



Companion[®]

User Manual

This document applies to;

Model: P200C

Product Version: v3

Firmware: v1.0

BLE Firmware: v1.0

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1 INTENDED USE

The P200 device family is intended to assist caregivers by detecting various physical indicators from a patient in bed which may denote a seizure, and notifying the caregiver to attend the patient in order to verify their well-being.

1.1 Indications for Use

The P200 device family is indicated for use with individuals who are subject to seizures, to detect various indicators which may denote a seizure. These indicators are:

- Repetitive Movement of shaking or jerking limbs.
- Excess moisture from sweating, enuresis or vomit.
- Repetitive or prolonged sounds.
- Bed vaciation.

1.2 Intended Users and Use Environment

The product is intended to be used as an aid to care givers. The user may be a layperson or health care professional.

The product is intended to be used in a variety of settings, including home and professional care settings.

1.3 Intended Patient Population

The use of the product is not restricted to any specific patient group.

1.4 Contraindications

- The P200 does not provide information for diagnosis.
- The P200 does not recommend any treatment or intervention.
- The P200 shall not be used as a primary monitoring device for vital physiological parameters (such as ECG, heart rate, respiratory rate) in clinical situations where the patient is in an immediate danger, such as during intensive care.
- The product shall not be used as a life sustaining or life supporting device.
- The P200 device family may be used only with suitable paired devices.

1.5 Device Lifetime

The typical expected life of the P200 in normal home use is 5 years.

Replace the P200 after this or earlier, if;

1. otherwise instructed; or
2. if any damage to the device is observed.






























See page 26 for recycling guidance. If any cracks or structural damage is observed, cease the use and replace the P200 immediately.

NOTE: the batteries must be replaced when the P200 does not start or if display indicates “**LOW BATTERY**”.

For service lifetime of the various sensors please refer to their own individual IFU's.

2 SAFETY

2.1 Explanation of the markings used on the device and in the documentation

	This is a Medical Device.		Indicates positioning of battery cell. + is positive terminal and - is negative terminal.
	Unique Device Identification.		The device is shipped in a standby mode, press and hold this button to turn the device on.
	Batch Code.		Moisture Sensor Input.
	Serial Number.		Bed Occupancy Sensor Input.
	Catalogue Number		Movement Sensor Input.
	Manufacturer.		Wired Alarm Output.
	Date of Manufacture.		Refer to instructions for use.
	Authorized representative in the European Community.		Importer.
	Keep Dry.		
	Type BF Applied Part.		
	Fragile, handle with care.		
	Temperature Limitation.		
	Humidity Limitation.		
	Protected against solid objects over 12.5 mm (e.g. a finger) and no protection against liquids.		
	Caution- Refer to instructions for use.		
	Consult instructions for use. Refer to instructions for use.		
	Product is for indoor use only.		
	CE Mark. (the product conforms with the essential requirements of the Medical Device Regulations (EU) 2017/745).		
	UKCA Mark. (the product conforms with the essential requirements of the UK Medical Device Regulations 2002).		
	Symbol of the European Waste Electrical and Electronic Equipment Directive (WEEE Directive) 2002/96/EC on waste electrical and electronic equipment.		
	Indicates that the product is in compliance with the European directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (commonly referred to as the Restriction of Hazardous Substances Directive or RoHS).		

2.2 Safety Precautions

This Alert-iT product has been designed with due regard to reliability and integrity. While it offers a highly vigilant alerting method, it is always possible that a distress condition can go undetected for a variety of reasons (including malfunction) and in life threatening situations it is advisable to use the Alert-iT system in conjunction with additional techniques. Neither the manufacturer nor its agent can accept legal responsibility to provide a system that is infallible.

The caregiver is responsible for assessing the risks of using this equipment and any settings pertaining to it.

- This device is designed only to be used as an aid for a caregiver.
- Ensure that the sensor leads are routed and secured to avoid the risk of trips, entanglement or strangulation.
- Ensure, by testing, that the alarm notifications are received at the caregivers location(s).
- The caregiver must never clear an alarm without checking the patient's condition.
- A risk assessment must be conducted to determine if the level of reliability offered by the device is sufficient or if additional equipment is needed. Consideration shall be given to the patients likelihood of tampering with the system.
- Clean and disinfect each item as needed in accordance with information on page 26.
- Regularly test the device as described in these instructions for use. See page 27.
- The device is not diagnostic and cannot differentiate between a tonic-clonic seizure and other repetitive movements.
- If this device is used with a pressure care mattress filled using a compression pump, some of the devices features may not function normally in some cases.
- Only use the monitor with accessories approved for use with this product and only in accordance with instructions.
- Do not use this device for any purpose other than that specified by the manufacturer.
- Do not let the device get wet.
- This product is for indoor use only in a dry environment.
- Some accessories are fitted with small screws and have plastic bags. Ensure these do not come into the possession of vulnerable people who may choke on them.
- Do not try to repair the device yourself.
- No maintenance of the product is allowed during use.
- Do not move or transport the device during use. If the bed equipped with the device needs to be moved remember to unplug all cables.
- If the equipment is modified in any way, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- Do not install this device near or on top of another device. However, if this cannot be avoided, the user must ensure that the device functions in the normal manner.
- Do not use the input / output connectors for any purpose other than that specified by the manufacturer. For example do not connect the connectors to telecommunications or local area networks.
- Equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- Remove the batteries when the device is not in use or when it is stored for an extended period. Alkaline batteries may become self-discharged, start leaking and contaminate the device.
- Do not use any rechargeable batteries or lithium-ion batteries! Lithium-ion batteries carry the risk of over heating and ruining the device.
- As with all electronic equipment there is potential for the equipment to interfere with or be effected by interference from other electrical or electronic devices. For this reason avoid placing the device, sensor or connecting cable(s) in close proximity to sensitive electronic devices or devices which produce strong electromagnetic fields such as radio transmitters, mobile phones or power cables.

2.3 Unintended adjustment of settings

- Incorrect alarm parameters may lead to false notifications OR may lead to the alarm notification not becoming activated when needed.
- To ensure correct operation of the device, position sensors in accordance with the instructions in this manual.
- Changing the radio address (without also changing it on the receiving equipment) will result in a RF Fail notification on the receiving equipment and any resulting alarm notifications will no longer be received.

2.4 Serious Incidents

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state of the European Union/country in which the user and/or patient is established.

‘Serious Incident’ means any incident that directly or indirectly led, might have led or might lead to any of the following;

- the death of a patient, user or other person
- the temporary or permanent serious deterioration of a patient’s, user’s or other person’s state of health
- a serious public health threat.

Manufacturer’s contact information can be found on the back page of this document.

3 PACKAGE CONTENTS

Please Note: The full package contents will vary depending on the exact system configuration and accessories ordered, but the following will always be included:



Companion



Movement Sensor Pad

- 1x **Companion** [P200C]
- 1x **Movement Sensor Pad** [P140B]
- 2x **1.5V AA Alkaline Batteries** (Not fitted) [P160D] (Not Shown)
- 1x **Mounting Kit** [Inc. screws, wall plugs, sticky pads, rubber feet] (Not shown)

4 COMPATIBLE PRODUCTS

Movement Sensor Pad:

- Light Weight [P140A]
- Medium Weight [P140B]

Moisture Sheets:

- Bed Sensor [P142A]
- Pillow Sensor [P142F]

Bed Occupancy:

- Mat (Large) [P143CAB]
- Mat (Small) [P143CBB]
- Ribbon (Long) [P143GAB]
- Bed Weight [P144B]

Note: For additional information please contact your equipment provider.

5 INTRODUCTION

These ‘instructions for use’ describe the use of the Alert-iT **“Companion”**.

The **“Product Version(s)”** these instructions apply to are shown on the front page of this document. This should be referred to and compared against the **“Product Version”** number shown on the product information sticker found on the top of your device. If this document is not suitable for your product please refer to the ‘support’ section of our website for alternative instructions.

- Follow all instructions provided in this document concerning the installation, use, cleaning and disposal of the device.
- The **“Companion”** is a medical device.

Product Description

The **“Companion”** (later **“device”** / **“control unit”**) is used to detect symptoms of seizures and can notify caregivers of the following;

- Abnormal bed movements. E.g. Uncontrolled shaking
- Repetitive or continuous sounds
- Moisture events
- Bed vacation

The product consists of a range of different sensors located on or under the mattress and a control unit where the sensors are connected to. The control unit should be placed on a table, hooked on a bed or mounted on a wall.

Caregivers are notified by visual and audible alerts (if enabled) and/or a notification via external system e.g. a wireless pager or wired call system.

Operating environment is typically a bedroom at a family home or care facility.

NOTE 1: The manufacturer cannot guarantee that the device will detect all episodes of seizure-induced body movements of the patient. E.g. incorrect settings. The device may trigger a false spasm movement notification, especially if the person lying on the mattress fitted with the under mattress movement sensor is awake OR if the settings are incorrect.

NOTE 2: The device may trigger a false sound notification, especially if the device is used in a noisy environment and the sound parameters are configured to be very sensitive.

NOTE 3: Always ensure the suitability of the device - particularly for small children - by conducting a test run. The recommended patient weight range for the **“P140A”** movement sensor is 6 kg to 25 kg. The recommended **“P140B”** patient weight range is 20 kg to 200 kg.

NOTE 4: The device is not diagnostic and cannot be used to verify whether the alerted body movement was caused by a tonic-clonic seizure. The occurrence of a tonic-clonic seizure can be verified, among other things, against electroencephalogram (EEG) data interpreted by a healthcare professional. This device cannot replace an EEG recording system.

NOTE 5: The movement sensor must only be used under the mattress and not in direct contact with the patient.

6 GENERAL OVERVIEW

6.1 Control Unit

The device emits regular radio transmission to form a failsafe 'heartbeat' that allows any receiving equipment to notify the caregiver if they are out of range or if the device has failed due to any reason.

Alternatively, the device can be connected to a wired nurse call system (The wired output needs to be enabled first).

Important Note: In order for the nurse call system to be able to detect if the wired output lead is broken or has been accidentally disconnected, it is essential to use the normally-closed (NC) connection pins.

The wired output will be activated for ~2 seconds upon any alarm or critical fault condition and reactivated every 2 minutes until the alarm is reset. The wired output will also activate for ~2 seconds if the unit is turned off, or if the batteries are removed.

The device operates on 2x AA size 1.5V alkaline batteries. No external power supply is required. Do not use any rechargeable or lithium-ion batteries! Rechargeable or lithium-ion batteries carry the risk of over heating, ruining the device and causing possible danger to the patient.

The device has three connectors;

- A movement sensor input.
- A moisture sensor input.
- A shared occupancy sensor input and wired output.

In order to use the occupancy input and the wired output at the same time a splitter is required (Not included).

On the front of the device there is a push button that can be used to acknowledge an alarm / fault notification or access the devices settings menu.

All essential device settings can be adjusted through the menu. All settings (including additional) are adjustable by connecting to the device using a smart phone or tablet via Bluetooth and downloading the Alert-iT app.

6.2 Movement Sensor

The movement sensor produces a millivolt alternating current when detecting movement. The control unit calculates the scale and frequency of the movement from this signal and, on this basis, detects possible spasm movements.

6.3 Moisture Sensor

The moisture sensors (bed / pillow sheets) provide a variable resistance dependant on their moisture content. The control unit calculates the resistance of the connected sensor and notifies the caregiver if the moisture content rises above the "**Moisture Level**" setting.

6.4 Sound Sensor

The control unit has an internal microphone that can be used to alert a caregiver to repetitive or prolonged sounds.

6.5 Occupancy Sensor

The occupancy sensor provides a closed connection when the patients weight presses down on it. The control unit detects when the sensor opens and alerts the caregiver after the set delay time.

7 INSTALLATION OF CONTROL UNIT

Remember: The device will need to be within easy reach in order to access the ●①● button (e.g. to clear alarms).

Option 1: Mounting to a wall

1. Plug in all desired sensor cables, and ensure they reach the desired mounting location. (Typically within 2 meters of the bed). Ensure the ●①● button is easily accessible.
2. A wall mounting kit containing sticky pads, velcro pads and screws has been provided to attach the rear mounting plate to a wall.
3. Using your preferred, method attach the rear mounting plate to the wall.
4. Slide the control unit onto the mounting plate until you hear a 'click'.

Option 2: Mounting with hook.

1. Attach the hook to the back of the control unit.
2. The control unit can now be hooked onto a bed frame.

Option 3: Mounting on table top

1. Attach the four rubber feet to each corner of the rear back plate.
2. Place control unit on the bed side table.

8 INSTALLATION OF SENSORS

Movement Sensor

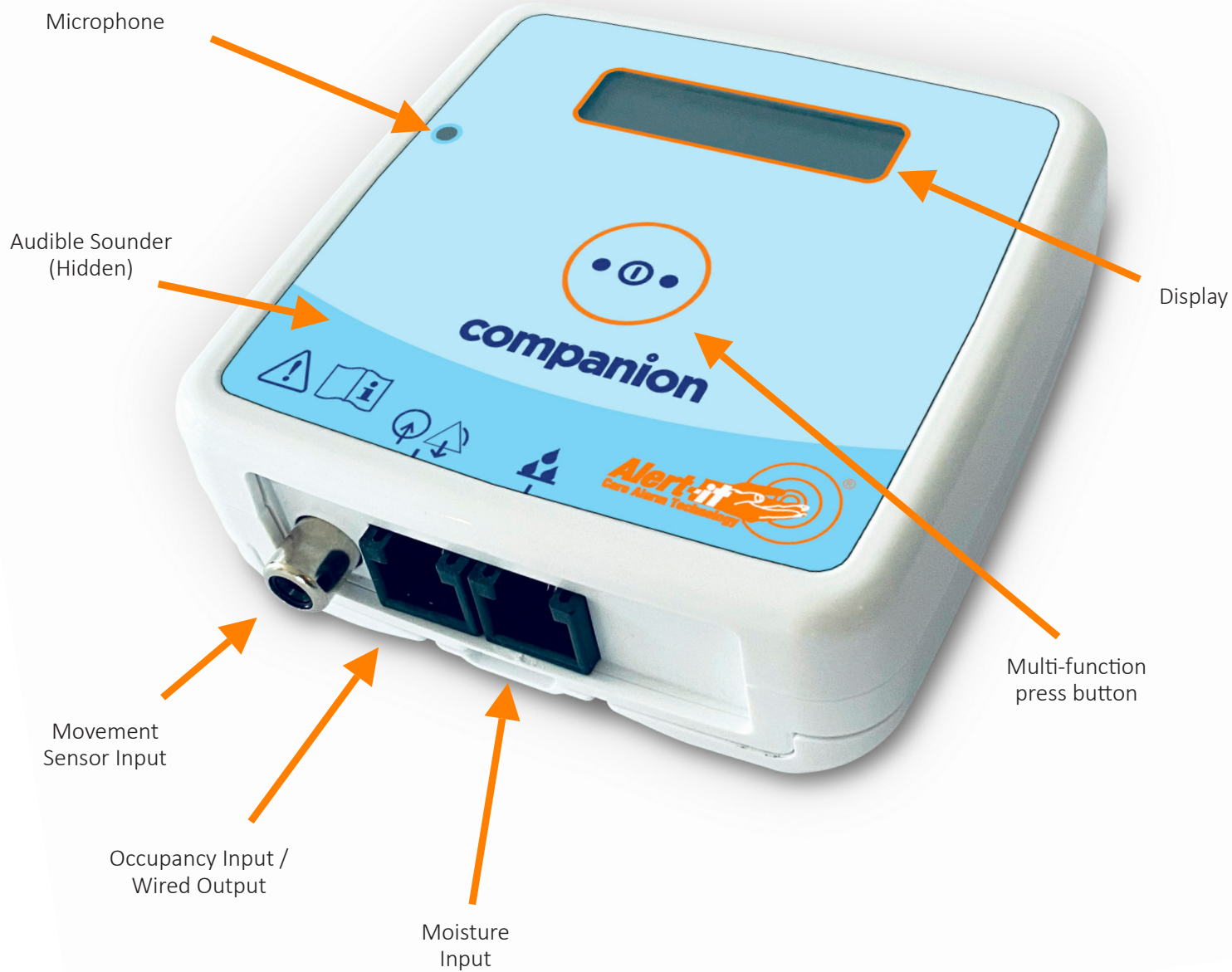
1. Place movement sensor pad under the mattress positioned directly below the patient at shoulder height.
2. The sensor should rest on a rigid flat surface.
3. Route the cable to ensure it does not become trapped or snagged.
4. Plug the yellow connector into the Movement sensor input, ensuring the cable is out of reach of the patient to prevent strangulation.

Occupancy Sensor (Optional)

1. Each sensor has its own fitting instruction, please consult these instructions before fitting.
2. Plug the connector into the Occupancy Input socket.

Moisture Sensor (Optional)

1. Each sensor has its own fitting instruction, please consult these instructions before fitting.
2. Plug the connector into the Moisture Input socket.



10 BASIC FUNCTIONS

10.1 Turning the device on

- Hold the central ●ⓘ● button for 3 seconds.

On power-up the display will illuminate and the model, software version, radio address and date will be displayed on screen for 5 seconds.

Note: If the batteries are removed for an extended period, the time and date will be lost. All logging features will not resume until the time and date is set again using the app.

10.2 Waking up the display

To save power, the display turns off after 45 seconds of inactivity.

- Briefly press the ●ⓘ● button to wake the display.

The displays back-light is controlled by a light sensor and will only turn on if it detects the room is dark.

10.3 Turning the device off

- Hold the ●ⓘ● button for 3 seconds until the menu is displayed.
- Click the ●ⓘ● button until “**POWER**” is displayed.
- Hold the ●ⓘ● button for 3 seconds. The device will now turn off.

Note: The device sends an “**Alarm Off**” fault code over radio (if enabled) and/or activates the wired output for 2 seconds (if enabled) when shutting down.

10.4 Active

The devices screen will display “**ACTIVE**” when the patient is being monitored.

You must ensure the display shows “Active” before leaving the patient unattended.

The display will turn off after 45 seconds to save power.

- Press the ●ⓘ● button to wake the screen up if required.

10.5 Snoozing

The device can be put into a snooze state to allow the patient to become settled without raising false alarms.

- Press the ●ⓘ● button briefly to wake the screen up if required.
- Hold the ●ⓘ● button for 3 seconds to enter the device menu.
- Hold the ●ⓘ● button for 3 seconds to select “**SNOOZE TIMER**”.

Device will now prevent any alarms from being raised for the duration of the snooze timer.

- To increase the snooze time, tap the ●ⓘ● button to add 5 more minutes.
- To cancel the snooze timer hold the ●ⓘ● button for 3 seconds.

10.6 Alarms

When an alarm is triggered, the display will show the cause of the alarm;

“SPASM ALARM”: Excessive bed movements have been detected.

“VACATION ALARM”: Patient has left the bed.

“MOISTURE ALARM”: The moisture sensor is wet.

“SOUND ALARM”: Sound alarm has been triggered.

10.7 Clearing and/or Suspending Alarms

NOTE 1: Check the patient first.

When an alarm is active (display flashing red), pressing the ●①● button will clear the alarm. If the alarming condition is still active, the alarm will temporarily be suspended until the alarm condition is resolved. The suspend feature allows the alarms to be silenced whilst the caregiver attends to the patient.

If any alarms are suspended the display will show;

“SUSPEND Spa”: Spasm alarm suspended until spasm movements stop.

“SUSPEND Vac”: Vacation alarm suspended until the patient returns to bed.

“SUSPEND Wet”: Moisture alarm suspended until dry sheet detected.

Multiple alarms can be suspended at the same time.

NOTE 2: You must ensure the display shows “ACTIVE” before leaving the patient unattended.

10.8 Active Faults

When a fault condition is raised, the display will show the fault condition e.g.:

“MOVEMENT SENSOR FAULT”:

If the Spasm alarm feature is enabled, to ensure the sensor has not been unplugged or damaged, if no movement has been detected for over **24 hours** a **“Movement Fault”** will be raised.

To prevent or clear the fault:

1. Briefly simulate spasm movement on the bed. The fault will clear within a few seconds.

If the movement fault does not clear, check the movement sensor & connections.

“OCCUPANCY SENSOR FAULT”:

If the Bed Vacation feature is enabled, to ensure the sensor has not been unplugged or damaged, if no presence has been detected for over **24 hours** a **“Occupancy Sensor Fault”** will be raised.

To prevent or clear the fault:

1. Briefly sit or apply pressure to the occupancy sensor. The fault will clear within a few seconds.

If the fault does not clear, check the occupancy sensor & connections.

“MOISTURE FAULT”:

If the Moisture detection feature is enabled and the **“self-test”** feature is also enabled, a fault will be raised immediately if the sensor is unplugged or faulty.

To clear the fault:

1. Check the moisture sensor & connections.
2. Is a compatible **“4-stud”** moisture sheet being used? Disable the **“self-test”** feature if not.

Note 1: Sheets typically only last for 90 washes. (See wash instructions).

Note 2: The **“Moisture self-test”** feature only works with compatible **“4-stud”** moisture sheets.

10.9 Suspending Faults

The **“Battery Low”** fault warning can be suspended by pressing the ●⌚● button. This will postpone the fault alarm for 12 hours.

11 NAVIGATING THE CONTROL UNIT SETTINGS MENU

Note: All essential settings are adjustable directly via the control units menu. However additional settings are adjustable through the “**Alert-iT**” app, and for ease of use it is recommended to use the app where possible.

11.1 Changing settings directly on the device

1. Press the ●ⓘ● button to wake the screen if required.
2. Hold the ●ⓘ● button for 3 seconds to open the “**Settings Menu**”.
3. Use short presses to cycle through the menu items until you reach the desired setting.
4. Hold the ●ⓘ● button to select a menu item.
5. Use short presses to cycle through available adjustments.
6. Hold the ●ⓘ● button to confirm selection.

Note: After 30 seconds the device will automatically exit the menu.

Menu Structure >

SNOOZE TIMER	>	5 minutes up to 60 minutes.
POWER	>	Hold to turn off monitor
TICK VOLUME	>	Off or 1 to 8.
SPASM DURATION	>	Off or 5 to 60 seconds
SPASM LEVEL	>	1 to 8.
SPASM RATE	>	Low, Medium or High.
SOUND DURATION	>	Off or 2 to 20 seconds.
SOUND LEVEL	>	1 to 8.
SOUND TYPE	>	Filter On or Filter Off
MOISTURE LEVEL	>	Off or 1 to 8.
BED VACATION	>	Off or 1 seconds to 24 hours.
EXIT SETTINGS	>	Hold to return to main screen.

All setting changes are instant.

11.2 Screen Options

Using the “**Alert-iT Configuration Tool**” app under “**Device Settings**” > “**Screen Options**” you can hide various options from the devices menu screen to prevent unwanted changes to those settings by the patient.

Changes to settings via the app can also be protected by a password.

12 USING THE ALERT-IT CONFIGURATION TOOL APP

The app is available for free on both iOS and android. It can be used to configure the device and view event and signal history from your device.

Search for “**Alert-iT Configuration Tool**” in either the “**Google Play Store**” or “**Apple App Store**” to find the app.

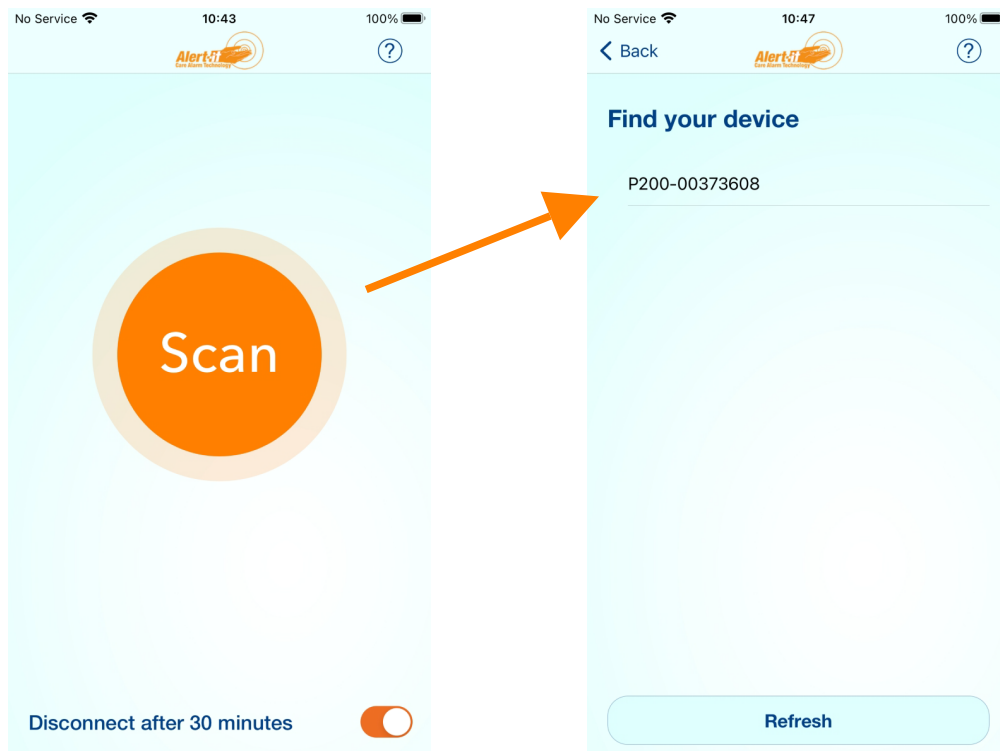
12.1 Connecting with the app

To connect the app to your device;

- Open the “**Alert-iT Configuration Tool**” app (available for android and iOS).
- Press the ●①● button on the front of the device to make it “**Advertise**”.
- Press the round “**Scan**” button in the app.
- After a few seconds “**P200 - Serial Number**” will appear. e.g. “**P200-0032485**”
- Ensure the serial number matches that of your device (It is printed on the top of the device).
- Tap the device name to connect.

You can assign a more memorable nickname for your device once connected (See the “**Device Settings**” section).

Note: The device will advertise continuously whilst in an alarm or fault condition and will advertise for 1 minute any time the ●①● button is pressed. The device only advertises for 1 minute to improve battery life and as a safety feature to help prevent anyone connecting to the wrong device. Enabling “**Always Advertise**” in device settings will make the device permanently available at the sacrifice of reduced battery life.



“**Disconnect after 30 minutes**”: The app will automatically disconnect from the device when not in use. If you wish to be connected to the app for longer periods, you should un-tick this box. (Please note: This will reduce battery life of the device.)

13 SPASM CONFIGURATION

This configures the device to raise an alarm if it detects repetitive movements for longer than the set duration.

The included movement sensor is required for this feature to work. It must be installed under the mattress beneath the patient at shoulder height.

There are three spasm settings that can be adjusted: **“Spasm Duration”**, **“Spasm Level”** & **“Spasm Rate”**.

Default Setting:

Spasm Duration: 20 seconds. Spasm Level: 4. Spasm Rate: Medium.

Spasm Duration

This sets how long the patients spasm movements have to continue for before an alarm is raised.

This setting needs to compromise between reliable and quick detection times verses false alarms.

For brief seizures a shorter duration may be required at the risk of increased false alarms.

Spasm Level

This setting adjusts how large the patients spasm movements need to be to trigger the alarm.

- A high spasm level setting (5 to 8) will only alert on larger movements.
- A low spasm level setting (1 to 4) will alert on smaller movements.

For example; A patient with very pronounced shaking using a thin mattress, a high level setting of **“5”** or more may be suitable, whereas very subtle shaking on a thick mattress may require a level setting of **“4”** or lower.

Once the pad is installed under the mattress, you can test the chosen level setting by simulating the known seizure movement intensity with your hand on the mattress. A **“#”** icon will appear on the screen if the movement is detected. If no **“#”** appears, try a lower **“Spasm Level”** setting.

Using a higher Spasm Level setting as possible is recommended to reduce false alarms.

Spasm Rate

This setting further helps to reduce false alarms by adjusting how long the gaps between individual jerking movements can be, whilst still being considered ‘continuous’ movement.

- A **“Spasm Rate”** setting of **“High”** needs to see at least one movement every 0.625 seconds.
- A **“Spasm Rate”** setting of **“Medium”** needs to see at least one movement every 1.25 seconds.
- A **“Spasm Rate”** setting of **“Low”** needs to see at least one movement every 2.5 seconds.

For example; If the patients shaking movements are constant throughout the duration of the seizure, a setting of **“High”** may be suitable. However, for seizures where the movement starts and stops, with gaps of several seconds in between, a setting of **“Low”** would be required.

Note: The **“Low”** setting is more prone to false alarms than the **“Medium”** or **“High”** settings.

Recommended Spasm Setup Procedure

Note: It is advised to setup and leave the device overnight to gather data then use the app to guide the following decisions.

- Step 1. Determine roughly how long the spasm movements last for and ensure the **“Spasm Duration”** setting is set appropriately. For example;
 - If the patients spasm movements last for 30 seconds or longer, a spasm duration setting of 20 seconds may provide an adequate response time whilst minimising false alarms.
 - If the spasm movements are very brief, a reduced spasm duration setting of 15 seconds or lower may be required to ensure these brief seizures are not missed. Other adjustments to reduce false alarms may be required here.
- Step 2. Review the **“Spasm Level”** setting. The level wants to be set low enough to ensure movements are not missed, but not so low that even movements outside of the bed are detected.
 - If the patients seizure movements are large and very noticeable, then the **“Spasm Level”** may be raised to minimise false alarms.
 - If the seizure movements are very subtle, then the **“Spasm Level”** may need to be lowered to ensure the movements are detected and seizures are not missed.
- Step 3. Review the **“Spasm Rate”** setting.
 - If the patients spasm movements during a seizure are continuous, and there are no gaps in the movements, then a **“Spasm Rate”** setting of **“Medium”** or **“High”** would be appropriate.
 - If the patients spasm movements during a seizure are infrequent and jerky, with gaps in between the spasm movements longer than a second, then a **“Spasm Rate”** setting of **“Low”** would be appropriate.

Follow Up Adjustments

Note: The following adjustments may need to be repeated over a number of nights;

- No seizures during the night, and no false alarms;
 - No adjustment required.
- No seizures during the night, but one or more false spasm alarms;
 - Consider increasing the **“Spasm Duration”** by 5 seconds.
 - Consider increasing the **“Spasm Level”** setting by one step.
 - Consider changing the **“Spasm Rate”** from **“Low”** to **“Medium”** or from **“Medium”** to **“High”**.
- One or more seizures during the night, but no spasm alarm was raised;
 - Consider lowering the **“Spasm Duration”** by 5 seconds.
 - Consider lowering the **“Spasm Level”** setting by one step.
 - Consider changing the **“Spasm Rate”** from **“High”** to **“Medium”** or from **“Medium”** to **“Low”**.
- If there was a seizure and a spasm alarm was raised;
 - No adjustment required.
- If there is no-one in the bed, and spasm alarms are being raised;
 - Consider increasing the **“Spasm Rate”** setting by one step.

14 SOUND CONFIGURATION

This setting configures the device to pick up any repetitive or continuous sounds that present themselves during a seizure such as shouts, clicks or grunts.

There are three settings that can be adjusted: **“Sound Duration”**, **“Sound Level”** and **“Sound Type”**.

Default Setting:

Sound Duration: 0 (Off). Sound Level: 4. Sound Type: Filter On.

Sound Duration

This setting adjusts how long the repetitive sounds need to continue for before the sound alarm is raised.

IMPORTANT NOTE: A duration setting of **“2”** seconds, is actually all sounds of 0 to 2 seconds in length, therefore the device will alarm on any single sound over the **“Sound Level”** setting. If using **“Sound Duration”** periods below 5 seconds it is recommended to set **“Sound Level”** to a higher level to reduce false alarms from doors closing etc.

Sound Level

This setting adjusts how loud the sounds need to be to trigger a sound alarm.

The higher the **“Sound Level”** setting, the louder the sound needs to be.

Sound Type

The device features a high pass filter that reduces any constant background noises in order to reduce false alarms

Filter On: When enabled, the filter will reduce any constant background noises like fans but will still pick up short abrupt sounds, such as clicks, grunts or shouts. This is recommended where possible as it helps to minimise false alarms.

Filter Off: No filtering is used, this is best suited for picking up long continuous sounds such as prolonged sighs, groans or shouts/screams.

14.1 Sound Logging Overview

The device features a 32 hour history of the received sound signals which can be used to fine tune the alarm parameters. But it is important to understand the limitations of the information provided when reviewing the sound signal charts.

The sound chart in the app displays the lowest sound signal received in each 5 second window.

This means large sounds of durations shorter than 5 seconds will likely not appear in the chart and that if a **“Sound Duration”** setting of 2, 3, or 4 seconds is used, the history chart will not accurately reflect the sounds that have lead to all sound alarms.

When configuring the **“Sound”** function, set the **“Sound Duration”** to a suitable length for the individual patient, then set the **“Sound Level”** to just above the point at which no bars are red during a normal seizure free period.

15 OCCUPANCY CONFIGURATION

This feature configures the device to raise a vacation alarm if the patient leaves the bed after a set delay.

NOTE 1: An occupancy sensor (sold separately) is required to detect the presence of the patient in the bed.

NOTE 2: The occupancy input is shared with the wired output. To use both a splitter is required (sold separately).

Default Setting:

Occupancy Delay: 0 (Off)

Occupancy Delay

This sets how long the user needs to be out of bed before the alarm is raised.

The bed vacation alarm is typically configured in one of three ways:

- The first is with an almost “**Instant**” time delay (1/2/5 seconds) so that the vacation alarm is raised as soon as the patient sits up (if the sensor is positioned suitably) or leaves the bed. This is useful when the user is at risk from falls and immediate assistance is required.
- The second is with a “**Delayed**” time delay (5 or 15 minutes), this allows the patient to visit a bathroom unassisted, but to raise a vacation alarm if they have not returned to bed and could have fallen or be having a seizure in the bathroom.
- The third is with an “**Extended**” time delay (15 hours). This is used to suspend some alarm functions in the morning when the patient leaves the bed, but raises a vacation alarm if they do not return to bed later that night.

Testing

To test the occupancy feature is functioning correctly:

1. Ensure the bed is vacant.
2. Wake the screen by pressing the ●ⓘ● button. The screen should show “**Vacant**”.
3. Press on the bed occupancy sensor, the screen should now show “**In Bed**”.

Occupancy Fault

The device will raise an “**Occupancy Sensor Fault**” if the occupancy alarm is enabled, but no one has been detected in bed for **24 hours**.

This is to protect against failure of the sensor, or failure to plug the sensor back in again after cleaning.

The fault will automatically clear if the sensor is OK and plugged in correctly when the patient returns to bed.

To manually clear the fault, press down on the sensor, then release it.

16 MOISTURE CONFIGURATION

This configures the device to raise an alarm if the moisture sensor detects moisture above a set limit.

NOTE 1: A moisture sensor is required (sold separately).

NOTE 2: The moisture level is checked every 20 seconds. There may be a delay of up to 20 seconds before the alarm condition is raised.

Default Setting:

Moisture Level: (Off)

Moisture Level

This setting adjusts how wet the moisture sheet needs to be before the moisture alarm is raised.

Moisture Level: 1 to 4 = Sensor damp. Can be used to detect excessive sweating.

Moisture Level: 5 to 8 = Sensor wet. Can be used to detect enuresis / vomit.

Recommended Setup

It is common for people to sweat significantly, even with limited activity, so a mid range level is usually recommended as a starting point for the first few nights while data is collected by the device.

After a few nights of normal use, observe the charts in the app then adjust the level as appropriate.

Testing

To test the moisture alarm feature is functioning correctly:

Moisture “Self-test” mode disabled:

1. Detach the moisture lead clips from the sensor sheet.
2. Press the two clips together to create a short circuit.
3. Within 10 seconds “**MOISTURE ALARM**” should appear on screen.
4. Stop pressing the two connectors together.
5. Within 10 seconds the moisture alarm notification should clear.

Moisture “Self-test” mode enabled:

Testing is automatic, manual testing is not required. Moisture fault will be raised if sensor is unplugged or damaged.

IMPORTANT NOTE: Do not use fabric softener when washing the moisture sensors (bed / pillow sheets).

The softener repels water and liquids begin to sit on top of the sheets surface, preventing the moisture sensor from working correctly.

17 DEVICE SETTINGS

There are additional settings that can be changed within the app's "**Device Settings**" menu.

Setting a nickname

The name that appears when you scan for the device can be changed to something more memorable. E.g. "**Jane**" instead of "**P200-00354321**".

Radio Address

If multiple devices are used at the same location, each device needs to use a unique "**radio address**" between 1 and 126. The device is supplied with a random address, we recommended only adjusting if duplication on site occurs.

Audible Alarm

This setting turns the internal buzzer on or off. [Default: Off]

Alarm Light

This setting turns the flashing red display on or off. [Default: On]

Backlight

This can be used to disable the control unit displays backlight if it is not needed. [Default: On]

Always Advertise

This setting makes the device always advertise (reduces battery life). [Default: Off]

Display Timeout

Adjust the timeout before the display and alarm light turns off when an alarm / fault is active.

Radio Output

Turns the Alert-iT Safelink radio on or off. [Default: On]

Wired Output

This setting turns the wired output on or off. [Default: Off]

Language

This sets the language on the devices screen. [Default: English]

Screen Options

Sets what items are visible on the devices menu.

Alarm Latching

Sets if alarms are latched or auto-reset.

Password

Set a password to prevent changes from being made via the app.

Note 1: The password does not prevent changes from being made using the devices menu. To stop changes from being made locally hide each of the settings using the screen options screen.

Note 2: You will need to contact your equipment provider for assistance if the chosen password is lost.

18 INSERTING BATTERIES AND BATTERY SERVICE LIFE

The device operates with 2 high quality AA size 1.5 V alkaline batteries.

Install and remove the batteries as follows:

1. Slide the back-plate off by lifting the latch at the bottom of the unit then sliding the back-plate downwards.

Note: If the device has been wall mounted, the latch is located at the bottom rear edge of the device, it should be pushed towards the wall and the device slid upwards.

2. Insert two high quality AA size 1.5V alkaline batteries into the device following the polarity symbols in the battery compartment. Slide the back-plate back on until it clicks into place.
3. Press and hold the ●⌚● button for 3 seconds to turn the device on.

Note: The internal clock needs resetting via the app if batteries have been removed for an extended period before any logging features will operate.

Battery life will vary between 3 and 12 months dependant on the features enabled, the frequency of alarms, how quickly alarms are responded to and how frequently the app is used to download data from the device.

The displays back-light / alarm-light, internal microphone and Bluetooth connection are the most power hungry features.

When the batteries are low, the display will flash “**LOW BATTERY**”, an audible sound will be made, and the device will start to transmit a low battery notification until the batteries are replaced. If using the wired output, the output will activate every 2 minutes. Pressing the ●⌚● button will suspend the alert for 12 hours, however the display will continue to display “**LOW BATTERY**” until the battery is replaced.

IMPORTANT NOTE: All alkaline batteries start to leak when empty, and a leak will contaminate the device. Remember to replace the batteries at least once a year to avoid any leaks. Remove the batteries when the device is not being used or when it is being stored for an extended period. The battery level can be checked via the app’s “**Status**” screen. Replace the batteries when necessary.

Device is tested and safe to use with the following alkaline batteries;

Manufacturer: NX-Power	Type: AA 1.5V	Model: PCA9010
Manufacturer: Duracell	Type: AA 1.5V	Model: MN1500 LR6
Manufacturer: Energizer	Type: AA 1.5V	Model: E91 LR6 AM3



Do not use any rechargeable batteries or lithium-ion batteries! Rechargeable or lithium-ion batteries carry the risk of over heating, ruining the device and causing possible danger to the user.

19 LOGGING

The control unit can store 33 hours of sensor data and 8000 “events” (which is typically several years worth of usage).

When the memory is full, any new data overwrites the old data.

NOTE: Power up and power down times are captured in the event history.

Downloading/Syncing data

The control unit uses Bluetooth Low Energy (BLE) as a power efficient way to send data to the app, however this is limited in speed. To download the full signal or event log will take up to 6 minutes, and will increase if the smart device and control unit are further away from each other.

20 INPUT AND OUTPUT CONNECTORS

Movement Sensor

Connector: Phono RCA Female.

Centre Pin = Signal.

Outer = 0 V.

Moisture Input (This port is electrically isolated from the other ports.)

Connector: RJ12.

Pin 3 & 4 = Moisture Detection.

Pin 2 & 5 = Fault Detection Resistor (For moisture self-test feature).

Occupancy Input and Wired Output

Connector: RJ12.

Pin 1 = Output. Alarm Normally Closed.

Pin 2 = Input. Bed Occupancy Signal.

Pin 3 = Output. Alarm Normally Open.

Pin 4 = Output. Alarm Common.

Pin 5 = Input. Bed Occupancy 0v.

Pin 6 = Not connected.

21 CLEANING

You can wipe the control unit, sensors and cables with a damp cloth, neutral cleaning product or mild disinfectant.



Avoid getting any liquid into the microphone hole or sensor inputs.

Always disconnect the nurse call cable (if used) before cleaning the device. Dry all parts well after cleaning.

22 LIABILITY OF THE MANUFACTURER

iTs Designs Ltd. (T/A Alert-iT Care Alarms) is liable to ensure the safety, reliability and performance of the device, provided that:

- the device is installed, used and cleaned in accordance with the instructions in these instructions for use.
- any changes to the device, maintenance and repairs are conducted by a person trained by Alert-iT or its representatives.
- any spare parts or accessories used have been approved by Alert-iT.

23 DISPOSAL OF THE DEVICE AFTER USE

In conformity with the Waste Electrical and Electronic Equipment Directive (WEEE Directive), the device must be collected separately and returned to an authorised collection facility. The owner must take the device to the waste collection point specified by local authorities.



For more information on how to dispose of the device, please contact the relevant authorities.

24 DECLARATIONS OF CONFORMITY

The manufacturer, iTs Designs Ltd., hereby declares that this product conforms with the relevant requirements of the Medical Device Regulations (EU) 2017/745.

The manufacturer, iTs Designs Ltd., hereby declares that this product is in compliance with the Radio Equipment Regulations (UK) 2017 and the Radio Equipment Directive (2014/53/EU).

The full text of the EU declaration of conformity is available at the following Internet address;

www.alert-it.co.uk/support/

25 ROUTINE CHECKS

25.1 Daily Checks

If “Vacation” feature is enabled

Ensure when the patient gets into bed, that the screen changes from “Vacant” to “Bed”.

If “Spasm” feature is enabled

Ensure when the patient first gets into bed, that the “#” symbol appears indicating the movement has been detected.

If “Sound” feature is enabled

Make a suitable sound (e.g. by clicking fingers) and ensure the “@” symbol appears on screen.

If “Moisture” feature is enabled

If self-test is not enabled: Press the two unused moisture sheet press studs together, and ensure a “MOISTURE” alarm is raised within 20 seconds.

25.2 Weekly Checks

Condition of the cables

Check the condition of the cables.

Position of the movement sensor

Check the position of the movement sensor under the mattress. The correct position is under the mattress at shoulder height of the patient .

Alarm Activation

Ensure the alarm notifications are being received by the caregiver(s). Manually trigger an alarm if required.

25.3 Startup and Monthly Checks

To ensure faultless performance, conduct the following tests at least once a month and when ever the device is re-installed.

Sensitivity

Check the Spasm / Sound / Moisture Sensitivity levels are still suitable. The log data can be used to guide this process.

Battery Level

Connect to the device via the app, check battery level percentage is sufficient until next check.

26 ALERT-IT LIMITED WARRANTY STATEMENT

In the unlikely event that your product needs guarantee service, please contact your provider, distributor or manufacturer. To avoid any unnecessary inconvenience on your part, we recommend you read these instructions for use carefully before seeking guarantee service.

YOUR GUARANTEE

By this Guarantee, Alert-iT guarantees the product to be free from defects in materials and workmanship at the date of original purchase for a period of three (3) years from that date.

If within the guarantee period the product is determined to be defective (at the date of original purchase) due to improper materials or workmanship, Alert-iT will, without charge for labour or parts, repair or (at Alert-iT's discretion) replace the product or its defective parts subject to the terms and limitations below. Alert-iT may replace defective products or parts with new or refurbished products or parts. All retained products and parts replaced become the property of Alert-iT.

TERMS

Guarantee services will be provided only if the original invoice or sales receipt (indicating the date of purchase, model name and dealer's name) is presented with the defective product within the guarantee period. Alert-iT may refuse free-of-charge guarantee service if these documents are not presented or if they are incomplete or illegible.

This Guarantee will not apply if the model name or serial number on the product has been altered, deleted, removed or made illegible.

This Guarantee does not cover transport costs and risks associated with transport of your product to and from Alert-iT.

This Guarantee does not cover:

- a. occupancy sensors or moisture sensors (see individual products for their guarantees).
- b. periodic maintenance and repair or parts replacement due to wear and tear.
- c. consumables (components that are expected to require periodic replacement during the lifetime of a product such as batteries).
- d. damage or defects caused by use, operation or treatment of the product inconsistent with normal use.
- e. damage or changes to the product as a result of:
 - i. misuse, including:
 - treatment resulting in physical, cosmetic or surface damage or changes to the product.
 - failure to install or use the product for its normal purpose or in accordance with Alert-iT's instructions on installation or use.
 - failure to maintain the product in accordance with Alert-iT's instructions on proper maintenance.
 - installation or use of the product in a manner inconsistent with the technical or safety laws or standards in the country where it is installed or used.
 - ii. the condition of or defects in systems with which the product is used or incorporated except other Alert-iT's products designed to be used with the product.
 - iii. use of the product with accessories, peripheral equipment and other products of a type, condition and standard other than prescribed by Alert-iT.
 - iv. repair or attempted repair by persons who are not authorised by Alert-iT.
 - v. adjustments or adaptations without Alert-iT's prior written consent, including:
 - upgrading the product beyond specifications or features described in the instructions for use, or modifications to the product to conform it to national or local technical or safety standards in countries other than those for which the product was specifically designed and manufactured.

- vi. neglect
- vii. accidents, fire, liquids, chemicals, other substances, flooding, vibrations, excessive heat, excess or incorrect supply or input voltage, radiation, electrostatic discharges including lighting, other external forces and impacts.

This guarantee covers only hardware components of the product.

EXCLUSIONS AND LIMITATIONS

Except as stated above, Alert-iT makes no warranties (express, implied, statutory or otherwise) regarding product or accompanying or constituent software quality, performance, accuracy, reliability, fitness for a particular purpose, or otherwise. If this exclusion is not permitted or fully permitted by applicable law, Alert-iT excludes or limits its warranties only to the maximum extent permitted by applicable law. Any warranty that cannot be fully excluded will be limited (as far as permitted by applicable law) to the duration of this Guarantee.

Alert-iT's only obligation under this Guarantee is to repair or replace products subject to these Guarantee terms and conditions. Alert-iT is not liable for any loss or damage relating to products, service, this Guarantee or otherwise, including- economic or intangible losses- the price paid for the product- loss of profits, revenue, data, enjoyment or use of the product or any associated products- indirect, incidental or consequential loss or damage. This applies whether that loss or damage relates to: impaired or non-operation of the product or associated products through defects or unavailability while with Alert-iT, which caused downtime, loss of user time or business interruption, inaccuracy of output from the product or associated products.

This applies to loss and damages under any legal theory, including negligence and other torts, breach of contract, express or implied warranty, and strict liability (even where Alert-iT has been advised of the possibility of such damages).

Where applicable law prohibits or limits these liability exclusions, Alert-iT excludes or limits its liability only to the maximum extent permitted by applicable law. For example, some countries prohibit the exclusion or limitation of damages resulting from negligence, gross negligence, wilful misconduct, deceit and similar acts. Alert-iT's liability under this guarantee will in no case exceed the price paid for the product, but if applicable law permits only higher liability limitations, the higher limitations apply.

YOUR LEGAL RIGHTS RESERVED

Consumers have legal (statutory) rights under applicable national laws relating to the sale of consumer products. This guarantee does not affect statutory rights you may have, nor those rights that cannot be excluded or limited, nor rights against the person from whom you purchased the product. You may assert any rights you have at your sole discretion.

27 TECHNICAL SPECIFICATIONS

Equipment is for continuous operation.

Control Unit

Model:	P200C Companion.
Power:	Battery Only. 2x AA 1.5V Alkaline (LR06).
Input and Output Connectors:	Movement sensor, Moisture Sensor, Occupancy sensor and Wired output.
Relay Output:	Max. 1A 30VDC. 0.3A 30VAC.
Switches and Controls:	One (On/Reset/Menu) press switch.
Signal Lights:	Red Alarm LED (Behind Display).
Sound Pressure Level Range:	50-54 dBA @ 1m.
Delay time from ALARM CONDITION to SIGNAL OUTPUT:	< 1s.
Maximum remote ALARM SIGNAL GENERATION DELAY:	< 1s.
Memory Retention:	All memory retained after power loss.
Mounting:	Wall mounting or bedside table.
Measurements:	89 x 89 x 30 mm (HxWxD).
Weight:	170g.
Colour:	White.
Casing:	ABS Plastic.
IP Rating:	IP20.
Service Life:	5 years.
Radio Frequency:	434.0750 MHz (P200xA).
Radio Output Power:	< 10 mW.
Radio Range:	600 meters (line-of-sight).
OR	
Radio Frequency:	869.2125 MHz (P200xB).
Radio Output Power:	< 10 mW.
Radio Range:	600 meters (line-of-sight).

Movement Sensor

Model:	P140*
Placing:	Under Mattress.
Measurements:	240 x 240 x 15 mm (HxWxD).
Weight:	465g.
Colour:	White.
Surface Material:	ABS Plastic.
Cable Length:	2.9m.
IP Rating:	IP20.
Service Life:	5 years.

Ambient Conditions

Operating Temperature:	5°C to 35°C (Use Indoors).
Storage Temperature:	0°C to 40°C.
Humidity Limit:	5% to 90% max. Non-condensing.

28 ALARM AND FAULT CODE LOOKUP

Shown in order of priority.

Alarms - High Priority

Urgent 20: **"Spasm Alarm"**.

Repetitive movements have been detected beyond the set limits.

Urgent 13: **"Sound Alarm"**.

The microphone has detected sounds beyond the set limits.

Urgent 11: **"Moisture Alarm"**.

The moisture sensor has detected moisture above the set limit.

Alarms - Medium Priority

[Audible alarm pattern = 3 beeps every 7 seconds]

Help 4: **"Bed Vacation"**.

The bed has been vacant for longer than the set duration.

Faults / Informational Alerts

[Audible alarm pattern = 1 beep every 15 seconds]

Fault 31: **"Battery Flat"**.

The internal batteries are flat. Replace the batteries immediately.

Fault 29: **"Alarm Off"**.

The device has been turned off or has shutdown due to low battery. Check the device.

Fault 24: **"Movement Fault"**.

The movement input has not detected any movements for over 24 hours. Test movement sensor.

Fault 21: **"Moisture Fault"**.

The moisture input has no moisture sheet connected. Check connections.

Fault 20: **"Occupancy Fault"**.

The occupancy input has not detected a change in occupancy state for over 24 hours.

Fault 19: **"Sound Fault"**.

The microphone has not detected any sounds for over 24 hours. Test Microphone.

Fault 16: **"Battery Low"**.

The internal batteries are low. Replace the batteries soon.

NOTE: If more than one alarm is active, then only the highest priority alarm is shown.



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For support please contact your equipment provider.

EU Importer to add details here, where applicable.

