

Companion Monitor with Enuresis Capability

User Handbook



ModelDescriptionP154ABRadio Companion Bedside Monitor (enuresis capable)P154BBWired Companion Bedside Monitor (enuresis 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
- Excessive moisture on a sensor sheet as may indicate an enuresis or vomiting episode
- 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.

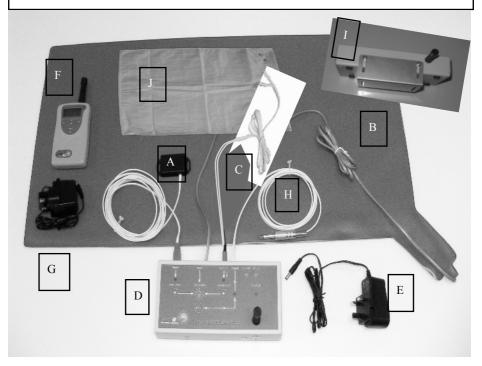
- Using a failsafe radio link to the Alert-it Safelink Pager
- Using a wired connection to a Nurse Call or Telecare device
- The system is designed for use in an indoor residential environment of 10-30°C and 90% RH max
- When not required, isolate from the mains by removing the power supply plug
- The 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 (e.g. 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

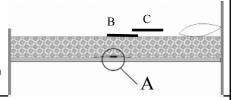


	Part Description	Part No	Cleaning
Α	Bed Movement Sensor	P114A	С
В	Bed Occupancy Mat (waterproof)	P143C	Α
С	Connecting Lead for J	P141A	В
D	Bedside Monitor	P154*	С
Ε	Power Supply for A	P113*	С
F	Pager	P138B	В
G	Power Supply for F	P153*	С
Н	Nurse Call/Annunciator Lead (optional)	P145*	В
I	Mounting bracket	P159A	В
J	Enuresis Sensor Sheet	P142A	D

^{*} following code letter denote acceptable variants (e.g. 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 sealed **Bed Occupancy** Sensor (B) is typically over the mattress, 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 Enuresis Sensor Cable (C) should be connected to the rear jack socket prior to connecting the Enuresis Sensor sheet(J), which is positioned on top of the mattress and any Bed Occupancy sensor (B) or pillow such as to become wet in the event of incontinence, salivation or vomiting. Only one pair of adjacent press-studs are used, the other is for testing (see later)

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. Only the recommended high safety supply must be used

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 moisture alarm will illuminate light B when the pad is wet (note there can be an 8 second delay due to the alarm being monitored when the green light flashes). The alarm is then transmitted after the time delay set on the switch (in common with the movement alarm). The alarm will only reset if the wet sheet is removed/replaced.

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	Assist01	yes	Client is in distress (Enuresis 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 e.g. 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

To prevent false Bed Vacation alarms the Bed Occupancy monitor 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.

Moisture: Check the red light B comes on when the two spare press studs are connected by a metal item (e.g. spoon or key). It is most important to perform this test after washing to ensure all the internal wires are intact. 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

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

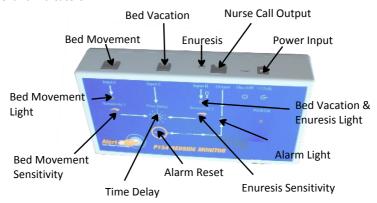


Battery Replacement

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

Battery Type: PP3 NiMH 1500mAh minimum)

Control 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

	Time (sec)	Rate (sec)
0	2.5	1.5
1	5.5	1.5
2	10	2
3	15	2
4	20	3
5	25	3
6	30	3
7	40	3
8	50	3
9	60	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. 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 that should be carefully read and understood before using the equipment.



This symbol indicates where a Patient Applied part is connected, for which it is important to follow these instructions carefully

- Ensure that the senor cable is routed and secured to avoid the risk of entanglement or strangulation.
- The Enuresis sensor cable (C) MUST be connected to the monitor prior to using the press-studs to connect the sheet sensor
- 3. Only the recommended power supply shall be used as it is certified to provide two means of patient protection to EN60601-1
- 4. Ensure the power cable is routed to avoid a trip hazard
- 5. Regularly check the power supplies for damage and potential shock risks
- 6. Clean and disinfect each item regularly in accordance with information herein
- 7. Regularly test all sensors as described hereon
- 8. Ensure, by testing, that the alarm is annunciated at the carer's location(s)
- 9. Operate power supply and charge pager away from direct heat and uncovered.
- 10. 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.
- 11. Only use the monitor with accessories approved for use with this product and only in accordance with instructions.
- 12. If the equipment is modified in any way, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- 13. 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.
- 14. Additional levels of mechanical protection may be needed for some patient disorders. Contact the manufacturers for advice
- 15. 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
- 16. 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
- 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/EC¹ Class 1 Medical Device

EN 14971:2007 Risk Assessment

EN 61010-1:2005 Safety

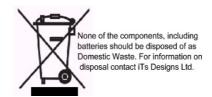
EN12182:1999 Assistive Technology

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	UQ1132			
Quick Start Wired	UQ1178			
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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