized access to data

⚠ **Precaution**
Unauthorized access to the system can cause risk of:

- loss of privileged or patient data
- copying of privileged or patient data
- erroneous patient data in the system
- installation of malware which again can infect other hospital systems
- loss of passwords
- compromised device performance.

Technical failures

⚠ **Precaution**
Technical failure from:
- software or hardware errors
- incorrect system mounting
- device overheating

can cause risk of:
- patient or user burn or electric shock
- device malfunction
- patient deterioration not detected
- fire.

Mechanical failures

⚠ **Precaution**
Mechanical failure from:
- bed trapeze hitting the device
- wall mount arm movement
- trolley tipping over
- someone tripping on the device and falling over it or having it fall on a person

can cause:
- device malfunction
- finger trapping
- cable breakage
- wall mount arm failure
- injury to patient, user or third party.

Power failures

⚠ **Precaution**
The system can encounter power failure from:
- battery failure, overcharged, short circuited or leaking battery
- reversed polarity of battery
- loss of main power or short circuited mains power
- cable breakage

can cause:
- loss of measurements
- missed and false alarms
- electric shock to users or patient
- compromised device operation
- loss of data and/or trend data
- gas leakage, explosion and fire hazard.

Software failures

⚠ **Precaution**
Software and firmware failure from:
- incorrect pairing to other device or system
- display unit is updated, but the system is not - or vice versa
- an implemented risk mitigation in software does not work

can cause:
- missed physiologic alarms, erroneous alarms or loss of alarm cause
- wrong validity of measured data
- system fails during operation
- wrong waveform displayed
- inconsistency between the input UI and the displayed UI
- standby graphics is not shown
- recorded data and/or trends are erroneous or lost
- software update is not performed as intended.

Technical communication

⚠ **WARNING**
Portable radio frequency (RF) communications equipment, including peripherals such as antenna cables and external antennas closer than 30 cm to any part of the sensor unit, as well as cables specified by the manufacturer, can cause degradation of the sensor unit's performance.
Keep RF communications equipment away from the proximity of the sensor unit.

⚠ **Precaution**
Technical communication error from:
- software or hardware update
- errors in third party auxiliary equipment
- system mounted in an environment with high electromagnetic interference

can cause the risk of:
- loss of communication to auxiliary components or hospital system
- erroneous display of data
- interference with measurements or other communications (Wi-Fi or 5G).

Storage and handling

⚠ **Precaution**
Storage and handling errors such as:
- storage outside recommended temperature and humidity range
- prolonged storage time

can cause:
- end-of-life to internal and external battery
- loss of firmware and software updates
- mismatch with printed "Instructions for Use"
- compromised device function
- compromised alarm system.

End-of-life

> ⚠ **Precaution**
> Defective or discarded device not properly disposed of according to “Installation and Service Manual” can cause environmental damage.

1.10 Compliance with standards

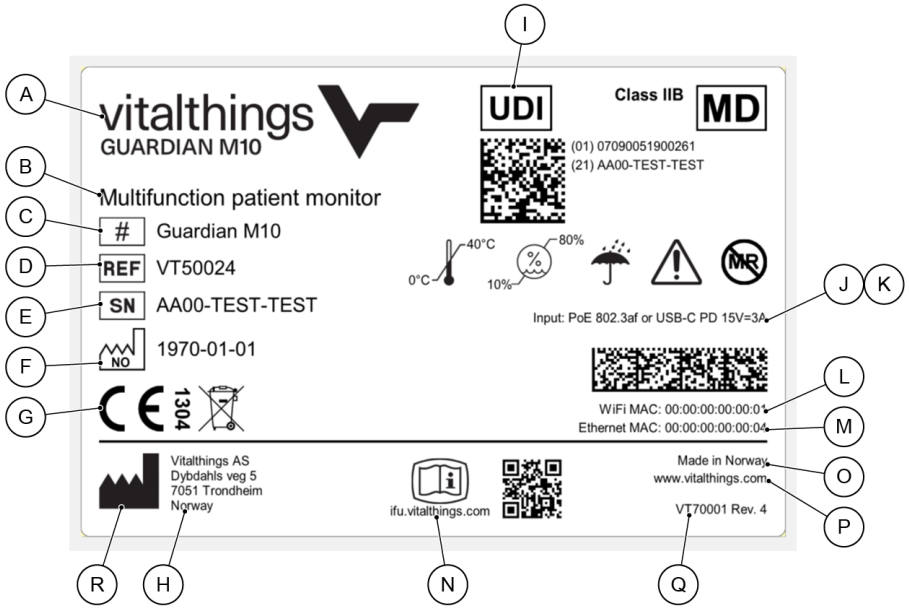
The Vitalthings Guardian M10 product family complies with the regulatory requirements of the EU regulation 2017/745 that is applicable for medical devices. The product family is tested to meet all applicable requirements in relevant EU Directives, EU regulations and European or international standards. 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
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

Standard	Description
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

1.11 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	

Callout	Field	Content	Additional information
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	
N	Instructions for use	URL & QR code with link to online representation	
O	Country of origin	Made in Norway	

Callout	Field	Content	Additional information
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 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
	Catalogue number	Identifies the manufacturer's catalogue number.	ISO 7000 Ref. No.: 2493
	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”

1.12 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.
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.

Name (abbreviation)	Definition
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.
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.

Name (abbreviation)	Definition
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.
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.

Name (abbreviation)	Definition
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.
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.

Name (abbreviation)	Definition
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.
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.

Name (abbreviation)	Definition
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 Components of the Guardian M10 system

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 a main power source, 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 7.

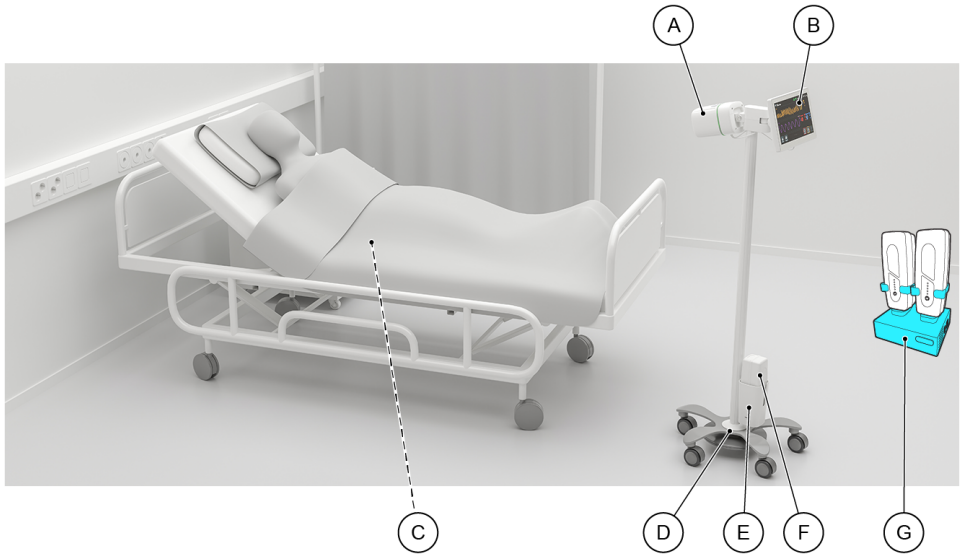
Stationary configuration

Callout	Item	Description
A	Sensor unit (VT50024)	The sensor unit measures the respiration rate of the designated patient. The sensor unit LED bar will light in case of an alarm. In addition, audible alarms can be generated.

Callout	Item	Description
B	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.
C	Pulse oximeter (Optional)	An optional pulse oximeter can be connected to provide additional data. The pulse oximeter measures oxygen saturation and pulse rate. The measurement results are transmitted by Bluetooth to the sensor unit.
D	Wall mount arm (VT50033)	The arm is installed to the wall. The position of the sensor unit can be adjusted in all dimensions.
E	Power supply (VT50031)	The power supply is located inside the bottom of the mount arm. The power supply gives power both to the sensor unit and the display unit.

The components under item A, B, D and E are necessary for the stationary configuration to operate, in addition to cables for power and connection (VT60001, VT25029) and components needed for mounting the display unit (VT50037, VT50038, VT50039). See more details in the “Installation and Service Manual”.

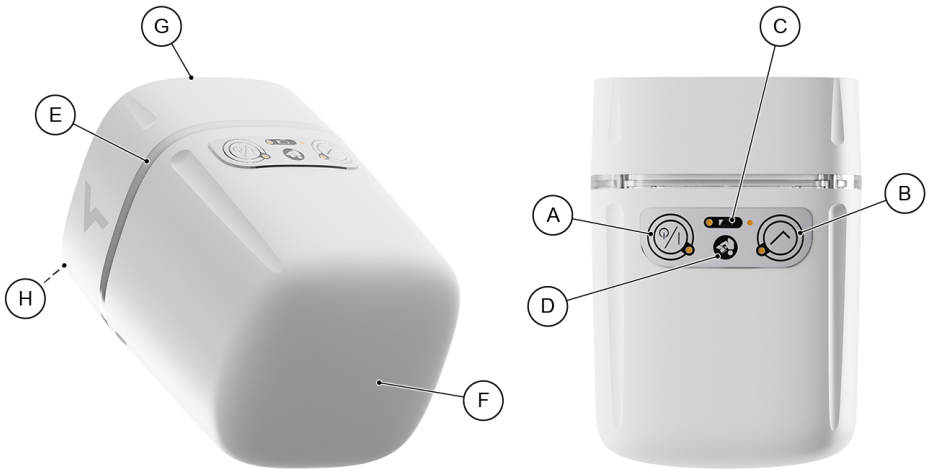
Mobile configuration



Callout	Item	Description
A	Sensor unit (VT50024)	The sensor unit measures the respiration rate of the designated patient. The sensor unit LED bar will light in case of an alarm. In addition, audible alarms can be generated.
B	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.
C	Pulse oximeter (Optional)	An optional pulse oximeter can be attached to the patient's finger and wrist to provide additional data. The pulse oximeter measures oxygen saturation and pulse rate. The measurement results are transmitted by Bluetooth to the sensor unit.
D	Trolley (VT50017)	The sensor unit and the display unit are installed on the trolley. The wheels can be locked. When monitoring, the trolley is placed beside the patient's bed, with the sensor unit pointed towards the patient's chest.
E	Docking station (VT58000)	The trolley is powered by a battery. The battery can be hot-swapped without interfering with the measurement functions.
F	Battery (VT58001)	The battery is placed in the docking station. The battery has capacity for approximately 14 hours of operation.
G	Battery charging station (VT58002)	The charging station is a separate unit that should be located in a convenient space. When a battery is placed in the charging compartment, charging will start automatically on page 76.

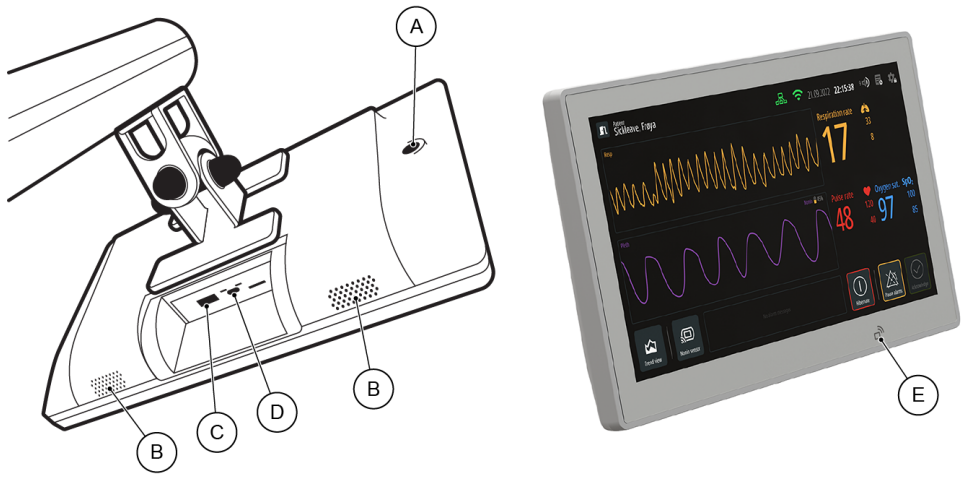
The components under item A, B, D and E, F, G are necessary for the mobile configuration to operate, in addition to cables for power and connection (VT60000, VT25028). See more details in the "Installation and Service Manual".

2.1.1 Sensor unit



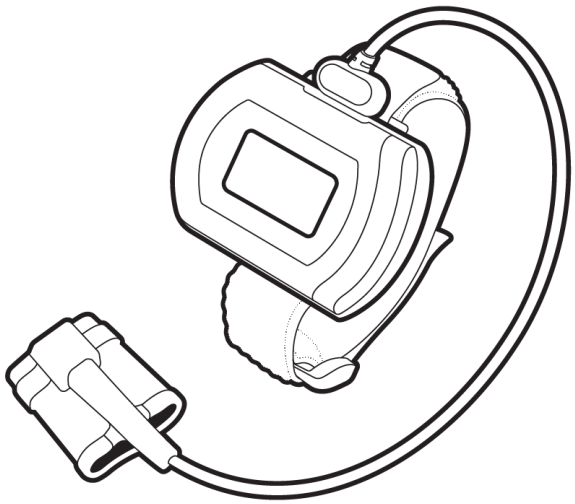
A	On/off button	A short press will turn the sensor unit on, and a long press will turn it off. Note that turning off the sensor unit will not turn off the display unit (see Display unit on page 28).
B	Acknowledge button	The button does not have a function in the current device version, see Version data on page 5.
C	Internal backup battery indicator	Shows the status of the internal backup batteries: • Green: Backup batteries are OK. • Red: Backup batteries are low. • Dark: The sensor unit is off.
D	Refer to instruction manual	Symbol to signify that the instructions for use must be read before operating the system.
E	LED bar	Shows colours based on the priority of the active alarm. See LED bar on page 58 for more information.
F	Front of the sensor	Pointed towards the chest of the patient.
G	Back of the sensor	The monitoring distance is to be measured from this position. See Positioning the sensor unit on page 32.
H	Speaker	Generates auditory alarm signals. See Alarm signals on page 58 for further information.

2.1.2 Display unit



A	On/off button	A short press will turn the display unit on, and a long press will turn it off. Note that the display unit will automatically be turned on when the sensor unit is turned on, but it must be turned off separately.
B	Speakers	Generates auditory alarm signals. See Alarm signals on page 58 for further information.
C	USB-A connector port	This can be used to connect a barcode scanner.
D	USB-C connector port	Connector between the sensor unit and the display unit, making the sensor unit the power source of the display unit.
E	NFC sensor area	Near-field communication (NFC) enables communication between two electronic devices over a distance of four cm or less. Both devices must be NFC compatible.

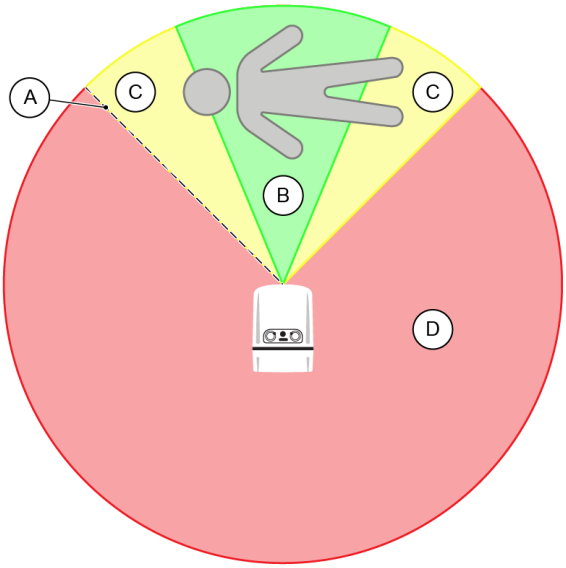
2.1.3 Nonin WristOx2® Model 3150 Pulse Oximeter BLE with 8000S Series reusable soft sensors (Optional)



Nonin WristOx$_2$® Model 3150 Pulse Oximeter BLE with 8000S Series reusable soft sensors are supported as an option to monitor pulse rate and oxygen saturation. For detailed visuals and descriptions of their functionality, visit the manufacturer's website at https://www.nonin.com/ or see their manuals.

2.2 Monitoring zones

There are three different monitoring zones: optimal zone, limited zone, and avoid zone. Understanding these zones is important to make sure that the monitoring is accurate and disturbances are minimal.



The radius (A) of the monitoring zones is set by maximum monitoring distance configured during installation.

Optimal zone

The optimal zone (B) is the primary monitoring zone. It is the zone directly in front of the sensor unit where measurements are obtained in the clearest and most reliable manner. The patient should be positioned so that their chest area is within the centre of the optimal zone. The zone covers an approximately 45-degree angle directly in front of the sensor unit.

Guidelines for the optimal zone include:

- Always make sure that the patient's chest area is within this zone during monitoring.
- Keep the presence of movement or other objects within this zone to a minimum.
- Make sure there are no obstructions or interference from other electronic devices in this zone.
- For correct positioning and mitigation of conflicts, see Checking that the sensor unit is correctly positioned on page 32 and Checking that no objects conflict with the functioning of the system on page 33.

Limited zone

The limited zone (C) is the 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. It extends to cover the immediate areas around the optimal zone, with an approximately 90-degree angle.

Guidelines for the limited zone include:

- Keep the presence of movement or other objects or persons within this zone to a minimum.

Avoid zone

The avoid zone (D) is a measurement zone of the sensor unit where the system cannot obtain reliable readings from the patient, but persons and moving objects within this zone **can have an effect** on the monitoring of the patient in the optimal zone. This zone must never be used for monitoring the patient.

Guidelines for the avoid zone include:

- Keep the presence of movement or other objects or persons within this zone to a minimum.

Best practices

- Familiarise yourself with the zones.
- Do regular checks to confirm that the patient's chest area remains within the optimal zone.
- Be mindful of potential disturbances, especially in busy clinical environments.
- In situations where it is necessary to introduce other persons and/or items into the monitoring zones (for example, to assist or consult a patient), standby mode on page 55 can be activated to pause monitoring for a defined period of time, avoiding potential disturbances and faulty alarms during the situation.

2.3 Data security

Guardian M10 is a programmable system. The device has hardware and firmware. IT (information technology) networks, such as the internet, are not necessary to operate the system. However, a Wi-Fi connection is necessary to update the firmware.

Hardware

The hardware consists of a sensor unit and a display unit. No other hardware can be used. If either unit is damaged, contact a service technician.

Firmware

The firmware only works in the specified hardware.

3 Positioning the sensor unit

Notice: Adjusting the sensor unit when there is an active monitoring session will cause the system to enter suspended mode on page 56.

This chapter covers the correct positioning of the sensor unit and what to take into account when it is positioned.

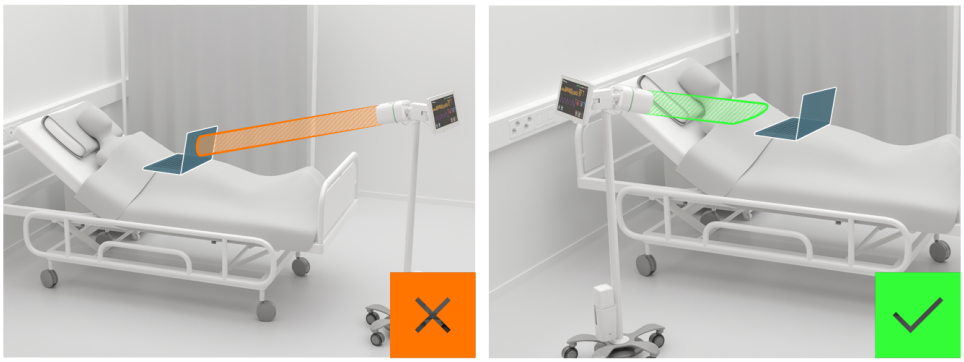
3.1 Checking that the sensor unit is correctly positioned

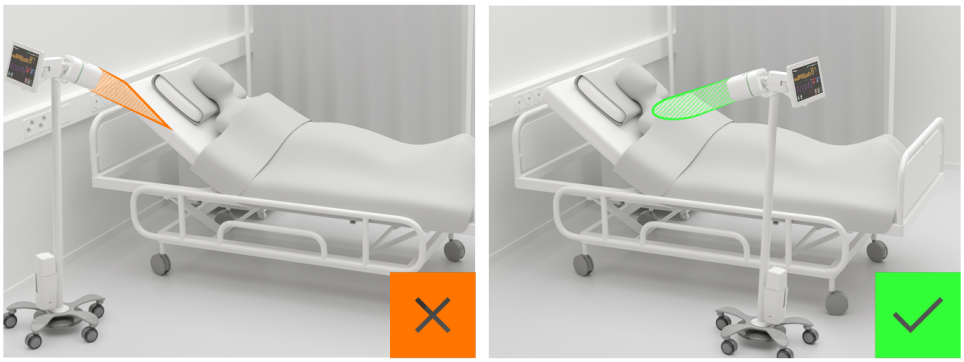
The direction of the sensor unit should always be towards the patient's chest area and placed in an optimal manner.

Direction of the sensor unit

The front of the sensor unit must be directed at the patient's chest area so that the patient's chest area remains within the optimal zone on page 29, even if the patient moves in bed, sits up or lies down. The patient's chest area must be able to stay within the minimum and maximum monitoring distances. The minimum distance is 0.5 metres, and the maximum distance is defined at installation. You can see it from *Device management view* > ***System information***.

Placement of the sensor unit





Keep in mind the usual movements or habits of a patient when you plan the placement of the sensor unit. It should not be blocked if the patient sits up or lies down after the monitoring is started, nor obstructed by objects that they can hold in their lap, such as computers or books.

For the mobile configuration, the sensor unit should be at the side of the bed, and as close as reasonable while obeying the other guidelines. The bed should be kept at a reasonably low level.

3.2 Checking that no objects conflict with the functioning of the system

Objects within a certain proximity to the sensor unit or the display unit can prevent the correct operation of the system. When making sure that no objects conflict with the functioning of the system, keep in mind the monitoring zones on page 29.

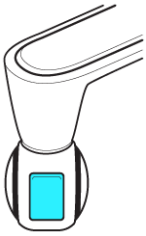
Always do a check of the configuration's surroundings:

- Make sure that there are no rotating table fans in the monitoring zones.
- Make sure that there is no Wi-Fi router within a one-metre distance of the sensor unit or the display unit.
- Make sure that there are no bed trapeze bars in the monitoring zones. This includes both the chain holding the trapeze bar as well as the trapeze bar itself.
- Make sure that window or bed curtains do not enter the monitoring zones.

- Make sure that lamps or wires hanging from the ceiling do not enter the monitoring zones.

3.3 Checking that the wheel locks are activated (Mobile configuration)

After the mobile configuration has been positioned correctly, wheel locks must be activated to prevent the unit from moving. The locks are placed at each wheel.



When the wheel lock is up, it is not activated, and the unit can be moved.

When the wheel lock is down, the lock is activated and the unit cannot be moved.

4 Setting up Guardian M10

This chapter gives information about the actions and checks required before monitoring can be started.

Detailed instructions for the installation and configuration of the system can be found in “Installation and Service Manual”.

4.1 Performing initial checks

Service technicians are responsible for the initial installation and set-up. See the sections below for what set-up procedures remain for you to do in a clinical setting.

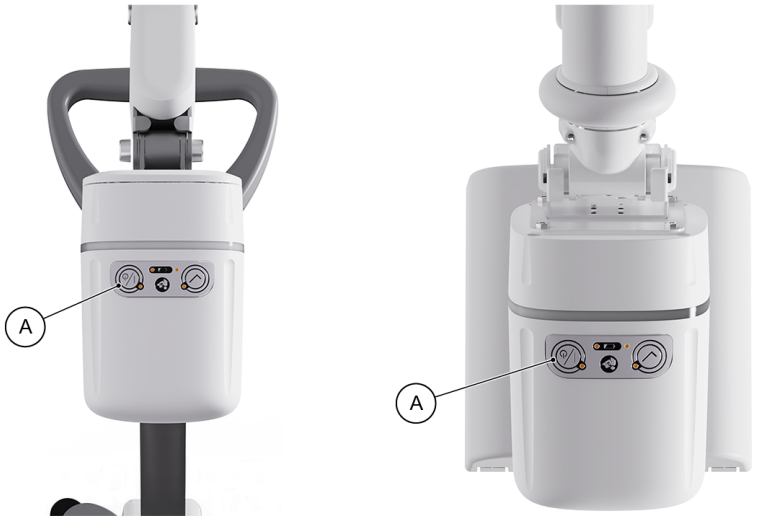
Stationary configuration checks

- Examine the sensor unit and display unit casings for signs of damage.
- Make sure that the sensor unit is correctly positioned on page 32. The sensor unit should point towards the chest of the patient at a distance of 1-2 metres. The largest movement of the chest when the patient breathes should be towards the sensor unit.
- Make sure that no objects conflict with the respiratory rate monitoring on page 33. Remove potential moving objects within 2.5 metres from the sensor unit.
- Make sure that the wall mount arm remains in the desired position after any adjustments.

Mobile configuration installation parts and checks

- Examine the sensor unit, display unit and battery docking station casings for signs of damage.
- Make sure there is a sufficiently charged battery on page 76 in the battery docking station.
- Make sure that the sensor unit is correctly positioned on page 32. The sensor unit should point towards the chest of the patient at a distance of 1-2 metres. The largest movement of the chest when the patient breathes should be towards the sensor unit.
- Make sure that no objects conflict with the respiratory rate monitoring on page 33. Remove potential moving objects within 2.5 metres from the sensor unit.
- Make sure that the wheel locks are activated on page 34.

4.2 Turning on the system



When the physical components of Guardian M10 have been examined, turn on the system by pressing the on/off button (A). The LED bar will light up green for two seconds when turning on.

4.3 Checking the power status

The power status of the system is shown with a symbol in *Main view*. Always check the power status of the system before you take it into use, and make sure it is not running on backup batteries.

Running on main power

When the system is running on main power, the symbol displayed in *Main view* changes according to the type of power source. If applicable, the current power level and remaining operation time are shown as well.

The system is powered by the mains power supply.

The system is drawing power from the trolley battery, and there is more than 60 minutes of operation time.

The system is drawing power from the trolley battery, and there is 30-60 minutes of operation time.

The system is drawing power from the trolley battery, and there is less than 30 minutes of operation time. The technical alarm “Trolley battery low. Less than 30 minutes remaining” will be generated when this happens.

For the mobile configuration, you can also check the LEDs on the battery on page 76 to determine the remaining charge before you turn on the system. If there are less than four LEDs lit, consider changing the battery on page 76 before you take the system into use.

Running on backup batteries

When the system cannot find the main power source, it switches to the backup batteries. The power status symbol in *Main view* is then replaced with either of these two symbols:

The system is running on backup batteries, and the battery status is adequate. The technical alarm “Main power lost” will be generated if main power is not restored within five minutes.

The system is running on backup batteries, and they are low on power. The technical alarm “Internal backup batteries low” is generated when this happens.

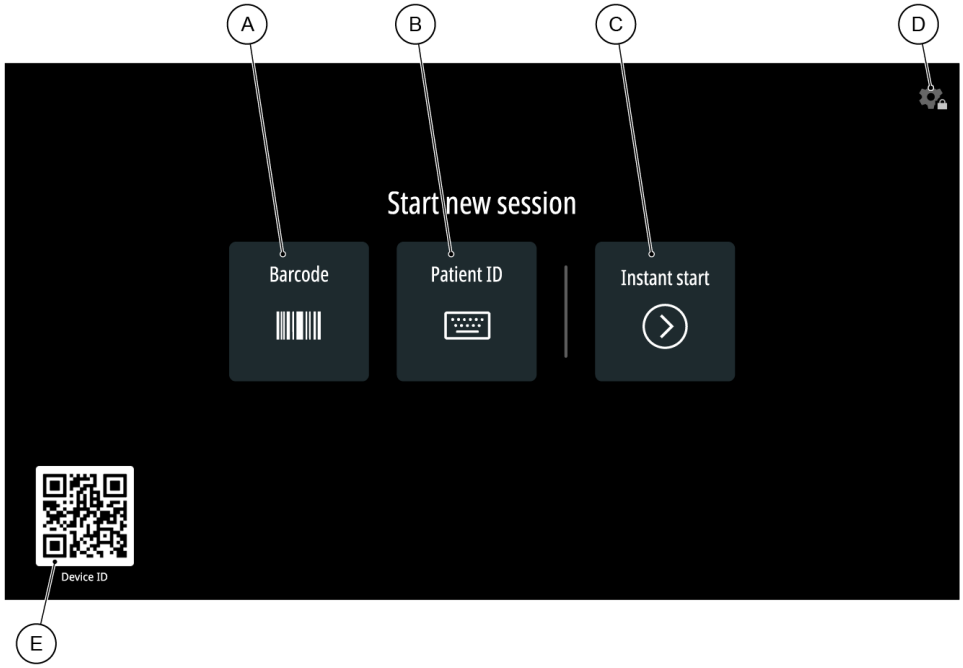
5 Operating Guardian M10

This chapter gives information about the views and controls of Guardian M10.

5.1 Patient management view

Patient management view is the default view when there is no active monitoring session. It is the view that opens up after the system is turned on and boot up is complete, and when a monitoring session is ended.

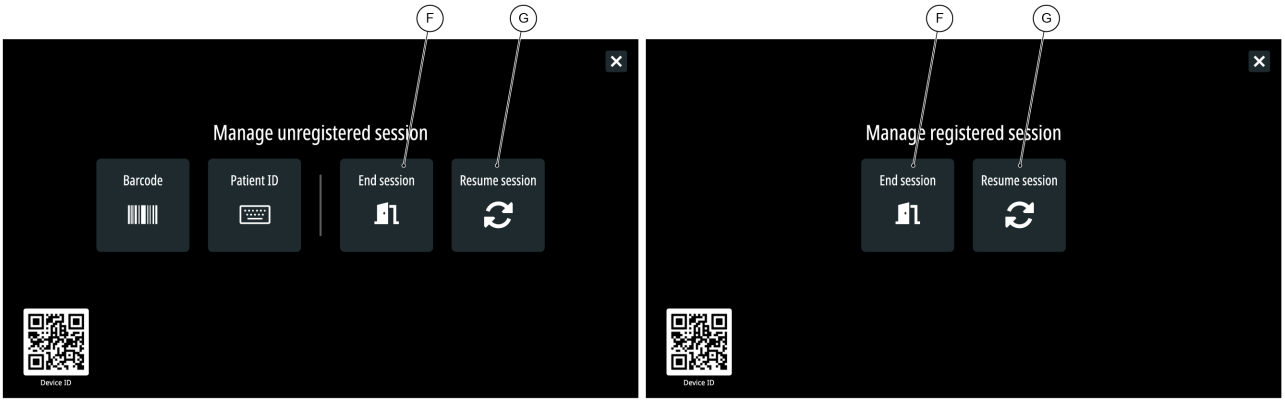
Layout for starting a new session



A	Barcode (Optional) > Tap to enter patient information with a barcode scanner.
B	Patient ID > Tap to register a patient with their patient ID.
C	Instant start > Tap to start monitoring with an unregistered patient.
D	*Device management view* > Tap to enter *Device management view*, or keep the icon pressed to activate cleaning mode on page 43.
E	Device ID (Optional) > Scan to identify the specific unit.

See Registering a patient on page 46 for more information on the patient registration methods.

Layout when accessed during monitoring of an unregistered/registered patient



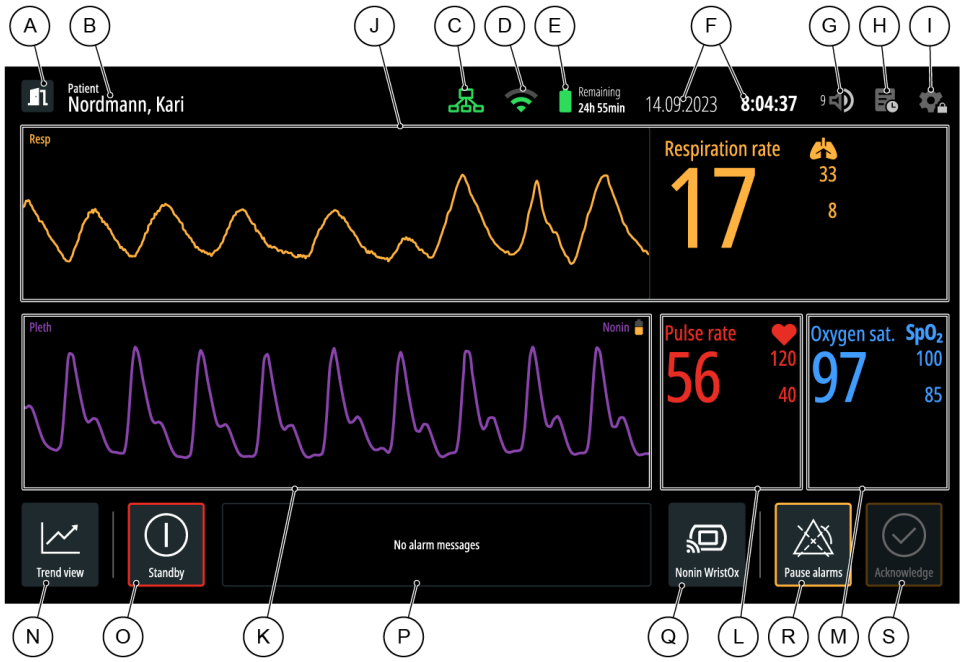
F	End session > Tap to release the patient and end the active monitoring session.
G	Resume session > Tap to return to *Main view* and continue the active monitoring session.

Layout when technical alarms are active

H	Alarm messages
I	Acknowledge button > Tap to acknowledge alarms.
J	Pop-up message

5.2 Main view

All main functions are located in *Main view*.

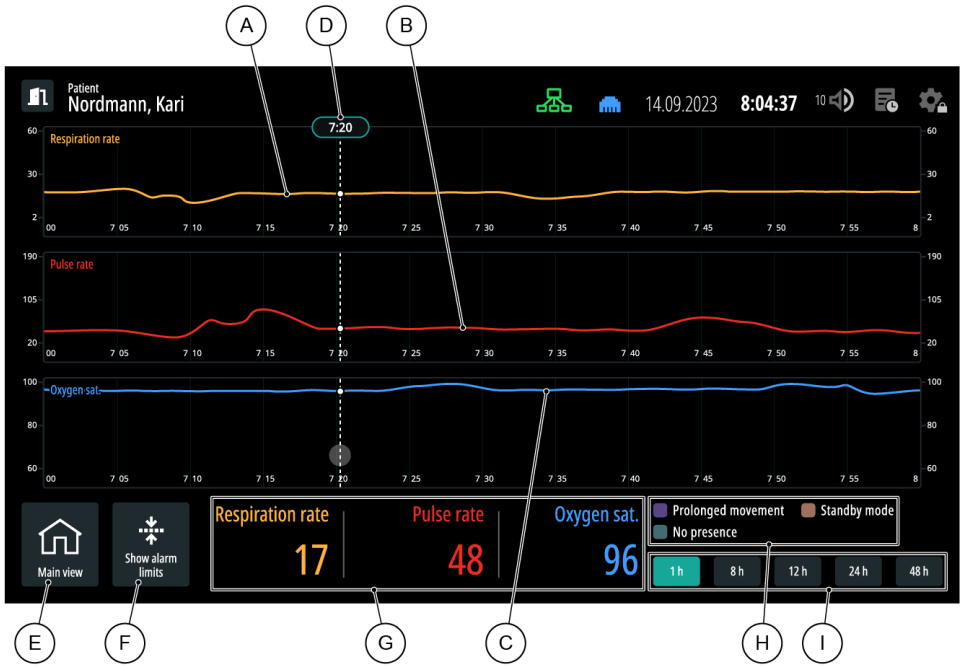


A	*Patient management view* > Tap to enter *Patient management view*.
B	Patient information > Tap to show the patient ID (if available) for 10 seconds.
C	Remotely connected system status
D	Network connection status
E	Power status > Shows the power status of the system. The symbol appears different based on the configuration (mobile or stationary). See Checking the power status on page 36 for further information.
F	Date and time
G	Volume > Tap to open the volume adjustment pop-up. 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.
H	Event log > Tap to open the event log overlay and view event history.
I	*Device management view* > Tap to enter *Device management view*, or keep the icon pressed to activate cleaning mode.

J	Respiration rate data
K	Plethysmograph and the pulse oximeter's battery status (Optional)
L	Pulse rate data (Optional)
M	Oxygen saturation data (Optional)
N	*Trend view* > Tap to enter *Trend view*.
O	Standby mode > Tap to activate standby mode.
P	Alarm message area
Q	Nonin WristOx icon > Tap to connect an optional pulse oximeter or view its connection status.
R	Pause alarms
S	Acknowledge alarms

5.3 Trend view

Tap the ***Trend view*** icon in *Main view* to open *Trend view*.



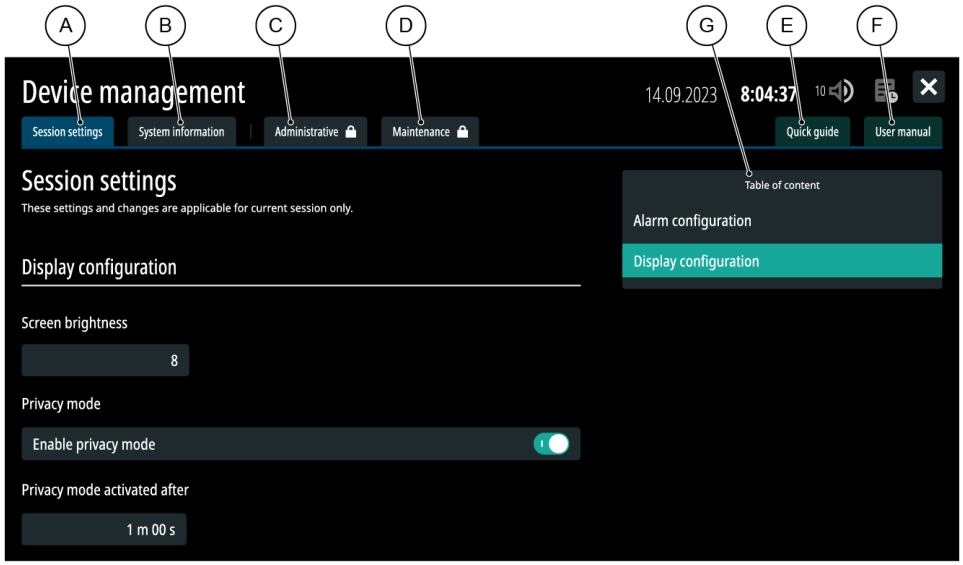
A	Respiration rate trend

B	Pulse rate trend
C	Oxygen saturation trend
D	Show-value line
E	Return to *Main view*
F	Show current alarm limits
G	Show-value section
H	Explanation of colours
I	Select timeline

5.4 Device management view

Tap the ***Device management view*** icon in *Main view* to open *Device management view*.

> Notice: If you have entered the PIN in a locked tab, but *Device management view* times out or you go to *Main view* yourself, you must enter the PIN again to be able to open and adjust the settings or functions in the locked tabs.



A	Session settings > Settings that can be changed by all users: alarm and display configurations.

B	System information > Information about the system: sensor unit, display unit and battery status data.
C	Administrative > Settings for default alarm system attributes, configuration of system, display and connection. You must enter the administrative PIN to access this tab.
D	Maintenance > Management and service information for service technicians. You must enter the administrative PIN to access this tab.
E	Quick Guide > Quick guide to key system operations.
F	User Manual > Opens this “Instructions for Use” in digital format.
G	Table of contents > Scroll and tap the titles in the box to navigate between different sections or chapters in the selected tab.

5.5 Using the touchscreen

Tap an icon on the screen to open a new view, or to show additional information.

Slide a finger across the screen to scroll.

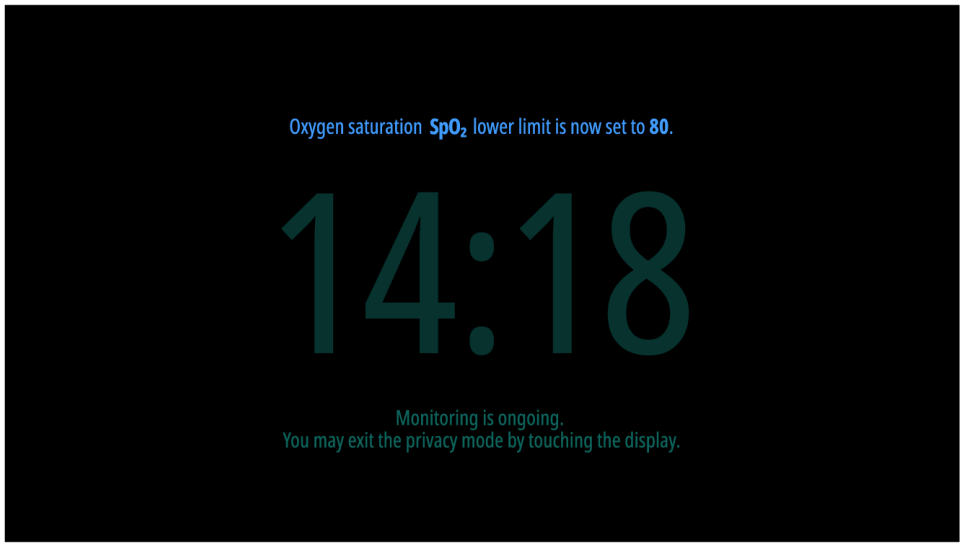
Icons are momentarily highlighted when you tap them to show that the touch is registered (A). If an icon cannot be interacted with, it is dimmed: for example, when there are no alarms to acknowledge, the ***Acknowledge*** button is dimmed (B).

When a state or a function is active, the border accent colour of the icon fills the icon. For example, when alarms are paused, the ***Pause alarms*** button (C) is filled with the border accent colour.

5.5.1 Privacy mode

Notice: If you have set the SpO_2 low alarm limit lower than 85, the current limit is displayed on screen when privacy mode is active.

If you do not touch the screen for a certain amount of time, and no alarms are active, the display enters **privacy mode**. When privacy mode is active, this screen is shown:



Privacy mode remains active until you tap the screen, or a physiological or a technical alarm becomes active.

Privacy mode is not enabled by default, but it can be changed from *Device management view* > ***Session settings*** > ***Enable privacy mode***.

To prevent non-personnel from seeing the patient's information, a PIN code can be activated in administrative settings to exit privacy mode. In the event of any physiological or technical alarms, the privacy mode will be exited regardless of configuration. For detailed instructions, see "Installation and Service Manual".

5.5.2 Cleaning mode

Notice: You cannot activate cleaning mode if alarms are active and unacknowledged.

For cleaning and disinfecting purposes, you can lock the screen by activating cleaning mode. To activate the cleaning mode, keep the ***Device management view*** *icon* on page 39 pressed. To exit the cleaning mode, keep the button ***Long press to resume*** pressed.

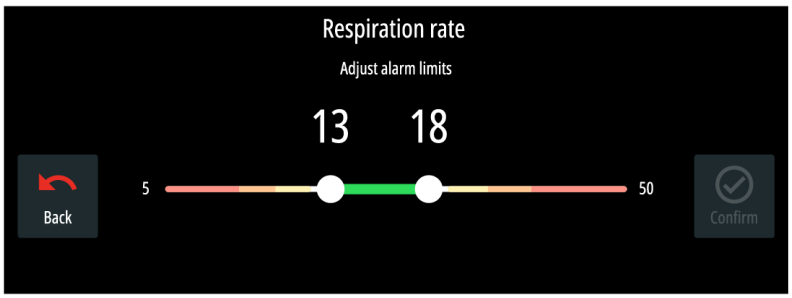
A white border and a text box show that cleaning mode is active:

The default view remains active and monitoring continues, but no touches on the screen are registered.

5.6 Navigating the screen and views

All views (*Patient management view*, *Trend view* and *Device management view*) are opened from their corresponding icons in *Main view* on page 39.

Close a view by tapping the ***x*** icon in the top right corner, or use the ***Main view*** icon on page 40 in the bottom left corner to return to *Main view*.



Close an adjustment window by tapping ***Back*** or ***Confirm***.

If you access another view or open an adjustment window, but do not touch the screen for a set period of time, the system automatically returns to the default view. The default view is *Main view* if there is an active session, and *Patient management view* if there is no active session.

5.7 Adjusting the display settings

Notice: Adjustments made in the ***Session settings*** tab are only applicable to the active monitoring session, and the default settings will be restored when the session ends. To define the default settings, see “Installation and Service Manual”.

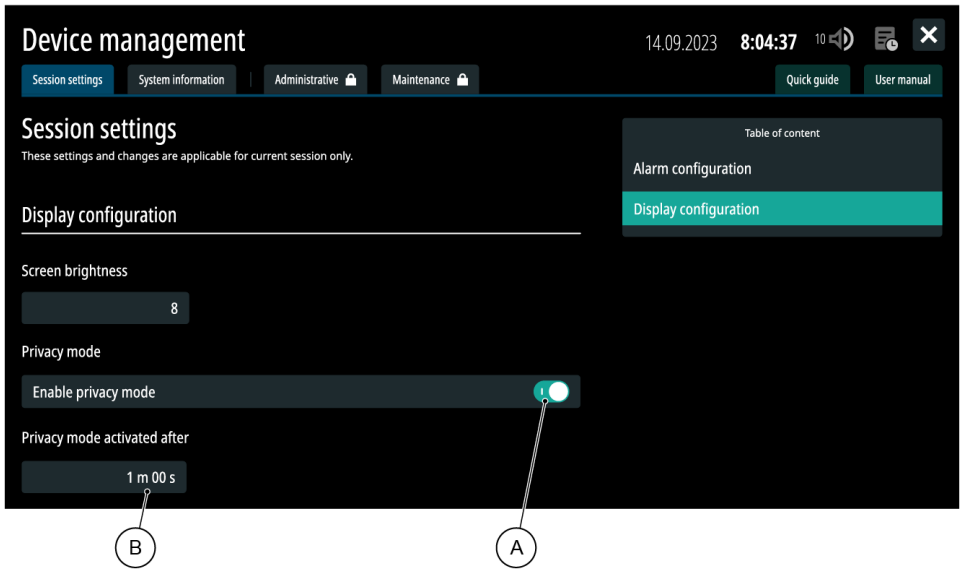
Access the display settings from *Device management view* > ***Session settings*** > ***Display configuration***.

5.7.1 Adjusting the screen brightness

The screen brightness can be manually adjusted in *Device management view.*

1. Tap the ***Device management view*** icon.
2. Access ***Session settings*** > ***Display configuration*** > ***Screen brightness***.
3. Drag the slider to a value between 1 and 10.

5.7.2 Adjusting privacy mode settings



A	Enable/disable privacy mode
B	Adjust the privacy mode activation time

6 Monitoring a patient

⚠ **Precaution**
Other people or moving objects within the monitoring zones can have an effect on the measurements.
Make sure that the patient is in the optimal zone on page 29, and that all zones are clear of other moving objects before you start monitoring.

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

ⓘ Notice: Make sure that there are no objects that can conflict with the functioning of the system on page 33.

This chapter describes the actions and procedures necessary for patient monitoring.

6.1 Registering a patient

ⓘ Notice: The monitoring data stored in the unit will be discarded after the monitoring session ends.

Patient management view opens automatically after the system is turned on, and is the default view between active sessions. The following registration methods are available:

Barcode (Optional): The patient is registered by reading the code on the patient's wristband with a barcode scanner (not included in delivery).

Patient ID: The patient is registered by entering the ID manually.

Instant start: The unit starts monitoring with an unregistered patient.

If you are taking the unit into use and *Patient management view* is not open, it could mean that the unit is already in use, or that the previous session was not ended correctly.

If you are unsure of the unit's readiness for patient registration, see Troubleshooting on page 78.

6.1.1 Registering a patient with a barcode scanner

1. Tap ***Barcode***.
2. Scan the code on the patient's wristband.
3. Make sure that the patient information is correct.
4. Tap ***Confirm***.

6.1.2 Registering a patient manually

1. Tap ***Patient ID***.
2. Enter the patient's ID and tap ***Confirm***.
3. Make sure that the patient information is correct.
4. Tap ***Confirm***.

6.1.3 Registering a patient after monitoring has started

When a monitoring session is started with instant start, patient is not registered.

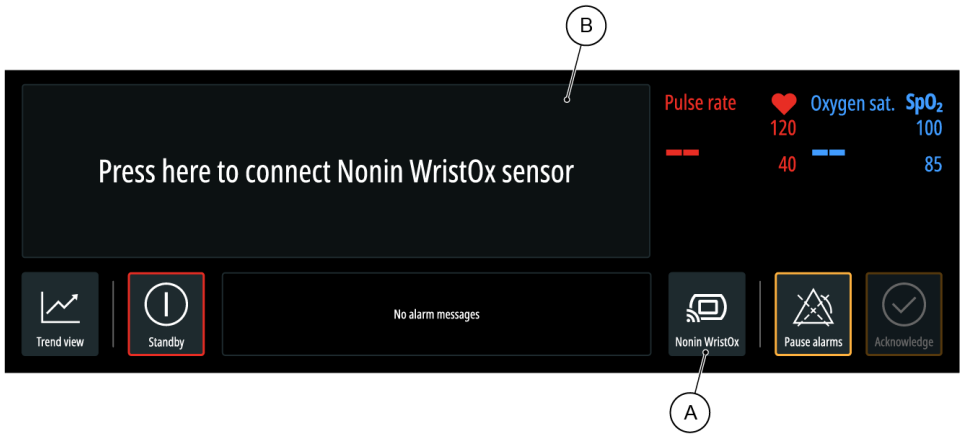
To register the monitored patient, either tap the ***Patient management view*** *icon* on page 39, or the ***patient information*** field to open *Patient management view*.

6.2 Connecting Nonin WristOx2® Model 3150 Pulse Oximeter BLE (Optional)

Precaution
During the pulse oximeter pairing, always confirm that the pulse oximeter you are connecting to is the correct one.
If a wrong pulse oximeter is connected, the patient will not be monitored.

Precaution
Do not move the pulse oximeter temporarily from one patient to another, when it is already in use with the patient registered on Guardian M10.
Moving a connected pulse oximeter to another patient can lead to patient deterioration not being detected.

Before connecting, make sure that the pulse oximeter you want to connect to has sufficient battery charge.



1. Tap the ***Nonin WristOx*** icon (A) in *Main view* or the pulse oximeter data area (B).
2. Follow the connection procedure shown on screen.
3. Tap ***CONFIRM*** to complete the connection procedure.

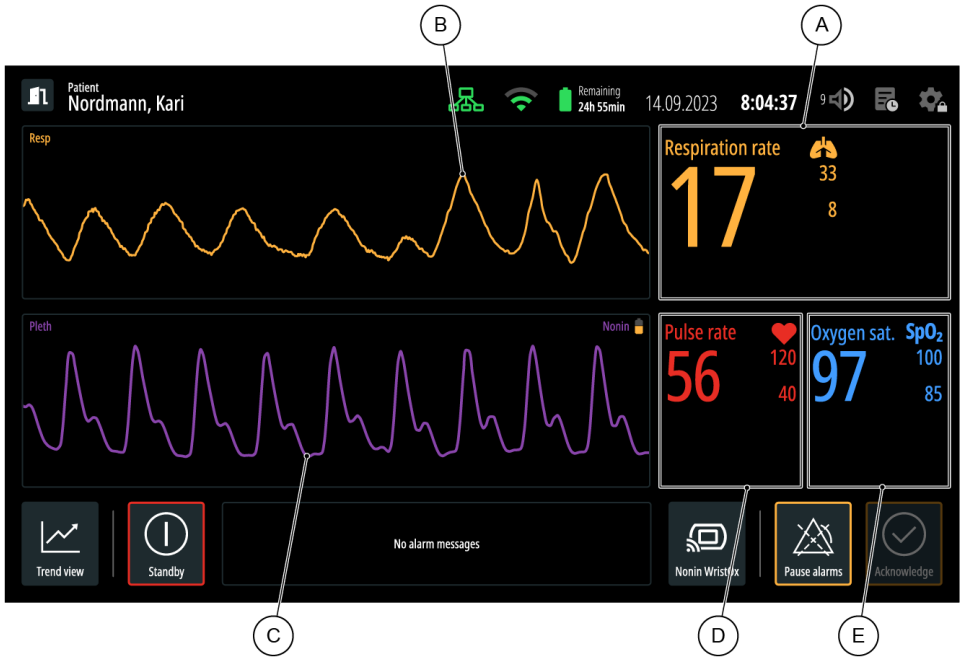
The pulse oximeter is connected. Data from the pulse oximeter shows in *Main view*. You can confirm that Guardian M10 is connected to the correct pulse oximeter by tapping the ***Nonin WristOx*** icon > ***Test connection***. The connected pulse oximeter then displays the value “CP” for a short time as confirmation. You can test the connection at any time during a monitoring session.

If you need to disconnect the pulse oximeter, tap the ***Nonin WristOx*** icon > ***Disconnect Nonin WristOx***.

If there are problems with the connection procedure or the selected pulse oximeter, see Troubleshooting on page 78.

6.3 Verifying that the unit is monitoring

To verify that the unit is monitoring, do a check for the following elements:



- Respiration rate value and alarm limits (A) are visible.
- Respiration waveform (B) is streaming.

Optional (if a pulse oximeter is connected):

- Plethysmograph (C) is streaming.
- Pulse rate value and alarm limits (D) are visible.
- Oxygen saturation value and alarm limits (E) are visible.

6.4 Viewing patient measurement data

Patient measurement data is shown in *Main view* and *Trend view*.

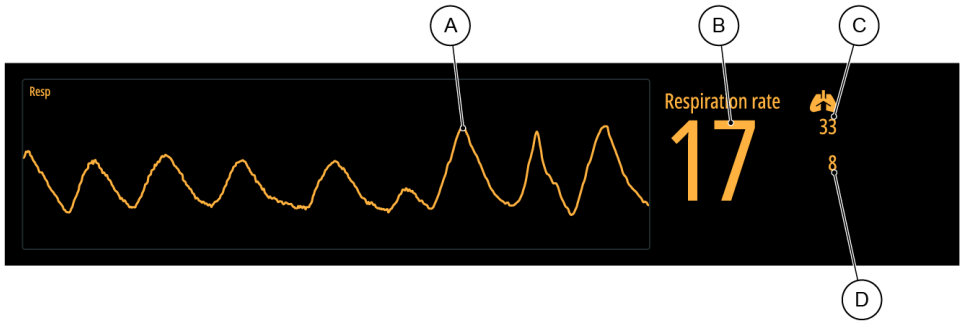
6.4.1 Viewing current measurement data

> **Precaution**
> Oxygen saturation (SpO_2) measurement does not replace the need to monitor respiration rate in clinical care.

Vitals currently being monitored by the system are visible in the *Main view*.

This data is shown for respiration rate:

- respiration waveform
- respiration rate value and alarm limits



The respiration waveform (A) gives a visual presentation of the respiratory movement when the patient is resting. The value (B) is the current respiration rate calculated over the last 60 seconds. The upper (C) and lower (D) alarm limits represent the values that, should the measured value be more than the upper alarm limit or less than the lower alarm limit, an alarm becomes active. They can be tapped to open the limit adjustment window.

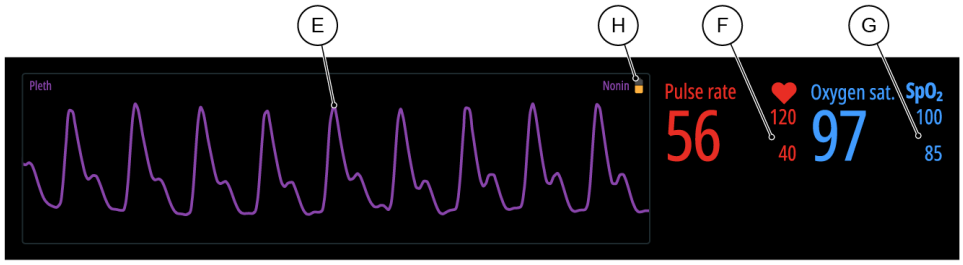
Keep in mind that certain technical alarms will affect the respiration rate area. For more information, see Visual signals for technical alarms on page 61.

If there is no pulse oximeter connected, this information is shown under the respiration rate data field:

To connect a pulse oximeter, tap the prompt text that is shown. For detailed instructions, see Connecting Nonin WristOx2® Model 3150 Pulse Oximeter BLE (Optional) on page 47.

After a pulse oximeter is connected, this data is shown:

- plethysmograph stream
- pulse rate value and alarm limits
- oxygen saturation value and alarm limits
- the remaining battery charge of the connected pulse oximeter



The plethysmograph stream (E) is formed based on the blood perfusion through the pulse oximeter. The peaks represent the pulse rate. If the patient's perfusion is poor or the components of the pulse oximeter are badly situated, the peaks are less pronounced. The pulse rate and oxygen saturation values are calculated by the pulse oximeter. For further information on how these values are formed, see the pulse oximeter manufacturer's instructions.

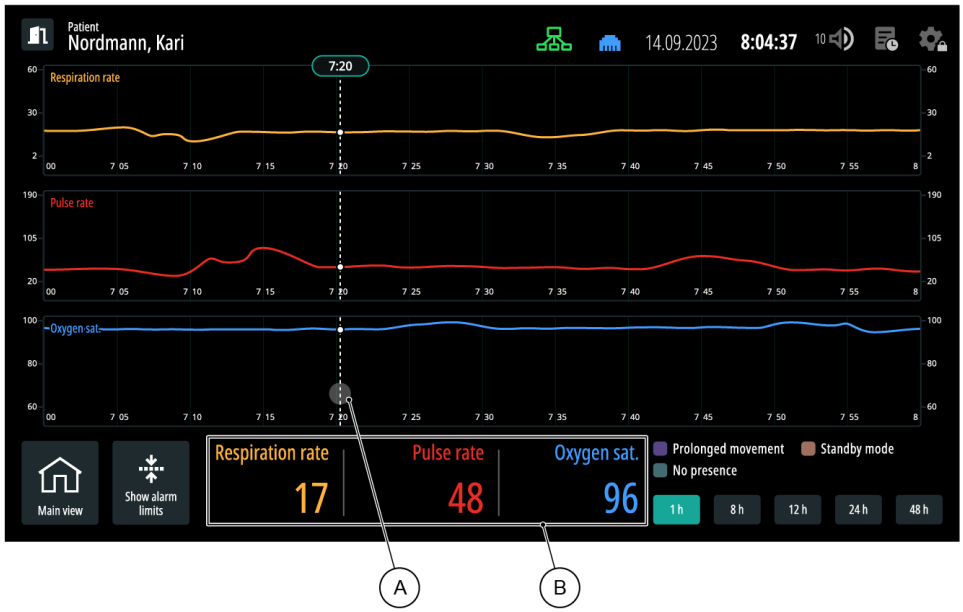
Like the respiration rate alarm limits, the alarm limits for pulse rate and oxygen saturation represent the values that, should the measured value be more than the upper alarm limit or less than the lower alarm limit, an alarm becomes active. To open the limit adjustment windows, tap the corresponding area (F) or (G).

The pulse oximeter's battery icon (H) displays the battery level of the pulse oximeter. The battery level is indicated with these three different colours:

- Green: 26-53 hours of operation time remain.
- Yellow: 5-26 hours of operation time remain.
- Red: battery is empty and must be replaced.

6.4.2 Viewing trending data in Trend view

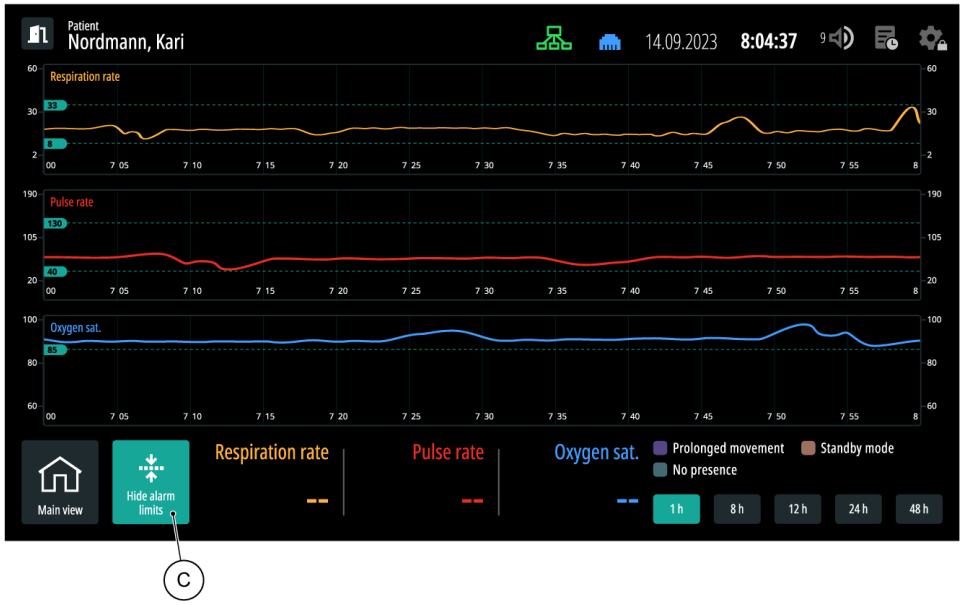
Trending data in *Trend view* is formed according to the respiration rate. The trend shows the variation of the measured vital on a timeline. If a pulse oximeter is equipped, pulse rate and oxygen saturation trends are shown as well.



When you open *Trend view*, the available trends are shown according to the default time selection, which is

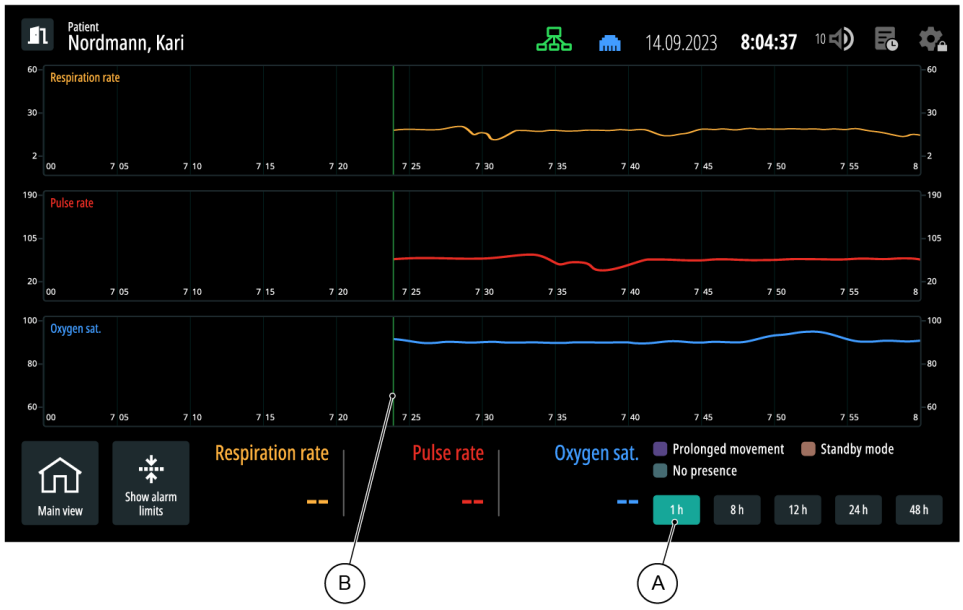
- 1 h, when the current session has continued 0-4 hours
- 8 h, when the current session has continued 4-10 hours
- 12 h, when the current session has continued 10-18 hours
- 24 h, when the current session has continued more than 18 hours

Tapping a point on the timeline (A) will show the values registered at that point (B).



Tapping (C) shows the alarm limits on each timeline.

Adjusting the timescale



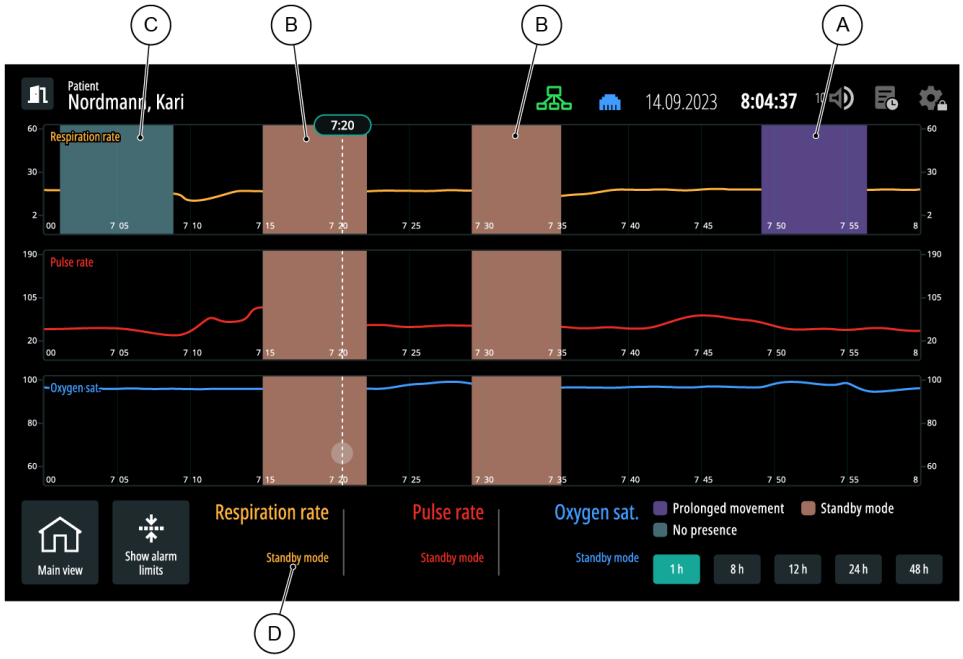
To change the timeline that is shown, tap the desired timescale option. The selected timescale option is highlighted (A).

If the timescale is longer than the duration of the current monitoring session, a green marker (B) shows the starting point of the session on the timeline.

Viewing events on the timeline

> Notice: Turning around in bed, eating, talking, and frequent sleep apnea or coughs can cause periods that are marked as “Prolonged movement” on the timeline.

> Notice: If sections on the timeline are marked with “No presence” even though the patient is on the bed and the unit is monitoring, check whether the sensor unit is correctly positioned on page 32.



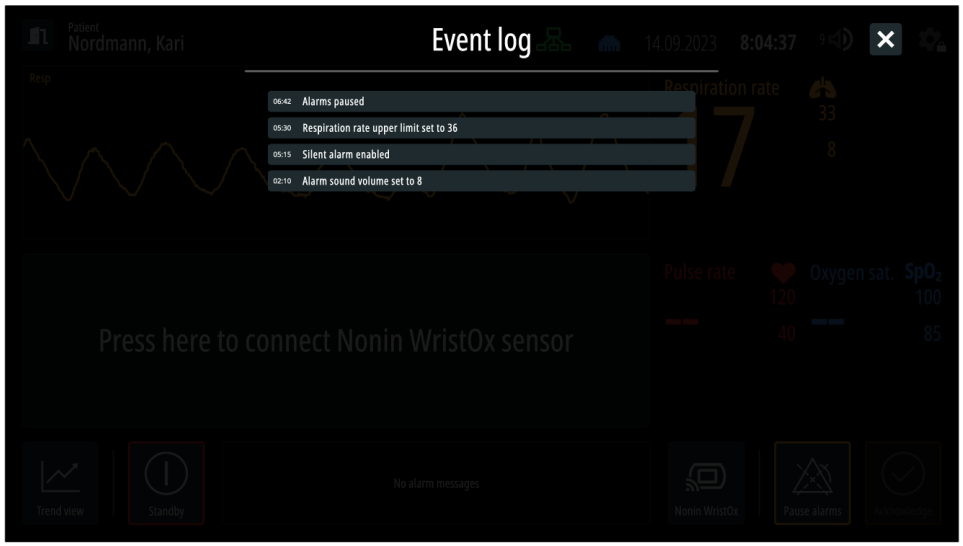
The following events can be marked on the timeline:

- Prolonged movement (A): Measuring of respiration rate was disrupted because the patient was moving.
- Standby mode (B): Standby mode was activated manually by the user.
- No presence (C): The system did not detect any presence.

During these events, the system does not monitor the intended vitals. If you tap a point on the timeline that aligns with an event, the event explanation (D) is portrayed instead of the value, as no value could be recorded.

6.5 Viewing events in the event log

Notice: The event log will be cleared for every new monitoring session, when the system powers down, or when it is restarted.



Certain system and alarm related events are stored in the event log. Each listing contains the date, time and message related to the event. The maximum length of the log is 604 800 entries, after which each new event will overwrite the oldest event in the log.

The event log only displays events that occur between the start and the end of a monitoring session.

Event type	Displayed text	Additional information
Alarm condition becomes active.	[Corresponding alarm message]	Corresponding alarm message is shown. For example, "*Pulse rate below limit: 36 (40, 130)*".
Alarm condition becomes inactive.	[Corresponding alarm message], *inactive*	Corresponding alarm message is shown, followed by "inactive". For example, "*Main power lost, inactive*".
The upper limit of a physiological alarm is adjusted.	*Respiration rate/Pulse/SpO_2 upper alarm limit set to* [new alarm limit]	For example, "*Respiration rate upper alarm limit set to 27*".
The lower limit of a physiological alarm is adjusted.	*Respiration rate/Pulse/SpO_2 lower alarm limit set to* [new alarm limit]	For example, "*Respiration rate lower alarm limit set to 9*".

Event type	Displayed text	Additional information
One or more alarms are acknowledged.	*Alarms acknowledged*	-
Alarms are paused, or alarms are no longer paused.	*Alarm signals paused* or *Alarm signals no longer paused*	-
Silent alarm timer is adjusted.	*Silent timer on display unit set to* [new value]	For example, "*Silent timer on display unit set to 1 minute*".
Patient information is changed.	*Patient information changed to* [new]	The system logs a change in patient information. This applies both to a registration of a previously unregistered patient, as well as changing the registered patient to a new one. For example, "*Patient information changed to Ola Nordmann*".
System mode is changed.	*System mode changed to* [new mode]	The system logs a change in a system mode from one to another. For example, "*System mode changed to privacy mode*". The following modes are logged: • active session • standby mode • suspended mode • cleaning mode • privacy mode
System settings are changed.	*System setting* [setting type] *changed to value* [value]	Any change made in the system settings is displayed. For example, "*System setting screen brightness changed to value 7*".

Event type	Displayed text	Additional information
User settings are changed.	*User setting* [setting type] *changed to value* [value]	User settings are different from system settings, as they're not persistent in the database, and only apply for the duration of the current session. Any setting change done by the user is logged. These settings include: • alarm delay for no new respiration rate • screen brightness • privacy mode activated after (time duration) • alarm volume

6.6 Activating the standby mode

Activate standby mode when you want to keep the session active, but pause the measuring of vital parameters. For example, in these situations:

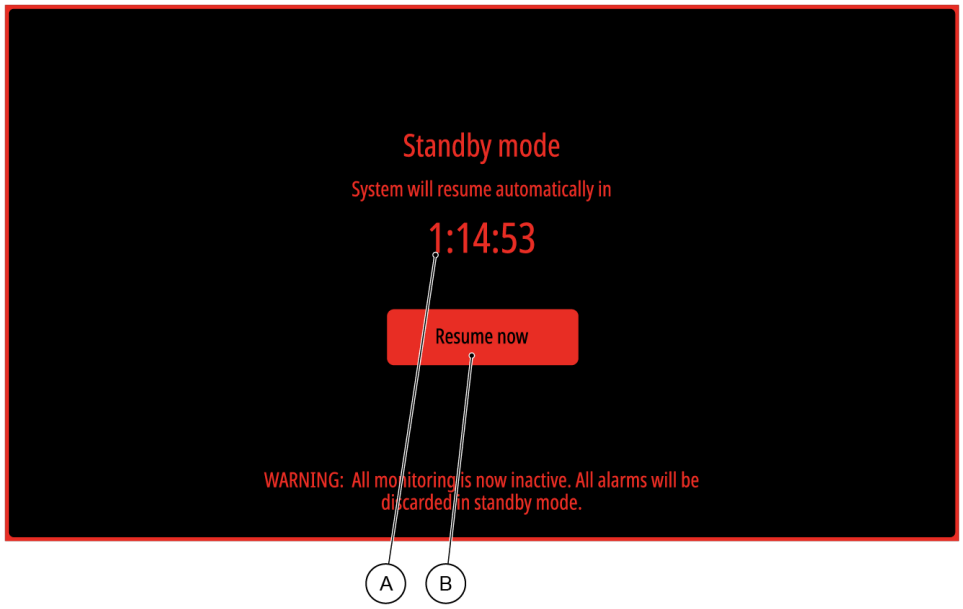
- You enter the monitoring zones. For example: to help, feed, or examine the patient.
- The patient leaves the optimal zone. For example: to use the bathroom, to maintain physical activity, or to undergo other medical examinations or treatment.

When the system is in standby mode, **no alarms will be generated**. Likewise, you cannot activate standby mode if any alarms are active.

⚠ **WARNING**
Always deactivate standby mode when it is no longer necessary.
All monitoring is stopped when the system is in standby mode. No alarms will be generated.

⚠ **Precaution**
If you are using the mobile configuration, make sure you have a sufficient remaining charge in battery power, and the system does not shut down while the standby mode is active.

1. Tap the ***Standby mode*** icon in *Main view*. A new window opens.
2. Select the duration of the standby mode.
3. Tap ***Confirm*** to start standby mode.



The system is now in standby mode. If you selected a timed duration, standby mode is automatically deactivated and monitoring continues when the timer on the screen runs out (A). If you selected indefinite, standby mode is active until you manually deactivate it by tapping ***Resume now*** (B).

6.7 Deactivating suspended mode

There are two states where monitoring is paused: the standby mode and the suspended mode. Standby mode on page 55 is intentionally activated by the user. In suspended mode, the system stops monitoring the respiration rate because of sensor movement. When the system enters suspended mode, a notification block (A) shows on the respiration rate data field, and you must follow the instructions provided on screen to deactivate the suspended mode and continue monitoring.

6.8 Ending patient monitoring

1. In *Main view*, tap the ***Patient management view*** icon.
2. Tap ***End session***.
3. Tap ***Confirm*** to end the monitoring session.

The monitoring session ends, and the default system settings are restored. *Patient management view* is now the default view.

If you are using the mobile configuration, you must also turn off the system. Turn off the display unit first by keeping the on/off button on the display unit pressed (see Display unit on page 28). After that, turn off the sensor unit by keeping the on/off button on the sensor unit pressed until the internal backup battery indicator turns dark (see Sensor unit on page 27).

7 Alarms

This chapter gives information about the alarms of Guardian M10, and how to identify them.

When there is an active monitoring session, alarms are shown in *Main view* on page 39. If alarms become active when you are in another view (for example, *Device management view*) or another mode is active (for example, cleaning mode on page 43), the system redirects you to *Main view*.

Note that the exception to this is the standby mode on page 55: no alarms are generated while standby mode is active.

When there is no active monitoring session, *Patient management view* on page 37 is the default view. This means that, should any technical alarms become active, they are shown in this view.

7.1 Alarm signals

The system uses sounds and visuals to indicate that an alarm is active. Both the display unit and the sensor unit can generate visual signals and alarm sounds.

By default, the alarm system generates alarm sounds on the display unit and not on the sensor unit.

In case the connection is lost between the sensor unit and the display unit, both the display unit and the sensor unit can generate visual signals and alarm sounds independently.

The sensor unit will also generate alarm sounds if there is an alarm that has not been acknowledged on page 71 for more than 5 minutes or if the alarms are not paused on page 73. This is a preventative mechanism in case alarm sounds cannot be generated on the display unit for any reason, for example, if the display unit speaker has malfunctioned.

7.1.1 Visual signals

Visual signals of alarms are represented as visual information on the screen (icons, colours, messages) and lights on the display unit or sensor unit.

LED bar

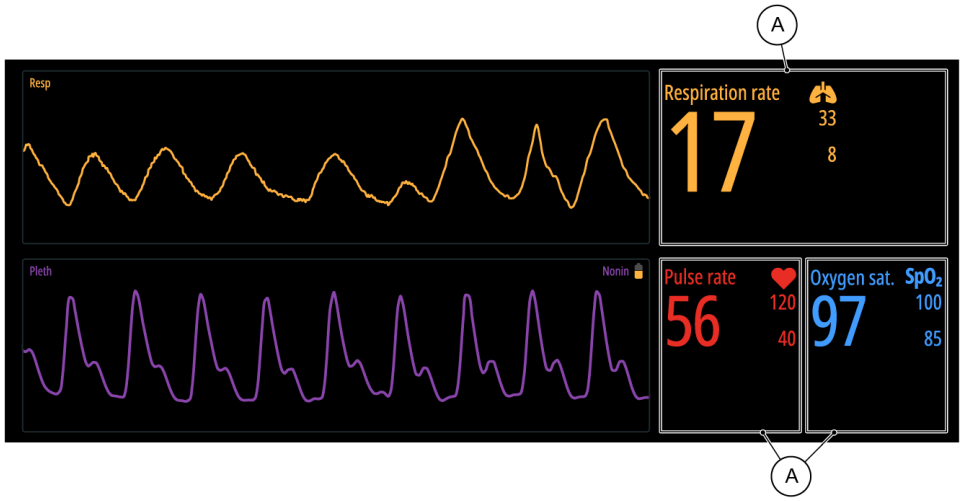
The LED bar is located on the sensor unit. It shows colours based on the priority of the active alarm. There are three colours in use:

- Red for high priority alarms
- Yellow for medium priority alarms
- Blue for low priority alarms

When there are multiple active alarms, the LED bar shows the colour corresponding to the highest priority alarm.

Vital areas and values

Notice: If the alarms have been paused on page 73, no visual signals for alarms are generated.



The colours of the vital area backgrounds (A) and values show the activity/inactivity of an alarm, whether it has been acknowledged or not, and what the priority of the alarm is.

Alarm			Background of vital area	Vital value
Active alarm	Not acknowledged	Latching or non-latching	Red or yellow based on alarm priority	Black
	Acknowledged	Latching or non-latching	Black	Alternates between different shades of red or yellow, based on alarm priority
Inactive alarm	Not acknowledged	Latching	Black	Alternates between different shades of red or yellow, based on alarm priority
		Non-latching	Black	Default colour: yellow for respiration rate, red for pulse rate, blue for oxygen saturation
	Acknowledged	Latching or non-latching		

Alarm messages

Alarm messages are shown in the message area of the display unit. Up to 16 alarm messages can be shown. An alarm that is no longer active and has been acknowledged is not shown in the alarm message area.

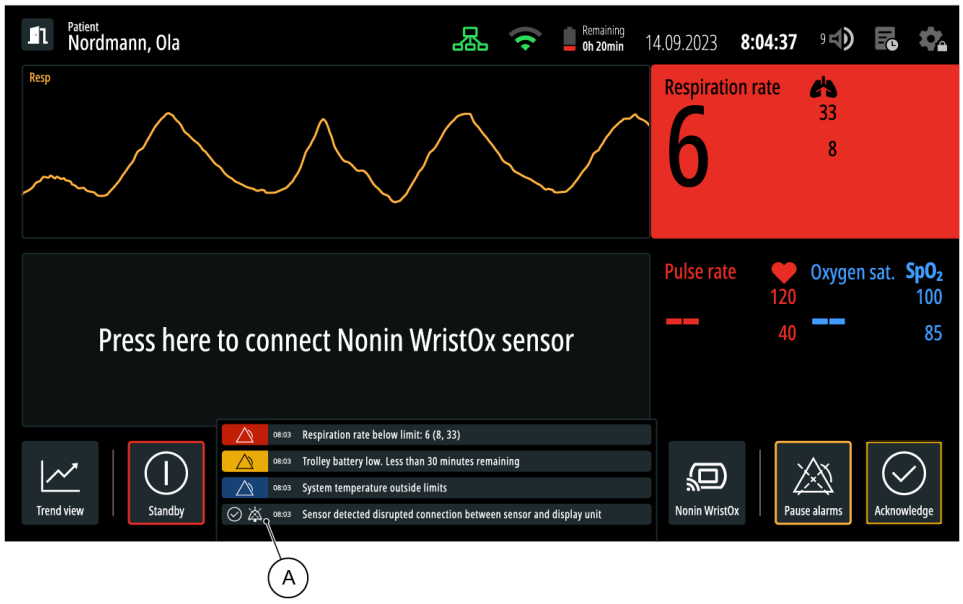
Sorting order of alarm messages

The alarms in the message area are sorted in the following order:

1. Unacknowledged alarms that are still active.
2. Unacknowledged alarms that are no longer active and are latching.
3. Acknowledged alarms.

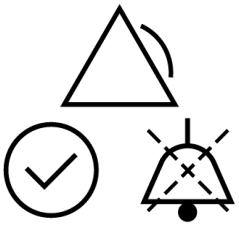
Within each group, the alarm messages are sorted first by priority (from highest to lowest), then by their timestamp (from newest to oldest).

Alarm state indication



The alarm state indication (A) has the following elements:

- Background colour: red/yellow/blue to show high/medium/low alarm priorities respectively, or grey to show acknowledged alarms.
- Alarm state icon: an alarm state icon can be included to show the alarm state. The alarm state icons are:



No icon

The alarm is unacknowledged.

The alarm is acknowledged.

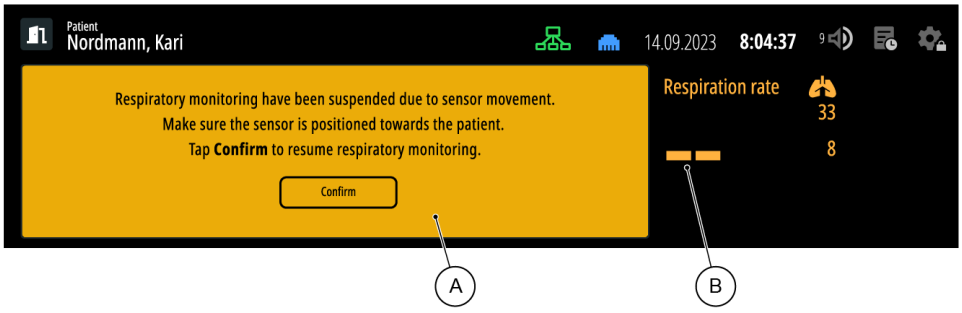
The alarm is latching and has not been acknowledged yet, but it is no longer active.

Visual signals for technical alarms

Generally, alarm messages are used as visual signals to tell the user that there is an active technical alarm. See Alarm messages on page 60 for more information.

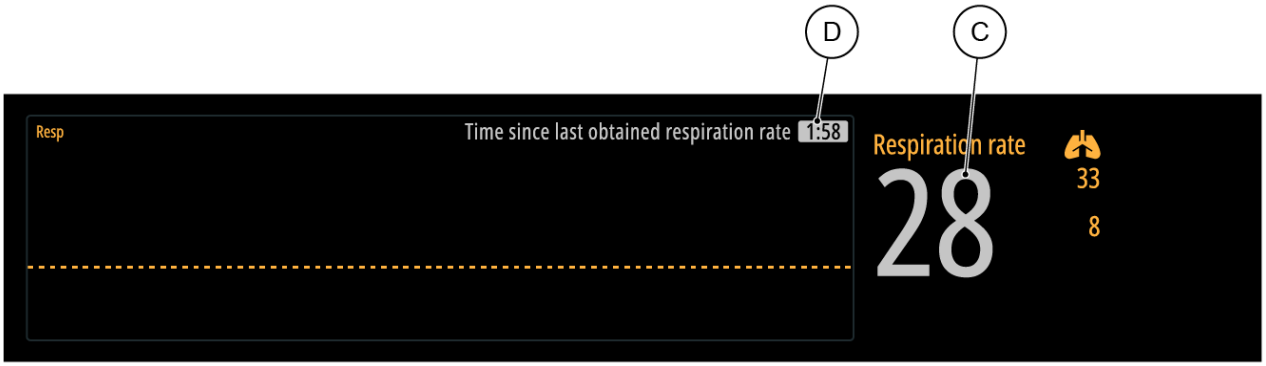
For some technical alarms, additional visual signals are generated.

Suspended mode

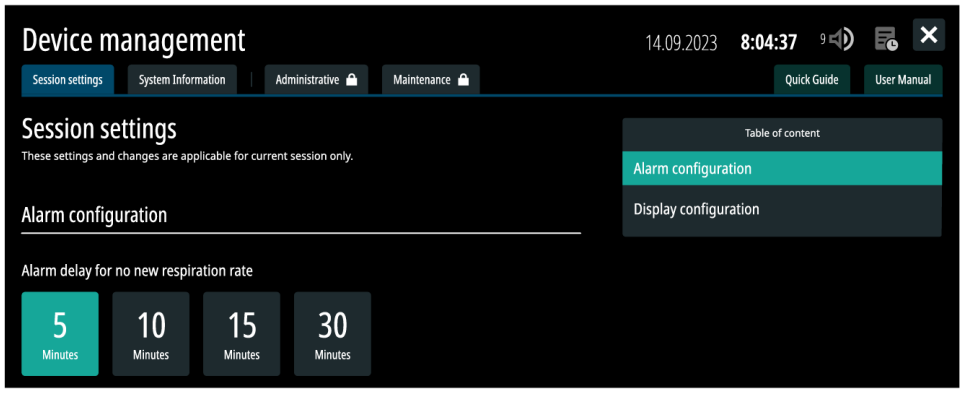


When the technical alarm "Monitoring suspended due to sensor moved during operation on page 67" becomes active, respiration rate monitoring is suspended, and the system enters suspended mode on page 56. On the display unit, a notification block (A) shows on top of the respiration waveform, and the respiration rate value (B) is unavailable.

No new respiration rate



When the system has been unable to obtain a new respiration rate measurement for more than 15 seconds, the display shows the last obtained respiration rate (C) and the time that has gone since that value was obtained (D). This information is shown in the respiration rate data section. The last respiration rate value alternates between light and dark grey colours. At this stage, no technical alarm is generated yet.



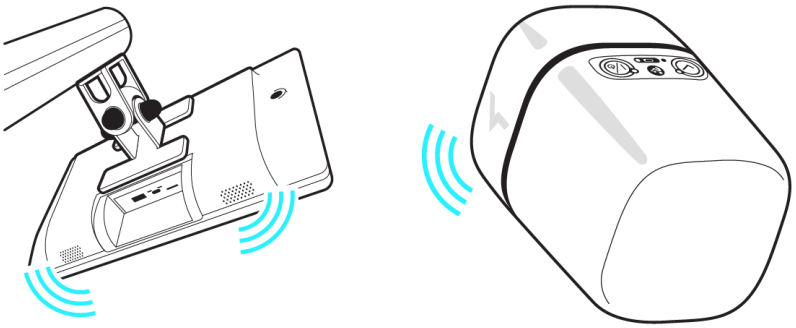
A technical alarm for no new respiration rate will be generated after a configurable time duration, by default five minutes. You can adjust the time duration during the active monitoring session in *Device management view* > ***Session settings*** > ***Alarm configuration***. After the current active session is ended the time duration will revert back to the default setting selected during installation.

Silent alarm state

Indication of the silent alarm on page 73 state is shown on the display unit. It shows that the silent alarm state is active. If the silent timer runs out and the **alarm is still active**, the alarm sound will be generated.

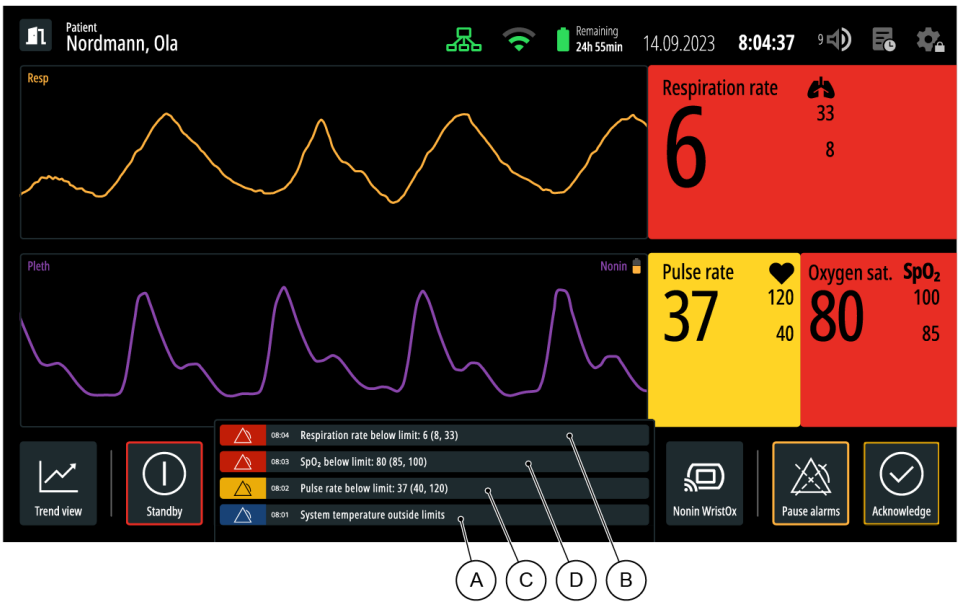
7.1.2 Alarm sounds

Alarm sounds are generated through the display unit or the sensor unit.



Alarm sound characteristics	Alarm priority		
	High	Medium	Low
Number of pulses in burst	10 Note: Grouped into groups of 3-2-3-2 pulses, time distance between the group is 150 milliseconds.	3	1
Pulse duration	50 milliseconds	155 milliseconds	490 milliseconds
Pulse spacing	20 milliseconds	80 milliseconds	-
Burst interval Note: The sound is played in a looping manner every x seconds shown here.	5 seconds	8 seconds	16 seconds

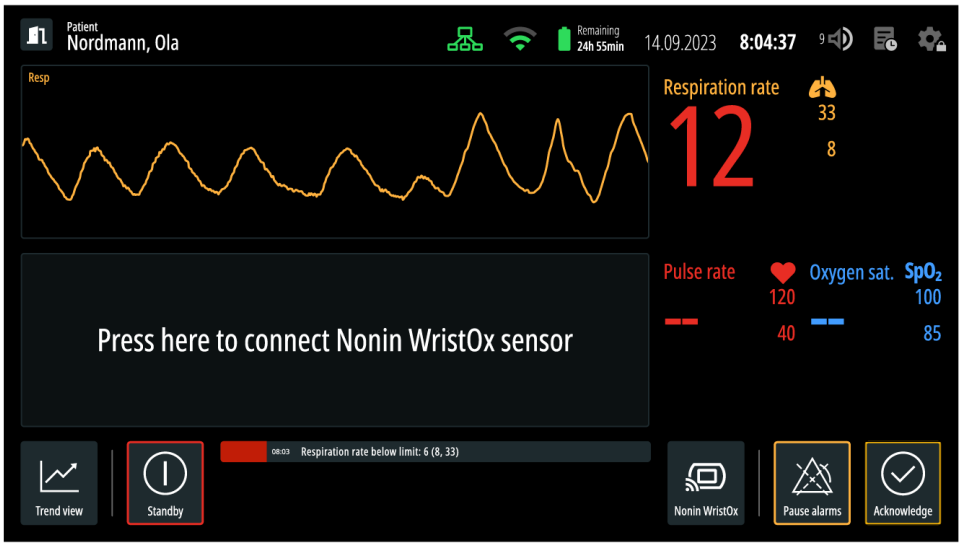
7.1.3 In case of multiple alarms



When multiple alarms are active at the same time:

- The display unit shows each alarm on the screen. For example, a technical alarm (A), a respiration rate alarm (B), a pulse rate alarm (C) and a pulse oximetry alarm (D).
- The LED light on the sensor unit is lit according to the alarm with the highest priority.
- The alarm sound is generated according to the alarm with the highest priority.

7.2 Latching alarms



Guardian M10 supports latching alarms, which means that visual signals of some alarms remain after the alarm is no longer active. Latching alarms let you know that an alarm condition has occurred. This is useful when there is an alarm condition that is active only for a short period of time.

Notice: Only the visual signal of a latched alarm remains. The alarm sounds are not latching.

The default latching setting for each alarm condition is included in the alarm lists, see section Lists of alarms on page 65.

A sequence of events in the example below illustrates a latched alarm:

- The respiration rate of a monitored patient drops below the alarm limit.
- The alarm for a low respiration rate becomes active.
- After a short period of the time, the patient's respiration rate goes back to normal.
- The low respiration rate alarm condition is latching by default: the visual signals remain visible on the display unit.

7.3 Annunciation delays

Annunciation delays are only applicable to physiological alarms. If an annunciation delay is in use for an alarm, it means that the alarm condition meant to trigger an alarm must be active continuously for a specific period of time before the alarm itself 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.

By default, the annunciation delays are not active. The annunciation delays and their timers can be configured as part of the initial installation. If you feel that these settings should be changed, request adjustments from an administrative user.

7.4 Lists of alarms

All alarms are shown in this section. They are categorized as physiological alarms and technical alarms.

7.4.1 Physiological alarms

Below is the list of the physiological alarms that the system supports, together with the default alarm limits and latching settings. The corresponding alarm message for each alarm is also included.

Alarm	Priority	Latching/Non-latching	Alarm message
Respiration rate low	High	Latching	*Respiration rate below limit: x (a, b)* x: measured respiration rate value a, b: current lower and upper respiration rate limit
Respiration rate high	Medium	Latching	*Respiration rate above limit: x (a, b)* x: measured respiration rate value a, b: current lower and upper respiration rate limit

Alarm	Priority	Latching/Non-latching	Alarm message
Pulse rate low	Medium	Latching	*Pulse rate below limit: x (a, b)* x: measured pulse rate value a, b: current lower and upper pulse rate limit
Pulse rate high	Medium	Latching	*Pulse rate above limit: x (a, b)* x: measured pulse rate value a, b: current lower and upper pulse rate limit
SpO_2 low	High	Latching	*SpO_2 below limit: x (a, b)* x: measured SpO_2 value a, b: current lower and upper SpO_2 limit
SpO_2 high	Medium	Latching	*SpO_2 above limit: x (a, b)* x: measured SpO_2 value a, b: current lower and upper SpO_2 limit

Physiological alarm limits

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

ⓘ Notice: The default values can be changed only by an administrative user. For further instructions, see “Installation and Service Manual”.

Guardian M10 has predefined alarm limits for respiration rate, pulse rate, and oxygen saturation:

Vital	Default for lower limit	Default for upper limit
Respiration rate [rpm]	< 8	> 30
Pulse rate [bpm]	< 40	> 130
Oxygen saturation (SpO_2) [%]	< 85	Off by default*

*The default upper limit for oxygen saturation is off by default. When a user adjusts 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.

7.4.2 Technical alarms

Below is the list of the technical alarms that the system supports, together with the alarm priority and latching settings. The recommended action and possible cause for each alarm is also included.

Alarm message	Priority	Latching/ Non-latching	Possible cause and recommended action
Pulse oximetry measuring error	Low	Non-latching	The pulse oximeter might be unable to measure pulse oximetry data due to: • poor perfusion • sensor has fallen off the patient’s finger Make sure that the pulse oximeter is properly put onto the patient’s finger.
Nonin WristOx battery below 10%	Low	Non-latching	Replace the pulse oximeter’s battery.
Nonin WristOx connection lost	Low	Non-latching	This alarm usually occurs when the communication with a connected and active pulse oximeter is lost, for example: through technical error, patient moved out of range, device out of power, or other similar causes. • Measure the patient’s distance to Guardian M10 to make sure they are close enough. • Check the pulse oximeter’s battery.
Trolley battery low. Less than 30 minutes remaining	Medium	Non-latching	This alarm occurs when trolley power time left is below 30 mins. Replace with a fully charged battery.
Monitoring suspended due to sensor moved during operation	Medium	Non-latching	This alarm occurs when the sensor unit is moved during a monitoring session. Examine the sensor unit position and make sure the unit is properly secured, see Checking that the wheel locks are activated (Mobile configuration) on page 34.

Alarm message	Priority	Latching/ Non-latching	Possible cause and recommended action
System temperature outside limits	Low	Latching	This alarm occurs when the internal temperature sensor is more than the predefined limit. An external cause can be the environment the sensor is placed in: the temperature in the environment is more than the recommended temperature limits (0-40°C). Measure that the environment temperature is within recommended limits (0-40°C). Power down the unit and let the temperature decrease before using it again. If the alarm continues, contact technical support.
Main power lost	Low	Non-latching	This alarm occurs when the main power is lost for over 5 minutes. • For stationary configurations: make sure that the power cable of the unit is connected to the power source. • For mobile configurations: make sure that the trolley battery is attached correctly. When main power is not available, the estimated operation time is at least 60 minutes before complete power loss.
Internal backup batteries low	Medium	Non-latching	This alarm occurs when the internal backup batteries are low on charge. The system will automatically shut down in a short while unless main power is restored. Make sure that the main power is available for the internal backup battery to be charged: • For stationary configurations: make sure that the power cable of the unit is connected to the power source. • For mobile configurations: make sure that the trolley battery is attached correctly and fully charged.

Alarm message	Priority	Latching/ Non-latching	Possible cause and recommended action
If reported by sensor unit: *Sensor detected disrupted connection between sensor and display units* If reported by display unit: *Display detected disrupted connection between sensor and display units*	Medium	Latching	This alarm occurs when the connection between the sensor unit and display unit is lost for more than 15 seconds. Make sure that the cables connecting the sensor unit and the display unit are properly attached.
Connection lost between Guardian M10 and remotely connected system	Low	Non-latching	This alarm occurs when the connection to remotely connected system solution through API is lost. Contact technical support.
Communication failure. Remotely connected system version is incompatible	Low	Non-latching	This alarm occurs when Guardian M10 or the backend integration have incompatible API versions. Contact technical support. Alarms on the remotely connected system might not work properly.
Incompatible software versions between display unit and sensor unit	Medium	Non-latching	Incompatible SW versions between the display unit and the sensor unit. Contact technical support.
Unknown or unexpected system failure	Medium	Latching	Unknown or unexpected SW or HW failure. Contact system support.

Alarm message	Priority	Latching/ Non-latching	Possible cause and recommended action
No new respiration rate for YY minutes	Medium	Non-latching	The system has been unable to obtain a new respiration rate measurement for more than YY minutes. The default is 5 minutes. This technical alarm becomes active in these situations: 1. Prolonged movement of the patient (patient is frequently moving about). 2. Patient is not present or not within the **optimal zone** of the configuration. 3. Other unknown causes. For situations 2 and 3, make sure that the patient's chest area is within the optimal zone, and nothing is blocking the line between the sensor unit and the patient. If possible, move the sensor unit closer to the patient. See Positioning the sensor unit on page 32 for further details. Additionally, if the patient is expected or known to be moving about frequently or leave the bed, you can adjust the time interval before this alarm is generated in *Device management view* > ***Session settings*** > ***Alarm configuration*** > ***Alarm delay for no new respiration rate***. You can also put the system in standby mode to pause monitoring during certain activities.

8 Handling alarms

This chapter gives information about how to handle alarms and adjust alarm settings, and view the alarm history of a patient.

When alarms occur, you can:

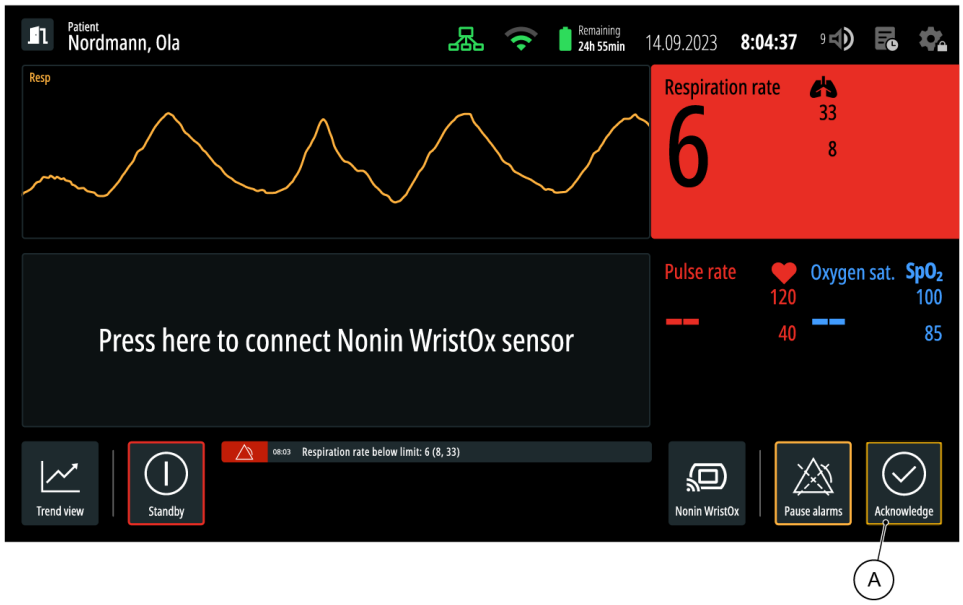
- Acknowledge alarms
- Pause alarms
- Adjust alarm limits

8.1 Acknowledging alarms

WARNING
When multiple alarms are active, always check all the alarms before acknowledging them.

Notice: The ***Acknowledge*** button is enabled only when there are alarms that can be acknowledged.

Notice: When you acknowledge alarms, the action is logged in the event log. For a full list of items stored in the event log, see Viewing events in the event log on page 53.



You can acknowledge alarms by tapping the ***Acknowledge*** button (A). If multiple alarms are active, tapping the ***Acknowledge*** button will have an effect on all of them. Alarms remain acknowledged for a period of five minutes.

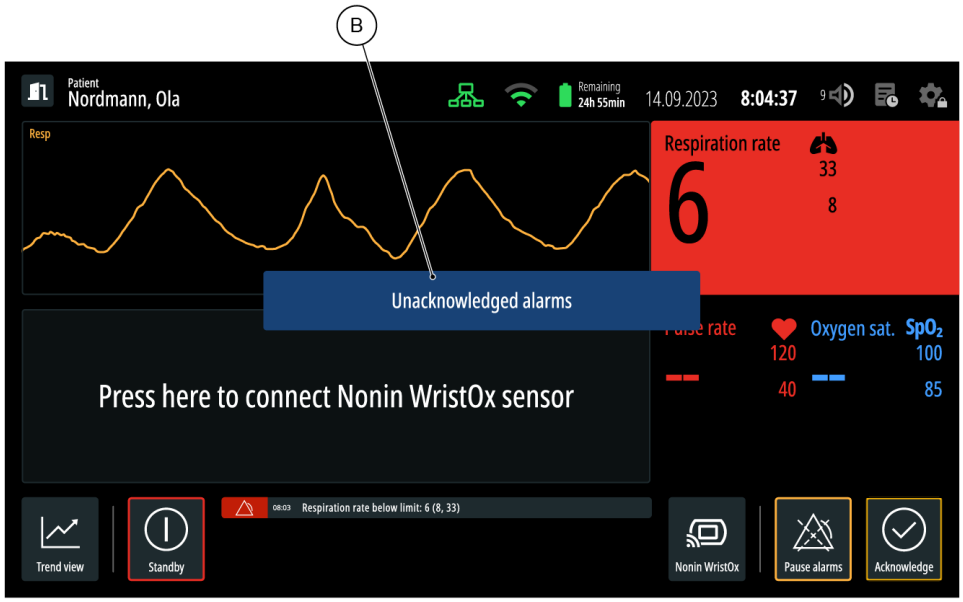
The alarm sounds and visual signals after acknowledging them (within a five-minute period of the alarm condition occurring) are as follows:

State of the alarm	Latching of the alarm	Alarm sounds	Visual signals

Alarm condition is still active	Latching or non-latching	Off	Visual signals are generated on the display unit as follows, until the alarm condition is no longer active:
			• Vital sections:
			  ◦ Numbers alternating between different shades of red/yellow.
			  ◦ Numbers replaced by "--" (indication of invalid respiration rate alarm).
			• Alarm message area: alarm message icon is changed from "unacknowledged" to "acknowledged" (see Alarm messages on page 60).

Alarm condition is no longer active	Latching or non-latching	Off	Off

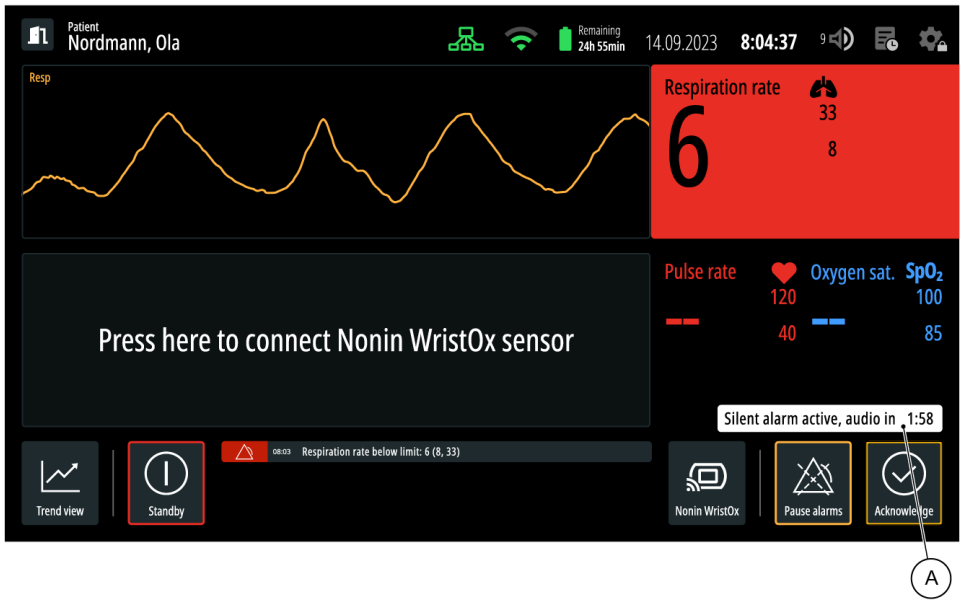
If you tap the ***Acknowledge*** button, but the alarm condition still remains active for more than five minutes, the alarm signals will be reactivated.



When there are unacknowledged alarms and you try to access another view or adjustment window, a pop-up message (B) is shown. This message **will not be shown**, however, if you try to open the respiration rate, pulse rate or oxygen saturation alarm limit adjustment windows. The pop-up

message remains for five seconds. If you try to access another view or adjustment window again and there are still unacknowledged alarms, the pop-up message is shown again.

8.1.1 Silent alarms



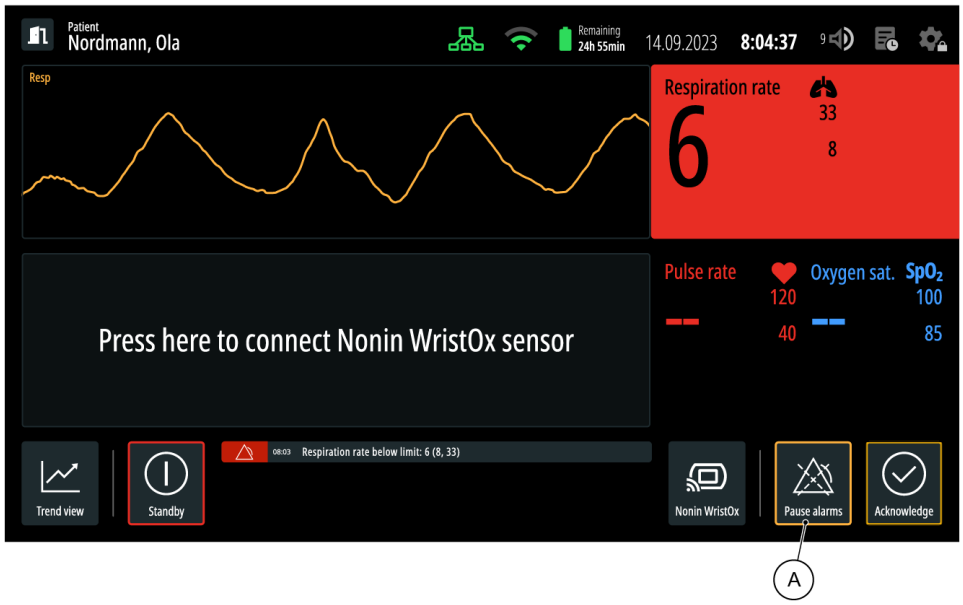
Silent alarm is a configuration that, if enabled, will give you a certain amount of time to acknowledge alarms before the alarm sound is generated. If the silent alarm configuration is enabled and a new alarm becomes active, the visual signals of the alarm behave as normal, but a signal of the silent alarm state and a timer is shown (A). The timer will show the amount of time left before the alarm sounds are generated. The alarm sound generation can be delayed for 30 seconds, 1 minute, or 2 minutes.

Silent alarm is a configuration that is by default off, but an administrative user can turn it on and adjust the time interval before alarm sounds are generated. For adjustment instructions, see “Installation and Service Manual.”

8.2 Pausing alarms

WARNING
New alarm signals are **not** generated when alarms are paused.

Notice: Pausing the alarms does not have an effect on the alarm message area.



You can pause alarms by tapping the ***Pause alarms*** button (A). If multiple alarms are present, tapping the ***Pause alarms*** button will take effect on all of them, as well as the alarms that are currently not active. By default, alarms can be paused for two minutes.

The alarm sounds and visual signals after tapping the ***Pause alarms*** button are as follows:

Time window and state of the alarm condition		Latching of the alarm	Visual signals	Alarm sounds
Within the two-minute pause period		Latching or non-latching	Off	Off
After the two-minute pause period has passed	If alarm condition is still active	Latching or non-latching	• Visual signals are generated on the sensor unit. • Visual signals are generated on the display unit.	On
	If alarm condition is no longer active	Latching	Visual signals are generated on the display unit (only for alarm conditions that have not been acknowledged).	Off
		Non-latching	Off	Off

8.3 Adjusting the alarm limits

Notice: Alarm limit adjustments done during a monitoring session will take effect only for the current monitoring session. The default alarm limits are restored when a new monitoring session starts, and when the system is restored after a shut down or complete power loss.

Notice: When a **physiological** alarm occurs, you can adjust the limits of that alarm so that the current vital measurements fall within the adjusted limits. As a result, the alarm sounds will not be generated for that alarm. Visual signals can still be generated, depending on the latching setting of the alarm.

Adjust the alarm limits in *Main view*.

1. Tap the desired vital section. The adjustment window opens.
2. Drag the sliders to the desired limits.
3. Tap ***Confirm***.

The adjusted limits are now used for the current monitoring session.

8.4 Viewing the alarm history of a patient

The alarm history of a monitored patient is found in the event log.

The event log includes information of the alarms that have occurred during the current monitoring session, up to the last 48 hours. To access the event log, tap the ***event log*** icon in *Main view* on page 39. An overlay shows on the screen, showing **all alarms** that have occurred during the current monitoring session up to the last 48 hours. For each alarm that has occurred, the information is shown as follows:

- Date and time when the alarm occurred.
- A description of the alarm condition event.

For a full list of events included in the event log, see Viewing events in the event log on page 53.

9 Cleaning and maintenance

This chapter gives information about the cleaning and maintenance tasks required in daily operation. The tasks described here are intended to be performed by the user.

For preventative maintenance and service, see “Installation and Service Manual”.

9.1 Cleaning and disinfecting the units

In daily use, only the display unit is touched regularly. The other parts can be cleaned with disinfectant according to the maintenance and cleaning intervals mandated by your institution.

Sensor unit

Use a clean cloth and disinfecting cleaner (91% isopropanol, 90% ethanol, or soap and water as necessary) to clean the unit.

Display unit

Activate cleaning mode on page 43 and use a clean cloth and disinfecting cleaner to clean the unit. As the disinfecting cleaner, use 91% isopropanol, 90% ethanol, or soap and water as necessary. You can consult the manufacturer’s instructions for further details.

Other components

See manufacturer’s instructions.

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See manufacturer’s instructions.

9.2 Checking the battery (Mobile configuration)

The mobile configuration has a battery that acts as its power source. The normal operation range of a unit that has a fully charged battery is 14 hours, and the remaining charge can be seen from the battery icon, the status LEDs on the battery on page 76, or *Device management view* > ***System information*** > ***Battery***.

In normal operation, the user only has to change and charge the batteries.

9.2.1 Changing the battery

> Notice: A technical alarm will become active if a new battery is not inserted within five minutes.

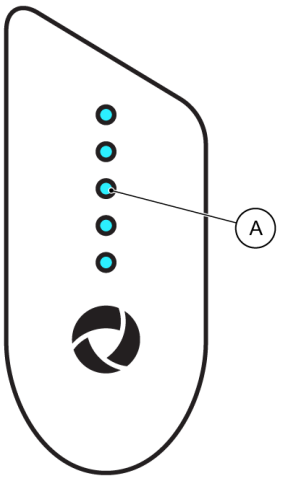
Use both hands to move one battery from the trolley’s battery docking station to the charging station. The system has backup batteries and will stay operational while swapping main batteries.

For detailed instructions and safety precautions, see the manufacturer’s instructions.

9.2.2 Charging the battery

The batteries are left to charge at a charging station. The locations of the charging stations are selected by your service and installation personnel, and should be easily accessible.

To prevent the batteries from deep discharging and failing, keep the charging station on even if the batteries have been charged to full capacity. Deep discharged batteries are completely discharged: they do not react to any buttons being pressed, or being placed in the charging station. No LEDs are lit. To recover a deep discharged battery, leave it on the battery charging station to charge until it is fully charged. Always recover deep discharged batteries before you take them back into use.



The charge level of the batteries is shown by the amount of LED lights (A) on the batteries. When there are

- Five LEDs lit: the charge level is 90-100%.
- Four LEDs lit: the charge level is 60-89%.
- Three LEDs lit: the charge level is 30-59%.
- Two LEDs lit: the charge level is 15-29%.
- One LED lit: the charge level is 0-14%.
- Zero LEDs lit: the battery is empty.

For detailed instructions and safety precautions, see manufacturer's instructions.

9.3 In case of signs of damage or malfunctioning of the device

Notice: Do not service, repair or do maintenance on Guardian M10 if it is in use.

In case you notice signs of damage or malfunction, see Troubleshooting on page 78 or refer to the "Installation and Service Manual".

10 Troubleshooting

This chapter provides an overview of the commonly identified problems and their solutions. If you find 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 contact and support information, or contact your medical device department according to your internal guidelines.

Sensor unit

Problem	Cause	Solution
The sensor unit does not work as expected.		Press and hold the on/off button on the sensor unit until the internal backup battery indicator turns dark. Turn on the system as described in Turning on the system on page 35.
There is visual damage to the unit.		Contact a service technician.
On/off button does not work.	Cables are loose, and internal battery is empty.	Examine cable connections.
	Battery of the mobile configuration is empty.	Change the battery from the docking station.

Display unit

Problem	Cause	Solution
The display unit does not work as expected.		Press and hold the on/off button on the display unit until the display switches off. If the display does not automatically power on, press and hold the on/off button again until the display is lit.
There is visual damage to the unit.		Contact a service technician.
On/off button does not work.	Cables are loose, and internal battery is empty.	Examine cable connections.
	Battery of the mobile configuration is empty.	Change the battery from the docking station.

System

Problem	Cause	Solution
The system does not work as expected.		Press and hold the on/off button on the sensor unit until the internal backup battery indicator turns dark. Press and hold the on/off button on the display unit until the display switches off. Turn on the system as described in Turning on the system on page 35.
I want to register a patient, but *Patient management view* is not available.	The system is not on.	Turn on the system.
	Standby mode is active.	End standby mode.
	The unit is frozen.	Press and hold the on/off button on the sensor unit to reset the system.
I cannot exit *Main view*.	There are active and unacknowledged alarms shown in the alarm message area.	If possible, acknowledge alarms.
There are active alarms in the alarm message area, but tapping the **Acknowledge** button on the display does not work.	Connection to the sensor unit is broken.	Check that the sensor unit is powered on and examine the cable connections between the display unit and the sensor unit.

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Problem	Cause	Solution
A pulse oximeter is connected to Guardian M10 but I'm uncertain if it is the correct sensor.	Press the ***Nonin WristOx*** icon in *Main view* and select ***Test connection***. Check for value "CP" on the pulse oximeter. Confirm or cancel the connection test from the display unit.	
Press here to connect Nonin WristOx sensor cannot be seen when a pulse oximeter needs to be connected.	There is a pulse oximeter, which is already connected.	Disconnect the previous pulse oximeter by tapping the ***Nonin WristOx*** icon and then ***Disconnect Nonin***. Now the text should show.

Problem	Cause	Solution
No devices found shows when a pulse oximeter needs to be connected.	Batteries of the pulse oximeter are empty.	Replace the batteries.
	Finger insertion doesn't turn on the pulse oximeter.	Refer to the pulse oximeter's manual.
	Retry connecting the pulse oximeter.	
The pulse oximeter shows the text "CP", but does not connect to Guardian M10. Plethysmograph is not visible. A technical alarm indicates that the connection is lost.	The pulse oximeter has run into an internal error.	Remove batteries from the pulse oximeter for a while. Wait until the pulse oximeter shuts down its display, then put back the batteries.
The pulse oximeter shows the text "Er 06", and does not connect to Guardian M10.	The pulse oximeter has run into an internal error.	Take the finger sensor off of the patient's finger, or remove batteries from the pulse oximeter for a while. Wait until the pulse oximeter shuts down its display, then put back the batteries and/or put the sensor back on the patient's finger.
The pulse oximeter is broken and needs to be changed.		Contact service personnel.

For other troubleshooting purposes or problems about the functions of the pulse oximeter, see the manufacturer's instructions.

11 Technical specifications

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

11.1 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

11.2 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

11.3 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/

12 Appendices

12.1 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.