

Radio Guardian Monitor Handbook

Guardian Solution S1020B With Plesio Pager

www.alert-it.co.uk

Introduction

The Alert-iT Guardian is a highly versatile monitor unit that employs a range of sensors to detect various presentations of seizure activity, before passing an alarm signal to a portable Alert-iT Pager. Your Guardian is preset to detect the key symptoms most commonly associated with tonic/clonic seizures, and has been supplied with sensors appropriate to your needs.

Before installing the Guardian, you will need to have sufficient knowledge of the client to make the necessary risk assessment as to the suitability of the equipment and sensors required to provide a safe environment with comprehensive support.

This handbook will help you install, test and adjust the settings of your Guardian and its sensors.

Once you have installed your Guardian, we will be pleased to offer you any assistance you require via our telephone help-line on 01530 239 900. Our working hours are 9am-5pm Monday to Friday.

Please test the operation of your Guardian and sensors at least once per week. We have included a simple form on page 30 which will help you keep track of this process.

Should you wish to change any of the operating parameters or modify your system, detailed handbooks are available on request (for hard copies), or on-line at: **www.alert-it.co.uk/support**

Please call 01530 239 900 or go online to **www.alert-it.co.uk/registration** and register your new equipment with our Service Team. You will be assigned an SRN (Support Registration Number) which will link your details and equipment to our database, ensuring that you always receive fast and efficient service and support. An additional benefit is that this will extend your warranty to three years at no extra charge.

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Product Information

The Alert-iT Guardian is without doubt the most versatile and sensitive epilepsy support monitoring system ever developed for home use.

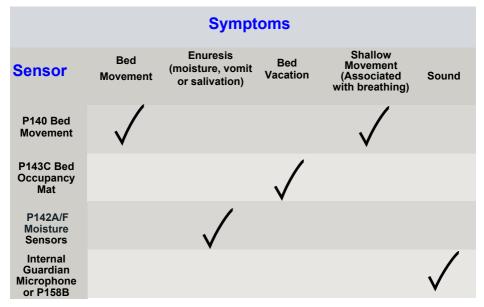
To get the most from your monitor, we recommend that on first installing it, you use only the tonic/clonic seizure functions for the first night. Setting the monitor up for this key role is an ideal introduction to using the controls and understanding the information on the display screen. You will then be able to progress quickly to using the other functions as described later in this handbook. In addition, our telephone Customer Support Team are here to assist you and can be contacted on 01530 239900.

The Guardian's wide range of settings, adjustments and nightly movement readings support the following symptoms:

- Tonic/clonic seizures from tremors to large movement
- SUDEP through failure of shallow movements associated with breathing
- Breathing problems though changes in shallow movement activity
- Enuresis, vomiting and salivation via the moisture sensor sheets
- - Immediate or prolonged bed vacation
- Sharp vocal sounds associated with seizures

The appropriate sensors for these symptoms can be verified on the table featured below.

Client Assessment



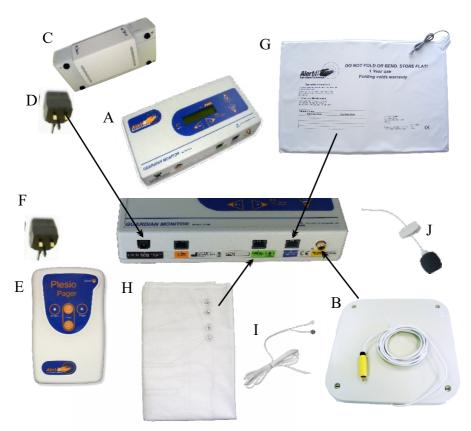
The Guardian and its Optional Sensors

Guardian Solution Contents:

Α	Guardian Bedside Monitor	P139*
В	Bed Movement Sensor (Included)	P140A
С	Bracket for wall or bed mounting (Included)	P159A
D	Power Supply for Guardian (Included)	P171*
Е	Plesio Pager	P168
F	Power Supply for Pager	P153B

Additional Items:

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G	Bed Occupancy Mat (optional purchase)	P143*
Н	Moisture Sheet(s) (optional purchase)	P142A/F
1	Connecting Lead for H (optional purchase)	P141E(S1016)
J	External microphone (optional purchase)	P158B



Part 1 - Quick-Start Guide

Using The Guardian

Basic controls: Standby



Basic controls: Adjustment Example



Switching The Unit On

Insert the power supply into the socket on the Guardian marked 'POWER 12V DC'. (Fig.1). Press the arrow button marked 'menu' to switch the Guardian on.

The Guardian incorporates an internal battery, ensuring that the monitor has a constant power source in case of power cuts. This battery will charge whenever the power supply is plugged in. If the battery indicator rectangles appear as solid shapes, the unit is charging; if they appear as outlines only, the unit is operating on its battery power alone.

If the battery becomes discharged then the monitor will emit an alarm noise (which sounds like a croaking frog) and a fault indication will be transmitted to the pager.

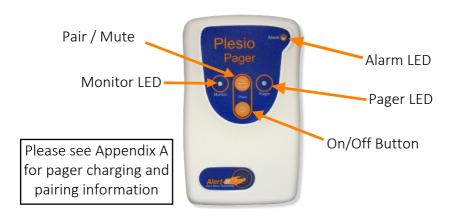


Power Supply Socket

Figure 1

Turning on the Plesio Pager

While the pager is shipped with some charge in the batteries, we recommend that you charge the unit for six hours before use. To turn the pager on, press and hold the ON/OFF button for 3 seconds. The pager will beep and all three LEDs will flash. The red Monitor LED will blip every 8 seconds to indicate that the pager is linked to the monitor, while the green Pager LED will blip every 4 seconds to show that the pager is active and listening for an alarm.



Sensor Installation and Basic Operation

The following sequence of first use of the sensors is highly recommended. This methodical approach gives you time to familiarise yourself with the way each sensor operates, and ensures that you will go on to use your Guardian confidently, safely and to its full potential.

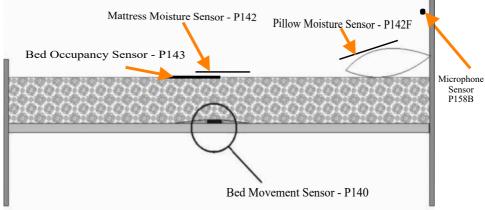


Figure 2

Positioning sensors on the bed

Spasm Movement

Designed to detect tonic/clonic seizures



Figure 3

Install the Sensor

Place the Bed Movement Sensor (P140A) underneath the mattress on a firm bed base (as per fig. 2), in a position below the torso. Connect the sensor into the Guardian monitor making sure that the sensor's yellow plug connects to the movement sensor plug (also marked with yellow as per figure 3).

Activate the Function

The Guardian is factory-set with this feature activated. It is pre-set for sending an alarm after detecting tonic/clonic movements lasting longer then 15 seconds at a rate of at least one movement every two seconds. To deactivate or alter these settings, please see page 17.

Test the sensor

Tap the mattress and note that the # symbol appears and remains visible for the duration of the delay time (this is 15 seconds at the factory setting).

Normal Operation

An alarm will activate if movements exceed the rate and time settings. The pager will display an alarm light, emit an audible alarm and vibrate (it can be silenced for 5 minutes while you attend to the client by pressing Mute on the pager). The alarm is cleared at the monitor by pressing the button marked Alarm Reset on the Guardian's front panel followed by pressing the Mute button on the pager. It is important to ensure that the Guardian resumes its ACTIVE mode once the occupant has returned to the bed.

Shallow Movement

Designed to support breathing-related seizures and SUDEP

Install the Sensor

Shallow movement is detected using the P140 Bed Movement sensor, which will have already been installed (see page 9).

Activate the Function

By default this is OFF on delivery. Use the MENU key to scroll to "Shallow" and select 'On' by pressing the Zz arrow. There are then four parameters to set:

- **Shallow Magnify (Sensitivity)**: The higher the number the smaller the movements detected, which reduces false alarms. However, the sensor MUST be tested for immunity to ambient vibrations (see pages 19-21)
- Shallow Delay (Identified as d on the display): How long the client stops moving totally to generate an alarm. At the start this is set to 60 seconds and refined later with observation of the clients general breathing pattern (see pages 19-21)
- Shallow Minimum (Identified as m on the display): The trigger level for slow breathing. At the start this should be set to 0 and refined later with observation of the clients general breathing pattern (see pages 19-21)
- Shallow Maximum (Identified as M on the display): The trigger level for fast breathing. At the start this should be set to off and refined later with observation of the clients general breathing pattern (see pages 19-21)

When setting these parameters to give fast reliable detection with minimum false alarms, the client's mattress type, physique and nighttime breathing patterns all need to be taken into account and adjusted for. To help you achieve this, we strongly recommend using the procedure on page 19 which uses the built-in movement recorder overnight to help establish the monitor's optimum settings.

Test the Sensor

A useful test facility is the "Tick Volume". This is the second option from the home screen as you scroll through the main menu. It is set to OFF by default, but after changing to 8 (full volume) a tick will be heard at every detected breath or shallow movement. To test the sensor; lie on the bed and note that a tick is heard or the breathing symbol (*) appears on the display at every breath.

Normal Operation

If any of the selected alarm conditions are exceeded, an alarm will be raised. Press RESET on the Guardian and 'Mute' on the Plesio Pager to clear the alarm. This will also suspend further alarms until a client is once again detected in bed (see explanation page 16). This prevents false alarms while the bed is unoccupied.

In-bed (active) detection occurs if:

- The sensor detects 10 shallow movements within one minute
- A Bed Occupancy mat is activated (see page 13)

Safety Note

The alarm is inhibited if the Bed Occupancy mat indicates the client has left the bed. This could stop the alarm activating if, for instance, the client curls up at the bottom of the bed away from the mat or falls from the bed prior to a seizure. If this is possible then the Bed Occupancy mat should either not be used or only set to alarm after only a few seconds to reduce any long-term risk.

Sound

Designed to detect seizures associated with vocal sounds

Install the Sensor

The Guardian features an internal microphone. However, an external microphone is also available and may be required to focus sound detection if the monitor is being used in a noisy environment (part number P158B - sold separately).



External Microphone Input

Activate the Function

This is turned off at factory settings. To activate the sound detection function, use the MENU key to scroll to "SOUND". There are then three parameters to set:

- **Sound Delay**: How long the sound sequence must go on for to trigger an alarm.
- **Sound Magnify**: This ranges from 1-8. The higher the number selected, the quieter the sound detected.
 - **Sound Rate**: How frequent the shouting or clicking has to be per minute.

Test the Sensor

Make a sharp click near the sensor and note that a) symbol appears on the display. The sensitivity (Sounds Magnify 1-8) can be adjusted.

Normal Operation

If the sound pattern matches the rate and carries on longer than the set delay, an alarm is generated. Press RESET on the Guardian and 'Mute' on the Plesio pager to silence and reset this alarm (Please 'Suspend Mode Explained' on page 16 for further details).

*If the client is detected out of bed (with either the Bed Occupancy Mat - see page 13, or the Shallow Movement detector enabled - see page 10), then the microphone will be inhibited to prevent false alarms.

Bed Occupancy (if applicable)

Install the Sensor Figure 4



Insert the sensor cable into the Guardian's Occupancy Monitor socket as shown in figure 4. Place the Bed Occupancy Sensor (P143*) on top of the mattress under a suitable cover sheet, in a position that ensures the maximum body weight is lying on the sensor. Typically this is the area beneath the upper torso. Positioning the sensor underneath the shoulder area is advised if an alarm is required before the user's feet touch the floor.

Activate the Function

The Guardian has this function turned off as its factory setting. To turn the function on, use the MENU key to scroll to "Bed Occupancy" and use the right-hand arrow (Zz) to select the time required for the occupant to be missing before the alarm is raised. A typical setting* would be 6-10 minutes to allow for a toilet visit, yet avoiding the danger of leaving the client unattended should a seizure occur in the bathroom (however, please see the safety comment regarding SUDEP on page 11). Please be aware - this sensor has safety implications when used in conjunction with the Shallow Movement or Sound functions (see pages 10 & 12)*

Test the Sensor

With the mat plugged in and the bed unoccupied, the word "vacant" should appear on the display. Lie on the bed and 'in-bed' should replace the 'vacant' message.

Normal Operation

When the occupant leaves the bed, this sensor will automatically inhibit the shallow movement and sound alarms. If the occupant fails to return within the prescribed time the alarm is raised. The alarm resets automatically if the client returns. Press 'Reset' on the Guardian and 'Mute' on the Plesio pager to silence and suspend the alarm once the occupant is being attended to. (Please refer to 'Normal Operation' on page 9 and 'Suspend Mode Explained' on page 16 for further details.)

^{*}Please note. Any settings must be supported by the risk assessment carried out for the individual.

Moisture (if applicable)

Install the Sensor

Connect the Moisture Sensor (P142) to its connecting lead using the press-studs (you must connect the studs to either the right or left- hand pair in the case of the mattress sheet). The other end of the lead plugs into the Guardian's green port (as shown in figure 5).





Figure 5

Please note that there are two types of sensor: either fitted over the pillow for vomit detection (P142F), or on top of the mattress (on top of the Bed Occupancy mat if fitted) in the region of the groin for enuresis monitoring (P142A).

Activate the Function

The Guardian has moisture detection turned off as a factory setting. To turn the function on, press the MENU key repeatedly until the "MOISTURE" option appears, and then use the right key (Zz) to adjust the degree of wetness required before the alarm is raised.

Test the sensor

To test the sensor, join the two spare stud connections (either left or right-hand pair) with a metal object to trigger an alarm.

Normal Operation

When the sensor sheet becomes wet, the alarm will sound. Press 'Reset' on the Guardian and 'Mute' on the Plesio pager to silence and suspend the alarm until a dry moisture sensing sheet has been connected (see explanation page 16).

Alarm Condition

The pager will automatically detect any failure in the communication system or catastrophic failure of the monitor.

All alarms can only be cleared at the monitor by pressing the button marked alarm/reset on the Guardian's control panel.

When the Menu/Reset button is pressed while the sensor is still detecting an alarm condition, then many of the alarms will show "SUSPENDED" (see explanation page $\underline{16}$) and will no longer send alarms to the pager until the safe condition is restored.

It is strongly recommended that you <u>check the Guardian has returned</u> to "ACTIVE" before leaving the user, as this ensures an alarm condition will be detected.



Type of alarm currently active

Duration of alarm currently active (in seconds)

Suspend Mode Explained

The word "active" on the main screen confirms that all the sensors are working and have sensed a safe condition for the bed occupant.

When the Alarm Reset Key is pressed following an alarm, or indeed at any time, sensors that could give false alarms when the occupant is out of the bed are temporarily suspended. They will then remain suspended until the occupant is sensed as being in the bed once again whereupon they will return to active mode automatically. This applies to the Shallow Movement, Sound and Bed Occupancy sensors. In addition the Moisture sensor is suspended until a dry sensor is detected.

If any sensor is suspended the the screen shows "Suspended" followed by the corresponding letter(s) indicating which sensors are suspended. All others sensors will still be active.

The following table defines the conditions that cause the sensor to become active.

	Sensor	Action to trigger Active mode	Effect when Suspended
S	Shallow	After 10 breaths or if Bed Occupied sensor active	Shallow alarms are not sensed when S is showing
S	Sound	After 10 breaths or if Bed Occupied sensor active (or always if one of these is not active)	Sounds are not sensed while S is showing
m	Moisture	When sensor dry	Moisture is not sensed while m is showing
b	Occupancy	When "in bed" sensed	The Bed Vacation alarm timer is stopped while b is showing.

Part II - User Settings & Adjustments

Spasm

Press the menu to scroll to the relevant spasm setting. Using the Mm (left) and zZ (right) arrow to alter settings sensitivity.



Spasm Delay is the amount of time the person is moving constantly before the alarm is triggered. The unit is supplied with a default setting of 15 seconds.

Spasm Magnify is the sensitivity adjustment for intensity of movement. 8 is most sensitive. Slight tremors will be setting 8. The unit is supplied with a default setting of 4.





Spasm Rate is set at a default of 2, meaning that the unit will alarm if there is 1 movement every 2 seconds (i.e. within the setting). Lowering spasm rate to 4 detects slower regular movements. E.g. Setting 4 could support, myclonic detection (1 movement every 4 seconds or faster, which triggers an alarm).

Shallow Maximum (default is Off) Starts at 20 MPM (movement/breaths per minute) maximum is 30. This is to detect rapid movements/breaths which may indicate panic attack or hyperventilation.



Tick Volume (Audible breathing sound)

The tick volume can be adjusted from OFF to the maximum of 8. (Default=OFF). A soft yet distinct sound Tick volume enables carers to maintain a discreet audible vigilance of the user's breathing pattern.



Enabling Shallow Minimum

Shallow Minimum monitors the average number of breaths taken per minute. When the function is turned ON and the person is in bed the Guardian should go into Active Mode within approximately 10 movements/breaths. It is important to ENSURE Active is displayed (and not suspend: see page $\underline{16}$) or the person will not be monitored for shallow movement and sound.





Enabling Shallow Delay

Shallow Delay is activated when Shallow Minimum is ON. Shallow Delay will alarm at when breathing ceases after a set time. Adjustable but factory set at 30 seconds, it will therefore alarm after no movements/breaths are detected within any given 30 second period (note - this is independent of the the Shallow Minimum setting, and essentially functions acts



as a failsafe feature to detect an absence of breathing movement.)

Shallow Magnify

Shallow magnify is to allow for variants in the size and weight of a person, compared to mattress type & density. The highest setting will reduce false alarms, provided there are no extraneous vibrations being picked up when no-one is in bed (such as from an airflow mattress).



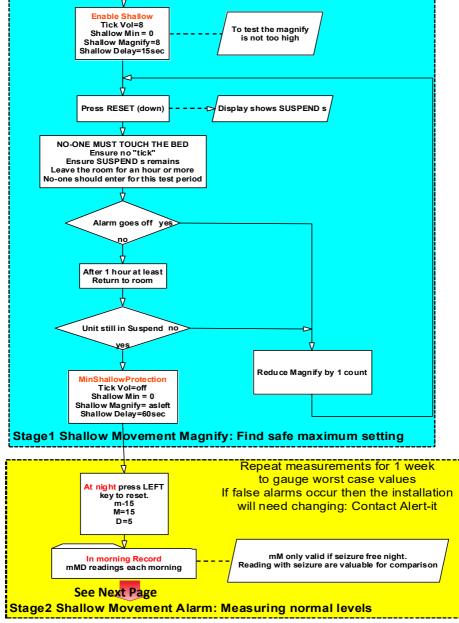


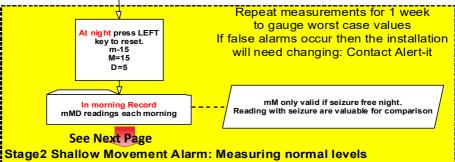
Recommended Procedure For Setting Shallow Movement Alarms

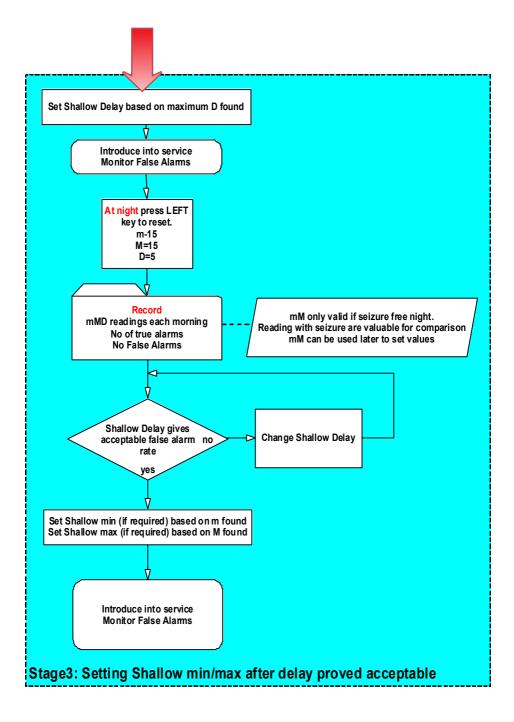
- 1. Using the TICK function is a good way to audibly check that the movement sensor is working. Turn the function on and select setting 8.
- 2. Set the Shallow Min to 0, Shallow Magnification at 8, Shallow Delay=15 and with no user in the bed and no one touching the bed, check that neither the * or # symbol do NOT appear on the screen. Then leave the unit in SUSPEND (press RESET key) for an hour with no-one in the room and check it remains in SUSPEND. Decrease the magnification if necessary to stop any sensor activity. This will set the optimum highest sensitivity to pick up movement safely. If the setting falls below 6 then contact the supplier as the installation may be an issue. This would apply if airflow or oscillating air mattresses are being used, where additional measures may be needed.
- 3. On the first few nights leave Shallow Max turned off but set Shallow Min to 0, Shallow Delay=60 and use the Mmd readings to decide on the most suitable settings.
- 4. Once the user is settled in bed, or sleeping, press the Mm button to reset and start the recorder. The readings on the Guardian's screen will show as M15m15d5. (See pic. below)
- 5. In the morning, and before the user is awake, note the new readings. Repeat for a number of nights to get a spread of readings and use these to set the alarm values with a margin to prevent false alarms. It is best to begin with Shallow Min=0 with Delay set by the d value as required and prove reliable operation before increasing the Min towards the m value (which can increase false alarms).
- 6. If the Guardian is an older unit unit that does not have the 'd' reading feature (v6.3), then a reliable value can be found by decreasing the Delay from 60 step by step until an acceptable value is reached without excessive false alarms. Experience suggests most people experience very low breathing levels with gaps in the early morning, which can trigger alarms without any apparent cause.
- 7. Validate operation during observed seizures and adjust the magnification and detection limits as required. Please call Alert-iT if you have any questions.



Shallow Movement Adjustment Procedure Begin using Guardian WITHOUT shallow Shallow Enabled to gain operational experience **Enable Shallow** Tick Vol=8 To test the magnify Shallow Min = 0 is not too high Shallow Magnify=8 Shallow Delay=15sec Press RESET (down) Display shows SUSPEND s NO-ONE MUST TOUCH THE BED Ensure no "tick" Ensure SUSPEND s remains Leave the room for an hour or more No-one should enter for this test period Alarm goes off yes







Bed Vacation

You will require an optional bed occupancy sensor to use this function. Please enquire about our P143 range.



When Bed Vacation is enabled, the Guardian is able to detect a bed being vacated for longer than 5 seconds. (This 5 second period is to allow for turning in bed, without causing a false alarm). Bed vacation delay setting allows the monitor to prevent Shallow Movement & Sound alarms while a person is out of bed for a set period of time (up to 24 hr).

Delay time predetermined increments

Delay time predetermined increments

SUSPEND sb good when bed unoccupied

Warning

It is important to ensure that the use of this setting is based upon an individual assessment to ascertain that the user does not move off the sensing area while in bed, as this could prevent the shallow movement detection from operating. For further advice, please contact Alert-iT support.





Sound Settings

Sound Delay

Where seizures can be detected by sound i.e. a clicking of palate, teeth chattering, lip smacking or similar, the Guardian has an internal microphone which can be enabled. N.B. an external microphone can be added as an option (P158B). Settings from 5 seconds up to 60 seconds can be selected, indicating the amount of continuous sound needed to trigger an alarm.





Sound Magnify

To enable this setting Sound Delay must be ON. To pick up lower volume sounds, increase Sound Magnify up to a maximum of 8. The display will show) symbol when sound is detected (see figure 6).

Sound Rate





To enable this setting Sound Delay must be ON. Sound rate picks up the rhythm of sound. E.g. For default setting 2; one sound in two seconds or faster which will trigger an alarm within the Sound Delay settings timeframe. When sounds are made less frequently increase the number up to 4.



Moisture

When moisture is enabled, it is used to detect bed wetting, salivation or vomiting. Detection is via optional sensing sheets, which need to ordered separately to suit your individual's requirements. Please enquire about our P142 range.

Moisture settings from 1 (moist) to 5 (wet) can be set to reflect the requirements of the user.





Other Settings

Snooze Function Zz

Whilst in snooze mode ALL alarms will be deactivated for the set period of time. This is useful for personal care or if the user is not settled and false alarms are being activated prior to sleep. To activate the Snooze feature, press the Zz arrow and select the desired time duration. Snooze can be cancelled at any time by pressing the Mm arrow once again - the Guardian monitor is now actively working. Please be aware that whilst in snooze mode the monitor will not pick up any alarms until the set time has elapsed, therefore we recommend extra vigilance during this time.

Reload Default Settings

Settings can be saved for the individual user. Please refer to Supervisor Handbook for instructions. Available on our website UH1075. Warning: If "Reload Default Settings" is pressed, this will reload the Factory Default Settings OR the settings saved as per the Supervisor Handbook. Therefore the individual settings, if not saved, will be lost.

Auto-test of sensors

If a sensor shows no sign of having produced a "normal" activity signal for 24 hours then a fault alarm is raised to prompt a full test by the carer to ensure the sensor has not failed. Please see page 26 for pager fault alarm messages and codes.

		-						
Alarm Setting & Pager Indicators	ager Ir	dicat	ors					
Function/Menu	Left	Range	ge	Comment	Default	Monitor Screen	Pager Indication	Your Settings
ID Number/Site No				Appears on screen at power up with software version				
On/menu key			menu	Press to scroll menu. Press any key also resets alarms		Active or Suspend	Red LED/Urgent Sounds/Vibrate	
POWER	off			Press to turn off (if enabled)		Blank		
Tick Volume	off	1	8	Volume of click on each shallow movement	OFF			
Shallow Minimum	off	0	10	MPM (Movements Per Minute) below which alarm triggers	OFF	SHALLOW MOVEMENT	Red LED/Urgent Sounds/Vibrate	
Shallow Delay ¹		10	09	Minimum time for Shallow movement alarm to be detected	30	SHALLOW MOVEMENT	Red LED/Urgent Sounds/Vibrate	
Shallow Maximum	off	20	30	MPM above which is alarm	OFF	SHALLOW MOVEMENT	Red LED/Urgent Sounds/Vibrate	
Shallow Magnify $^{ m 1}$		1	8	Set for optimum movement detection using tick or st symbol	9			
Spasm Delay	off	2	09	Time for spasm to set alarm	15	SPASM MOVEMENT	Red LED/Urgent Sounds/Vibrate	
Spasm Magnify $^{ m 1}$		1	8	Set for optimum detection of spasm using # symbol	4			
Spasm Rate ¹		1	4	Seconds between movements - a spasm is assumed if faster	2			
Sound Delay	off	5	09	Time for sound level to set alarm	OFF	TRANSIENT SOUND	Red LED/Urgent Sounds/Vibrate	
Sound Magnify $^{\mathrm{1}}$		1	8	Microphone sensitivity	4			
Sounds Rate ¹		1	4	Seconds between sound bursts: a spasm is assumed if faster	2			
Moisture	off	1	2	Fault alarm if sensor open circuit. Covers moist to wet.	OFF	MOISTURE	Red LED/Urgent Sounds/Vibrate	
Bed Occupancy	off	5 s	24h	Time allowed for vacancy before alarm. Shallow alarm inhibited.	OFF	BED VACATION	Red LED/Urgent Sounds/Vibrate	
Reload Default				Snapshot saved in "hidden menu"				

Alarm Settings & Pager Indication

	Other alarms without set-up parameters		
Function	Pager	Comment	
Monitor off	Red Flash and regular 'du-de-du' alarm tone	Unit has been turned off (warning)	
Battery Low	Red Flash and regular 'du-de-du' alarm tone	Connect charger	
Radio Fail	Steady Red and regular 'du-de-du' alarm tone	Must be corrected urgently	

Alarm Indication is Flashing Red Alarm Light, Vibrate and Tune

All sensors are monitored for signs of correct operation. If no sign of operation occurs for 24 hours a fault warning is given to obligate a test of sensors as shown in the following table:

Fault	Source	Action to clear /confirm fault
Red flash	Movement Sensor	Tap bed
Red flash	Spasm Sensor	Tap bed
Red flash	Sound Sensor	Clap hands
Red flash	Occupancy Sensor	Sit on bed
Red flash	Moisture sensor	Fit new dry sensor

Unless otherwise agreed, the Guardian will be shipped only to create alarms in response to spasm movement, to prevent the confusion of many alarms activating as soon as the unit is turned on. The other alarm functions can then be enabled one at a time as confidence is gained at each level. The table on page 15 shows the recommended default start setting for alarms and the pager indication that will occur. It can be used to record the actual settings used.

Maintenance

Cleaning

It is recommended to regularly clean both units by wiping with cotton wool pads moistened (compressed until dripping stops) with a mild detergent (0.5% washing-up liquid) solution or by using an alcohol or baby wipe. Avoid getting any liquid into containers.

Pager Pairing Instructions - see appendix A

Compliance

- The system complies with 93/42/EEC as a Class 1 Medical Device for use in a Home Heathcare environment
- The system complies with EN60601 for Class 2 Electrical Safety and does not need a protective earth and Group 1 Class B for EMC in a Home Healthcare environment

On radio versions only:

 The system has a radio transmitter compliant to EN300-220 operating at 434.075MHz wideband 10mW power (class 8) less than 1% duty cycle (class 2)

Bibliography

Full handbook: www.alert-it.co.uk/support



Important Safety Information

- 1. Ensure that the sensor cable is routed and secured to avoid the risk of entanglement or strangulation.
- 2. Ensure the power cable is routed and secured to avoid the risk of entanglement or strangulation.
- 3. Regularly check the power supplies for damage and potential shock risks
- 4. Ensure, by testing, that the alarm is annunciated at the carer's location(s)
- 5. Regularly test sensors as defined herein
- 6. Use only the power supply and batteries recommended
- 7. Operate power supply and charge pager away from direct heat and uncovered.
- 8. As with all medical 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 monitor, sensor or connecting cable in close proximity to sensitive electronic devices or devices which produce strong electromagnetic fields such as radio transmitters, mobile phones or power cables.
- 9. Only use the monitor with accessories approved for use with this product and only in accordance with instructions.
- 10. If the equipment is modified in any way, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- 11. The carer must conduct a risk assessment to determine if the level of reliability offered by the monitor is sufficient or if additional monitoring is needed. Contact the manufacturer for assistance with Risk Evaluation Tools.
- 12. Additional levels of mechanical protection may be needed for some patient disorders. Contact the manufacturers for advice
- 13. The advanced pagers "Extended User" option should be disabled if there are concerns that the carer may turn-off the pager inappropriately and ignore alarms
- 14. Some accessories are fitted with small screws and have plastic bags. Ensure these do not come into the possession of vulnerable patients who might choke on them
- 15. Any sensor over the mattress (Bed Vacation or Incontinence) has the potential to cause pressure sores . The carer must assess this risk and monitor the use of these products if used
- 16. Any sensor over the mattress could pose a fire hazard if in contact with an ignition

Routine Testing Sheet

Test	Signature	Date
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The Alert-it system has been designed with due regard to reliability and integrity. While it offers a highly vigilant monitoring 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 monitoring techniques (e.g. video). Neither the manufacturer nor its agent can accept legal responsibility to provide a system that is infallible. The carer is responsible for assessing the risks of using this equipment and any settings pertaining to it.



Appendix A

Plesio Pager

Ensure the monitor is turned on. Pairing is only possible within 30 seconds of powering up the pager. To pair the Monitor to the Pager place the monitor close to the pager and press and hold the Pair button on the pager. Stimulate any radio transmission from the monitor (to do this press the reset button, trigger an alarm or just wait for the 8 second Safelink® signal).

If successful you will hear a beep and see the red Monitor LED blip when pairing is successful, you can then release the pair button. A lower burp with no red light indicates the monitor is too far away to pair. This protects against falsely pairing with another, distant, monitor.

To clear all paired monitors from the pager memory, press and hold both the ON/OFF button and the Mute/ Pair button together within the first 30 seconds after power-up, until the ensuing tone sequence has finished sounding and the green Pager LED illuminates, then release both buttons.

Notes

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01530 239 900

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Social

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Epilepsy Forum



