

Companion Monitor with Sound Capability

User Handbook



| Model | Description |
|--------|---|
| P154AA | Radio Companion Bedside Monitor (sound burst capable) |
| P154BA | Wired Companion Bedside Monitor (sound burst capable) |

One of a range of Alert-it Care Alarms available from:





The handbook covers the essential instructions for the safe installation, setting and use of the Companion monitor designed to support the care of those with epilepsy. The version covered has the ability to detect:

- Excessive Bed Movement as typified by a Clonic Seizure
- Repetitive Sound Patterns (grunts, click or shouts) that can be associated with an epilepsy episode or Continuous sound above a set level
- Bed Vacation (instant or prolonged) as may pose a risk to the user.

It is NOT suitable for seizures characterised by stillness or stiffness as typified by a Tonic seizure, for this please ask about the Guardian Monitor.

Another version of the Companion is able to detect Vomiting or Enuresis, please seek advise if this is required.

Two alarm output capabilities are covered.

- Using a failsafe radio link to the Alert-iT Safelink Pager
- Using a wired connection to a Nurse Call or Telecare device
- The system is designed for use in an indoor residential environment of 10-30°C and 90% RH max
- When not required, isolate from the mains by removing the power supply plug
- The service life for the monitor is expected to exceed 5 years. Some of the sensors may, however, only be guaranteed for 1 year due to the harsh environment in which they operate (eg Bed Mats where urine contamination is frequent). Hence the carer needs to be vigilant and test the units as prescribed herein to detect deterioration..

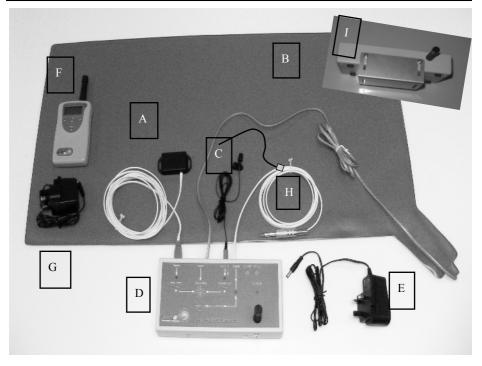
The system complies with 93/42/EEC as a Class 1 Medical Device

The system complies with EN60601 for Class 2 Electrical Safety and does not need a protective earth.

The radio systems complies with EN 300 220 and uses 434.075Mhz

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.

The following figure is to illustrate how, in general, the P154 will be connected to any sensing elements used. The system documentation should be read for details of the exact parts provided and any specific installation, test and safety instructions

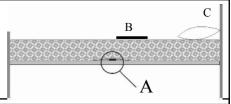


| | Part Description | Part No | Cleaning |
|---|--|---------|----------|
| Α | Bed Movement Sensor | P114A | С |
| В | Bed Occupancy Mat | P143C | Α |
| С | Microphone | P158A | С |
| D | Bedside Monitor | P154* | С |
| Ε | Power Supply for A | P171* | С |
| F | Pager | P138B | В |
| G | Power Supply for F | P153* | С |
| Н | Nurse Call/Annunciator Lead (optional) | P145* | В |
| I | Mounting bracket | P159A | В |

^{*} following code letter denote acceptable variants (eg country specific connection)

Quick Reference Sheet: Installation

Install the **Bed Movement** Sensor (A) underneath the mattress on a compliant bed base or the foam pad supplied., in a position below the rib cage. Its task is to monitor the smallest bed movements transmitted through the mattress.



The **Bed Occupancy** Sensor (B) is typically on top of the mattress under a suitable cover sheet, in a position that ensures the maximum body weight is lying on the mat, typically below the upper torso. Alternative sensors can be supplied to order, which may fit under the mattress or under the bed leg. See system information for details

The microphone is plugged into the rear socket (C) and positioned near to the user.

The P154 Monitor is robust and often positioned under the bed, provided access to the RESET button is unimpaired. Alternatively a bracket is available to allow the unit to be wall mounted or clipped over a bed head..

If the bracket is used then the P154 aerial can be mounted in an alternative position on the side rather than the front.

To do this remove the plastic cover screw from the side hole not used by the bracket. Unscrew the aerial and screw into the exposed hole.

For the wired versions the Nurse Call lead is plugged into the OUTPUT socket and will have been supplied with a training connector suitable for the Nurse Call system specified, to which it should be connected

The mains power adapter E should be connected to the monitor and left powered to keep the standby battery fully charged. It is recommended that this is not within reach of the patient to serious prevent damage that could result in a shock risk.

All cables should be run to avoid damage by moving bed parts or inquisitive patients. The power lead should be run to avoid a rip hazard

Quick Reference Sheet: Operation

The monitor is turned on using the rear recessed on-off switch. It is recessed to prevent accidental turn-off. The radio system will warn against subsequent battery failure but any wired system cannot do this. Hence it is important to observe the indicator lights after pressing reset. If they all flash permanently then the battery is becoming exhausted.

After power-on or RESET the monitor enters a 30 second test period during which the green power light is flashing (see TEST PERIOD)

Normal Operation

When the test period is over the light A stays on after each movement of the bed for the "rate time" set on the switch. To register an alarm the movement must be faster than this rate so that the light stays on permanently for the time period set on the switch (see table). The same applies to sound triggers, which will show on light B (provided the Bed Vacation situation has not permanently set the light on).

If the bed is vacated, then the red light B will be on permanently and after the set period (default 6 minutes) an audible alarm will be raised for 20 seconds, after which the alarm will be sent if the bed remains unoccupied. This audible alarm is optional and disabled by an internal link if it would upset the patient.

The movement and sound alarms are still active while the Bed Vacation light is on (in case a failure of the mat has falsely indicated vacation)

ALARM

The following table shows how any detected alarm condition is signalled on the monitor, on the pager (radio version) or via the Nurse Call

| P154 Indication | Pager Alarm | Nurse-Call | Meaning |
|--|-------------|------------|--|
| None | RF Fail | no | Radio signal lost from the node |
| Red light A on steady | Urgent01 | yes | Client is in distress (Bed Movement Alarm) |
| Red light B on steady | Urgent02 | yes | Client is in distress (Sound Alarm) |
| Red light B flashing | Urgent10 | yes | Client is in distress (Bed Vacation Alarm) |
| Red light A flashing | Urgent11 | yes | Client is in distress (Additional senor eg Floor Mat) |
| On power-up or RESET all LED's will flash as warning | Fault31 | no | Battery is client's system needs charging |

Quick Reference Sheet: Operation (cont)

The alarm will normally be cleared by pressing the area marked RESET on the front panel. To special order a version that automatically resets once the alarm condition is passed is available. This is not recommended but assists when the patient is prone to damaging exposed equipment

Suspending Bed Vacation & Sound Detection

To prevent false alarms, especially in the day, the Bed Occupancy & Sound monitoring does not restart activity after RESET until the pad detects a person has returned to bed first. Hence the user can easily disarm the function during the day, by simply pressing the RESET button after leaving the bed (and before any alarm is raised)

Essenstial Performance Testing

On a daily basis check the operation of the various sensors during the 30 second test period following RESET .

Bed Occupancy: The red light B will be on permanently if the bed is vacant (or the plug removed). Sit on the bed to activate the pad and the light should go out.

Movement: Check the red light A flashes when the bed is depressed with force (equivalent to the expected seizure), but not at other times.

Sound: Check the red light B flashes when small sharp sounds (eg a finger click) is made near where the user would reside. If a Bed Occupancy sensor is fitted, then it must be activated by sitting on the bed (to extinguish light B) to see this test.

Radio Fail:

The above tests are sufficient to prove the integrity of the radio based system as any other failure will result in a loss of communications and the *RF Fail* error appearing on the pager, **Nurse Call Fail:**

To test the integrity of the Nurse Call lead and system it is essential to trigger a false alarm at regular intervals, at a frequency determined by the reliability of the Nurse Call and vulnerability of the patient.

Quick Reference Sheet: Maintenance

Cleaning:

The following is a general guide line based on the components listed on page 3. Where a different sensor has been supplied, then please refer to the cleaning instructions supplied with that sensor. A series of techniques are described and the appropriate method is shown in the table on page 3.

Technique A

Wetting with strong disinfectant. This can include immersion provided plugs and any obvious breathing holes are avoided.

Technique B

Wiping with cotton wool pads moistened (compressed until dripping stops) with a mild detergent (0.5% washing up liquid) solution.

Technique C

Wiping with disposable 70% isopropyl alcohol wipes. Ensure that any plugs are completely dry before reinserting into the sensor input socket on the monitor.

Technique D

Full immersion in detergent , water and optional disinfectant. See component washing instructions for details

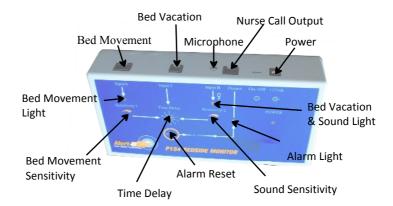


Battery Replacement

As the battery has a standby function it is unlikely to need replacing for 5 years. It should be tested and rejected if it fails to maintain the unit working for 14hrs following a full charge for 2 days. Under the unit is a small compartment which houses the 9v rechargeable battery

PP3 NiMH 1500mAh minimum)

Controls and Indicators



Quick Reference Sheet: Adjustment

Any adjustment to Bed Movement or Sound detection is made during the 30 second test period after switch on or RESET, when the effect can be observed on the red indicators. The controls have been designed to be tamper resistant and an adjustment tool is housed in the battery compartment underneath

Bed Movement Sensitivity Adjustment

The *sensitivity* controls the level at which the stimulus is detected. The requirement is for the SENSITIVITY 1 to be turned as far clockwise as possible, but without the RED light A flickering or being on until the bed is moved. This will leave the unit in its most sensitive state.

Sound Sensitivity Adjustment

A good starting place is the slot vertical (half-way) For maximum sensitivity turn the control clockwise, with the small screw-driver supplied . Set the control to pick up the required level of sound, without background noise giving such continuous stimulation as to create a false alarm

Time Delay Adjustment

The delay is a time for which the distress condition (sound or movement) must occur before the alarm is sent and is set by altering the position of small rotary switch according the table. The period should be set to minimize false alarms during normal movement.

As delivered the sensitivity should be suitable for detecting spasms in a domestic bed and the time delay of 15 seconds (position 3) will normally be a good compromise between speed of detection and avoiding false alarms during nocturnal restlessness or short, self-healing spasms. Please refer to the TESTING procedure for confirming acceptable operation.

The sound detection is time is set according to the movement time delay, and is different for the two models

Sound detection I suspended if Bed Vacation is detected following RESET

| P154BA Sound Bursts | | | | |
|---------------------|---------------|---------------|--------------------|---------------|
| | Bed Movem | ent | Transient Sound | |
| | Time (sec) | Rate (sec) | Time (Sec) | Rate (Sec) |
| 0 | 2.5 | 1.5 | 2.5 | 1.5 |
| 1 | 5.5 | 1.5 | 5.5 | 1.5 |
| 2 | 10 | 2 | 7 | 1.5 |
| 3 | 15 | 2 | 7 | 2 |
| 4 | 20 | 3 | 10 | 3 |
| 5 | 25 | 3 | 10 | 3 |
| 6 | 30 | 3 | 10 | 3 |
| 7 | 40 | 3 | 10 | 3 |
| 8 | 50 | 3 | 10 | 3 |
| 9 | 60 | 3 | 10 | 3 |

Bed Vacation Time Setting

The default setting is 6 minutes, which is used to detect potential collapse out of bed, while allowing the user freedom for visiting the bathroom for instance. After pressing RESET the Bed Vacation & Sound sensing are suspended until Bed Occupancy is again detected. This can be changed in the range 5 seconds to 21 minutes, but requires removal of the P154 base and a reset procedure using the links exposed. For this please refer to the UH1102B P154 Installers Handbook

Auto-Learn

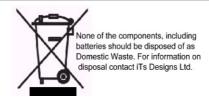
If the monitor was supplied without the Bed Vacation function, then the P154 switch sensor inputs will be "self-learning" for ultimate flexibility. This means the state of these sensors (open or closed) at the time of the REST button being pressed is taken as the "safe" state and an alarm raised should they subsequently change. Hence the units can be used with Bed or Floor mats, provide the safe condition is always present when the RESET is pressed. The process for fixing the detection for Bed Vacation only is to be found in the UH1102B P154 Installers Handbook

Safety Instructions and Warnings



This symbol indicates there are warnings and precautions associated with the use of this equipment. This instruction manual should be carefully read and understood before using the equipment.

- Ensure that the senor cable is routed and secured to avoid the risk of entanglement or strangulation.
- 2. Ensure the power cable is routed to avoid a trip hazard
- 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. Clean and disinfect each item regularly in accordance with information on page 7
- 6. Regularly test sensors as defined herein
- 7. Use only the power supply and batteries recommended
- 8. Operate power supply and charge pager away from direct heat and uncovered.
- 9. 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.
- Only use the monitor with accessories approved for use with this product and only in accordance with instructions.
- 11. If the equipment is modified in any way, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- 12. 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 manufacture for assistance with Risk Evaluation Tools.
- 13. Additional levels of mechanical protection may be needed for some patient disorders. Contact the manufacturers for advice
- 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
- 16. Any sensor over the mattress could pose a fire hazard if in contact with a smouldering cigarette.



| This system is certified to the following European Standards | | | |
|--|------------------------------|--|--|
| 93/42/EEC: 2007/47/EC ¹ | Class 1 Medical Device | | |
| | | | |
| EN 14971:2007 | Risk Assessment | | |
| EN 61010-1:2005 | Safety | | |
| EN12182:1999 | Assistive Technology | | |
| EN 61010-1-2:2004 | EMC | | |
| EN 300 220-1 V2.1.1 (2006-04) | Permitted radio transmission | | |
| 2002/95/ECRoHS | Permitted Materials | | |

¹Alert-it Care Alarms are social aids designed and manufactured in accordance with 93/42/EEC as Class 1 Medical Devices. They are intended to improve the vigilance of carers to distressing side-effects of various diseases, such as Epilepsy and Dementia. They do not monitor vital physiological processes and should not be expected to diagnose any disease or predict the onset of any symptoms.

| Additional Documents | | | |
|--|---------|--|--|
| Installer Handbook (Appendix) | UH1102B | | |
| Quick Start Radio System | UQ1133 | | |
| Quick Start Wired | UQ1134 | | |
| Epilepsy Support risk calculator | UT1167 | | |
| Product Selection for Epilepsy Support | UT1166 | | |
| You tube Instruction Videos Index | UT1198 | | |

Support

For technical support please fax or Email:

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...using technology to care for carers