Companion Mini

Alert-A

PICOMED

companionmini

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USER MANUAL

| This document applies to; | |
|---------------------------|------|
| P176A Product Version: | 9 |
| P176A Firmware: | v1.0 |
| P168 Product Version: | 1 |
| P168 Firmware: | v4.0 |

UH1462A-ENG Companion Mini User Manual Version: 12.0.0 [24 May 2024]



LESS STRESS CARING

Plesio

Pager

Pager

Pair Mute

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Monitor

Alarm 🔵

Congratulations on your Alert-iT purchase

Your product has been manufactured by a team of industry experts with more than 20 years of experience designing, manufacturing and distributing care alarms.

With a commitment to quality and innovation we are able to bring you a robust and reliable system to aid carers and the safeguarding of individuals.

Please read this quick start guide carefully to ensure the correct set up, use, and maintenance of your new product for years to come.

If you have any questions or require assistance in regards to the Companion mini or any other Alert-iT product please contact your equipment provider.

For equipment provided directly by Alert-iT, please call: +44 (0) 1530 239 900.



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Intended Use

This product has been designed to discreetly monitor the user with high performance sensors which detects fine movements. The carer is then alerted via Alert-iT's failsafe "Safelink[®]" radio system.

Indications for Use

The product is intended to detect an increase in repetitive movement in the bed and to alert caregivers to the increased movement which may indicate a seizure. The Companion Mini is intended to be used when the individual is in bed either during the night or during the day.

Intended Users and Use Environment

The product is intended to be used as an aid to caregivers. The user may be a layperson or healthcare professional.

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

Intended Patient Population

The product is intended for use with individuals over 3 years old who may require monitoring whilst in bed.

Contraindications

- The product does not provide information for diagnosis.
- The product does not recommend any treatment or intervention.
- The product may only be used with suitable paired devices.

Device Lifetime

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

Replace the product after this or earlier, if;

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

See page 19 for recycling guidance. If any cracks or structural damage is observed, cease the use and replace the product immediately.

Note: the batteries must be replaced when the product does not start or if the receiving equipment indicates the battery is low.

Safety

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| Explanati | on of the markings used on the device and in the documentation |
|-------------|--|
| MD | This is a Medical Device. |
| UDI | Unique Device Identification. |
| LOT | Batch Code. |
| SN | Serial Number. |
| REF | Catalogue Number. |
| | Manufacturer. |
| $\sim \sim$ | Date of Manufacture. |
| EC REP | Authorized representative in the European Community. |
| Ť | Keep Dry. |
| Ţ | Fragile, handle with care. |
| IP20 | Protected against solid objects over 12.5 mm (e.g. a finger) and no protection against liquids. |
| Â | Caution - Read the safety precautions before use. |
| | Refer to instructions for use. |
| | CE Mark. (the product conforms with the essential requirements of the Medical Device Regulations |
| CE | (EU) 2017/745). |
| X | Symbol of the European Waste Electrical and Electronic Equipment Directive (WEEE Directive) 2002/96/EC on waste electrical and electronic equipment. |
| RoHS | 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 |

Indicates positioning of battery cell. + is positive terminal and - is negative terminal.

to as the Restriction of Hazardous Substances Directive or RoHS).

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.

Safety Precautions



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.

- 1. This device is designed only to be used as an aid for a caregiver.
- The caregiver must never clear an alarm without checking the patient's condition.
- Ensure the pager power cable is routed to avoid a trip hazard.
- 4. Ensure, by testing, that the alarm notifications are received at the caregivers location(s).
- 5. 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 15.
- **7.** Regularly test device as described in these instructions for use.
- 8. The device is not diagnostic and cannot differentiate between a tonic-clonic seizure and other repetitive movements.
- 9. Use only the 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.
- Operate power supply away from direct heat and uncovered.
- **12.** Do not let the device get wet.
- This product is for indoor use only in a dry environment.

- 14. Some accessories are fitted with small screws and have plastic bags. Ensure these do not come into the possession of vulnerable people who might choke on them.
- 15. Do not try to repair the device yourself.
- **16.** No maintenance of the device is allowed during use.
- **17.** If the equipment is modified in any way, appropriate inspection and testing must be conducted to ensure continue safe use of the equipment.
- 18. 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.
- 20. 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, pager or charging cable in close proximity to sensitive electronic devices or devices which produce strong electromagnetic fields such as radio transmitters, mobile phones or power cables.
- Regularly check the power supplies for damage and potential shock risks.
- 22. Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

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.

In The Box

| | The Companion Mini Pack Contains: | | | | |
|---|------------------------------------|--|--|--|--|
| А | 1 x Companion Mini - [P176A] | Includes 2x AAA 1.5V Alkaline Batteries (LR03. Non-rechargeable) | | | |
| в | 1 x Plesio Pager - [P168] | | | | |
| С | 4 x Velcro Pads | | | | |
| D | 1 x Foam Block | Fitted under the mini to improve sensitivity | | | |
| Е | 1 x micro-USB Cable | Used to change alarm settings | | | |
| F | 1 x 9v Pager Power Supply - [P153] | [Not shown] | | | |



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Device Installation

This handbook covers everything you need to know to install, test and maintain the Companion Mini.

The Companion Mini is designed to be fitted and used in 4 steps:

Step 1) Turn on the Companion Mini (see below).

Step 2) Turn on the pager (see page 9).

- Step 3) Positioning and testing (see page 10).
- Step 4) Using the Companion Mini (see page 11).

Turning on the Companion Mini

The Companion Mini monitor is supplied with batteries fitted but needs to be turned on before use.

To activate the Companion Mini, press and release the recessed " \mathbf{O} " button on the front of the monitor using a pen tip or similar tool [See figure 1].

The green light will illuminate briefly to indicate the unit is turned on. The Companion Mini is now ready to be positioned under the mattress.

Turning off the Companion Mini

If the Companion Mini is no longer needed it can be turned off by press and holding the "O" button for 8 seconds.

Release the button and the light will flash red rapidly for several seconds upon shutting down.

The Companion Mini will send an "Monitor Off" fault notification to the pager upon shutting down.



Figure 1

Turning on the Pager

To turn the Pager on, press and hold the "①" button for 3 seconds, the pager will beep and all three LEDs will flash once.

- The green "Pager" light will flash every 8 seconds to show that the pager is awake and listening for alarm signals.
- If the green "Pager" light flashes rapidly, the pager requires charging (see page 14).
- If the Companion Mini is turned on, you will now see the red
 "Monitor" light on the pager flash every time it receives the Safelink radio signal from the mini.

PLEASE NOTE:

While the pager is shipped with some charge in the batteries, it is recommended that the pager is charged before use (See page 14).

The pager MUST be turned on whilst on charge. Turning the pager off will extend the charging time.



Turning off the Pager

To turn the pager off, press and hold the " \mathbf{O} " button for 3 seconds. The pager will bleep and all three lights will flash 3 times.

PLEASE NOTE:

If a pager cannot detect its paired monitor, it will raise a "fault" alarm (see page 12).

This is due to the pager not receiving the regular failsafe Safelink heartbeat radio signals from the Companion Mini.

To stop the fault warning, check the Companion Mini is turned on and test it.

If the Companion Mini is no longer required, it will need to be un-paired from the pager (see page 14)

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Positioning and Testing

The Companion Mini performs best if placed under the mattress, beneath the patients usual torso area. However, due to the wide variety of bed types and mattresses, it is advisable to test the device as per the instructions below.

Step 1) Place the Companion Mini under the mattress on the base of the bed frame, in a central location underneath the torso area.

Step 2) Test the devices operation by simulating the movement that needs to be detected.

Note 1: If the Companion Mini is struggling to detect the repetitive movements, the provided foam block can be used to increase the devices sensitivity. The foam is intended to be placed underneath the Companion Mini.

Note 2: To improve alarm detection or to reduce false alarms, the Companion Mini's alarm parameters can be adjusted using the Alert-iT Profile Editor software which is available to download for free (See page 18).

If the device is now operating as expected, the Companion Mini can be secured to the bed frame using the provided velcro pads.

Operation Overview

The Companion Mini will raise an alarm notification upon detection of repetitive movements larger than the "Movement Level" setting that continue for longer than the "Movement Duration" setting. If there is a gap in the repetitive movements for longer than the "Movement Rate" setting, the duration counter will reset.

These 3 alarm parameters are adjustable via the Alert-iT Profile Editor software (see page 18):

- Movement Level. (How sensitive the device is to movements)
- Movement Duration. (The duration the repetitive movements need to continue for)
- Movement Rate. (The gaps between individual jerking movements)

Once an alarm has been triggered, further alarms are inhibited for 2 minutes after the repetitive movements cease. This period is also adjustable, see "Suspend Duration" in the profile editor.

System Operation

You should now have the Companion Mini installed in the bed, and the pager turned on and receiving the Safelink[®] signals. Indicated by the red "**Monitor**" light flashing on the pager each time one is received.

If the pager stops receiving the failsafe radio signal from the Companion Mini, the pager's "**Monitor**" light will be permanently lit and an intermittent "**Fault**" tone will sound.

If the Companion Mini's battery gets low the pager's "**Monitor**" light will flash every second, to indicate that you should now change the battery in the Companion Mini. (see page 15).

Alarm Mode

When repetitive movements are detected, the pager will audibly alarm, vibrate and the red "**Alarm**" light will illuminate.

Pressing the "Pair/Mute" button will temporarily mute the alarm tone and stop the pager vibrating for 5 minutes.

60 seconds after the repetitive movements have stopped, the pagers audible alarm tone will resume, pressing the **"Pair/Mute"** button again will clear the pager (If previously muted, this will be the second press).

SAFETY NOTICE:

The Companion Mini will continue to send the alarm notification until the repetitive movements have stopped for 1 minute.

After 1 minute, the Companion Mini will send the "All Clear" signal.

Upon receiving the "All Clear" signal, the pager will remain in its alarm state until the "**Pair/Mute**" button is pressed.

You MUST always check the user even if the alarm appears to have cleared.

The tables below give an indication of the status of the Alert-iT devices based on Light, Sound and Vibration condition(s).

Operational Modes of the Plesio Pager

| STATUS | Vibration | Beeping/ Tone | "Pager" Light (Green) | "Monitor" Light (Red) | "Alarm" Light (Red) |
|---|-----------|-------------------------------|--------------------------|----------------------------|----------------------------|
| Stops receiving failsafe radio from Companion Mini | No | Du-Di-Du Tone every minute | N/A | Solid (Permanently lit) | N/A |
| Alarm mode with ongoing movement | Yes | Ongoing alarm tone | N/A | Flash every Second | Solid (Permanently lit) |
| Muted Alarm Mode with ongoing movement | No | No | N/A | Flash every Second | Solid (Permanently lit) |
| Alarm mode with movement stopped - Pair to clear | Yes | Ongoing alarm tone | N/A | Blips On | Solid (Permanently lit) |
| Companion Mini battery getting low | No | No | N/A | Flash every Second | N/A |
| On and paired to Mini- listening for alarm signals | No | No | N/A | Blips On | N/A |
| Switching Off | No | Three Beeps | 3 Flashes | 3 Flashes | 3 Flashes |
| Switching On | No | Once | Flash Once | Flash Once | Flash Once |
| Pager battery getting low | No | No | Flash every Second | N/A | N/A |
| Pager battery getting very low | No | Sound every minute | Flash every Second | N/A | N/A |
| Pager - Boost Charge Mode | No | No | Solid with blipping off | N/A | N/A |
| Pager Trickle Charging | No | No | Solid (Permanently lit) | N/A | N/A |
| On (battery power only) | No | No | Blips On | N/A | N/A |
| Off | No | No | N/A | N/A | N/A |

Test Mode - i.e. for positioning and setup

| Action | Pagers Audible Sounder | Pagers "Pager" Light (Green) | Pagers "Monitor" Light (Red) | Pagers "Alarm" Light (Red) | Companion Mini's "Alarm" Light |
|-------------------------------------|------------------------------|------------------------------------|------------------------------------|----------------------------------|--|
| Button pressed on Companion Mini | N/A | N/A | N/A | N/A | Flashing Green |
| Movement Detected | Du-Di-Du Tone | N/A | Flashes 3 times | N/A | Illuminates Red for Movement Rate period (Permanently lit) |

Pairing/Clearing a Monitor to the Plesio Pager

| Action | Pagers Audible Sounder | Pagers "Pager" Light (Green) | Pagers "Monitor" Light (Red) | Pagers "Alarm" Light (Red) |
|--------------------------|--|------------------------------------|------------------------------------|----------------------------------|
| Pairing: Pair successful | Beeps Once | N/A | Once | N/A |
| Clearing Paired devices | Multiple beeps followed by single beep | Flashes once at single Beep | Solid until single Beep | N/A |

Pager Function

Pager Charging

The pager's battery should last approximately 3 days depending on how many alarm cycles it goes through during this period.

When the pager's battery starts to get low the green "**Pager**" light (Figure 2) will start to flash green every second indicating the pager should be plugged into the provided charger. When the pager's battery is very low, the pager will start making an audible "**Fault**" sound every minute.

When charging, the green "**Pager**" light will blip off every 8 seconds during boost charge, then will turn solid green when the battery is approaching full charge.

Charge for at least 12 hours.

Please Note: The pager MUST be turned on whilst on charge. Turning the pager off will extend the charging time.

Pairing Instructions

The Companion Mini will usually be paired to the pager before it is shipped to you. If you should ever need to pair the items again, please follow the instructions below:

Step 1) Turn the pager off, then back on again (Pairing is only possible within 30 seconds of powering up the pager).

Step 2) Place the monitor close to the pager (Pairing is restricted to nearby devices).

Step 3) Press and hold the "Pair/Mute" button on the pager.

Step 4) While still holding the "**Pair/Mute**" button. Stimulate any radio transmission from the Companion Mini (press the "**O**" button, trigger an alarm, or just wait for the regular safelink signal every ~12 seconds).

If successful, you will hear a beep sound and see the pagers "**Monitor**" light flash red. A lower "burp" sound with no red light flash indicates the monitor is too far away to pair (This protects against pairing with another distant monitor).

Un-Pairing Instructions

Note: It is not possible to un-pair a single monitor using this method, you can only clear everything.

Step 1) Turn the pager off, then back on again (Un-pairing is only possible within 30 seconds of powering up the pager).

Step 2) Press and hold the "**Mute/Pair**" button and the "**O**" button on the pager together until the ensuing tone has finished and the pagers "**Pager**" light flashes green.

Step 3) Release both buttons. The pagers paired monitor memory is now empty.

Routine Testing

It is recommended to test the system weekly by simulating the repetitive movements that you want the device to detect on the bed and ensuring the alarm is raised and received by the pager.

A "Routine Testing" record sheet is provided on page 17.

How to Clean the Devices

It is recommended to clean the devices as needed 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 the micro-USB connector.

Changing Batteries in the Companion Mini

Step 1) Remove the back of the Companion Mini by inserting a small tool into the slot to depress the catch and release the case back (see figure 3).

Step 2) Remove the old batteries and dispose of them appropriately.

Step 3) Observe the polarity markings on the base of the case (see figure 4).

Step 4) Insert the new batteries (see figure 5). Note: 2x AAA Alkaline 1.5V. LR03. Non-rechargeable.

Step 5) Clip the rear case back into position.

Step 6) After changing batteries, the Companion Mini will be turned on, replace the device under the mattress and test the device.





Figure 4



Figure 5

Warranty Information

For 3 years from the date of purchase of the initial equipment (excluding batteries), Alert-iT will offer you;

- Access to support between the hours of 9.00am and 5.00pm each weekday (excluding Public Holidays) via the telephone help-line for the purposes of fault diagnosis and the provision of advice.
- Repair (or if this is not possible-replacement) of faulty equipment free of charge, however, the equipment must be returned to Alert-iT at your own expense.
- After inspection by Alert-iT, any equipment that is deemed to have been damaged, rather than failing due to a technical fault will only be repaired after you have agreed to being invoiced for the cost of repairs and delivery.
- This agreement will terminate 3 years after the initial date of purchase, regardless of any new equipment being issued in the interim period.

Please note that liquid ingress voids warranty.

Serial Number:_____

| Test | Signature | Date |
|------|-----------|------|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | | |
| 9 | | |
| 10 | | |
| 11 | | |
| 12 | | |
| 13 | | |
| 14 | | |
| 15 | | |
| 16 | | |
| 17 | | |
| 18 | | |
| 19 | | |
| 20 | | |

Changing Settings on the Companion Mini

All Companion Mini's are supplied with the following default settings;

 \bigcirc Movement Level = 3.

3 = Most Sensitive. 9 = Least Sensitive

- Movement Duration = 15 seconds.
- Movement Rate = 3 seconds.

Available Adjustments: 8s to 35s. Available Adjustments: 1s to 6s.

Available Adjustments:

If required, these settings can be adjusted using the Alert-iT Profile Editor software which is available to download for free from our Support page; www.alert-it.co.uk/support

Installation instructions are available within the download.

A USB lead is provided to connect between the Companion Mini and your Computer.

Using Profile editor

Step 1) Connect the Companion Mini to the PC using the provided USB cable. The light will start flashing rapidly green.

Step 2) Open the "Alert-iT Profile Editor", click "Connect New Device".

Step 3) Click on "Movement Settings".

Step 4) Make any desired settings changes. Click "Save to device".

The following icon will be found on your computer desktop after profile editor has been installed.



| Radio Settings | Movement Level | |
|-----------------|---------------------------------------|--|
| Configuration | 2=Very Sensitive, 5=Least Sensitive 3 | |
| vement Settings | Movement Duration | |
| | 15.0 esconds | |
| | Movement Rate | |
| | 3.0 ÷ seconds | |
| | Alarm Latch Duration | |
| | 1 iminute | |
| | Suspend Duration | |
| | 2 🗢 minutes | |
| | | |
| | | |



Plesio Pager

Companion Mini

| Model: | P168 | Model: | P176A |
|------------------|-----------------------------|------------------|---------------------------------|
| Power: | 1.3mm 9V DC | Connections: | Micro USB Type-B (Programing on |
| Weight: | 161g | Weight: | 80g |
| Material: | White ABS Anti-microbial | Material: | White ABS Anti-microbial |
| Dimensions (mm): | 120 x 70 x 20 (HxWxD) | Dimensions (mm): | 100 x 44 x 16 (HxWxD) |
| Batteries: | 2x AA Ni-MH 1.2V | Batteries: | 2x AAA 1.5V Alkaline (LR03) |
| | (HR6. Rechargeable) 2400mAh | Battery Life: | 12 months |
| Battery Life: | 80 hours (100 typical) | Radio Frequency: | 434.075MHz (P176*A) |
| Charging Time: | 12 hours | Radio Frequency: | 869.2125MHz (P176*B) |
| Radio Frequency: | 434.075MHz | Radio Power: | <10mW |
| Service Life: | 5 years | Radio Range: | 450m (Line-of-sight) |
| Sealing: | IP52 (not waterproof) | Service Life: | 5 years |
| Operating Temp: | 5°C to 35°C (Used Indoors) | Sealing: | IP20 (not waterproof) |
| Humidity Limit: | 5% to 90% max. | Operating Temp: | 5°C to 35°C (Used Indoors) |
| | Non-condensing. | Humidity Limit: | 5% to 90% max. Non-condensing. |
| Storage Temp: | -30°C to 50°C | Storage Temp: | -30°C to 50°C |

Certification

The manufacturer, iTs Designs Ltd., hereby declares that the Companion Mini 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/



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.





iTs Designs Ltd T/A: Alert-iT Care Alarms Fernie House, Unit 3 Coalville Business Park Jackson Street Leicester, UK. LE67 3NR



Leisner ApS Korsvangcentret DK - 5610 Assens Denmark

For support please contact your equipment provider.

LESS STRESS CARING