Advanced Pager®

User Manual

This document applies to;

Model:	P137
Product Version:	v10
Firmware:	v8.13+

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1 INTENDED USE

The P137 Advanced Pager is intended to assist caregivers by notifying the caregiver to attend the patient in order to verify their well-being.

1.1 Indications for Use

This device is designed and manufactured as a social aid intended only to be used as an aid for a caregiver. Intended to improve the vigilance of the caregiver to distressing side-effects of various diseases. The system does not monitor vital physiological processes and should not be expected to diagnose any disease or predict the onset of any symptoms.

1.2 Intended Users and Use Environment

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

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

1.3 Intended Patient Population

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

1.4 Contraindications

There are no contraindications.

1.5 Device Lifetime

The typical expected life of the P137 in normal home use is 5 years.

Replace the P137 after this or earlier, if

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

See page 17 for recycling guidance. If any cracks or structural damage is observed, cease the use and replace the P137 immediately.

NOTE: the batteries must be recharged when the P137 does not start or if display indicates “BATT LOW”.

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

2 SAFETY

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

This is a Medical Device.

Unique Device Identification.

Batch Code.

Serial Number.

Catalogue Number

Manufacturer.

Date of Manufacture.

Authorized representative in the European Community.

Keep Dry.

Fragile, handle with care.

Temperature Limitation.

Humidity Limitation.

Caution - Refer to instructions for Use.

Consult instructions for use.

Refer to instructions for use.

Product is for indoor use only.

CE Mark. (the product conforms with the essential requirements of the Medical Device Directive (93/42/EEC).

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

2.2 Safety Precautions

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

- This device is designed only to be used as an aid for a caregiver.
- Ensure that the power lead is routed and secured to avoid the risk of trips, entanglement or strangulation.
- Regularly check the power supplies for damage and potential shock risks.
- Ensure, by testing, that the alarm notifications are received at the caregivers location(s).
- The caregiver must never clear an alarm without checking the patients's condition.
- A risk assessment must be conducted to determine if the level of reliability offered by the system 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 17.
- Only use the power supply and batteries recommended.
- Operate power supply and charge the pager away from direct heat and uncovered.
- Do not use this device for any purpose other than that specified by the manufacturer.
- Do not let the device get wet.
- This product is for indoor use only in a dry environment.
- Some accessories are fitted with small screws and have plastic bags. Ensure these do not come into the possession of vulnerable people who may choke on them.
- Do not try to repair the device yourself.
- No maintenance of the product is allowed during use.
- If the equipment is modified in any way, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- Do not use the input / output connectors for any purpose other than that specified by the manufacturer.
- 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 or power cable(s) in close proximity to sensitive electronic devices or devices which produce strong electromagnetic fields such as radio transmitters, mobile phones or power cables.
- The full pager specification is met as a portable unit. It may, however, be affected by mains bourne interference while on charge, but the Safelink™ safety function remains unaffected.

2.3 Unintended adjustment of settings

Changing the monitors radio address (without also changing it on the receiving equipment) will result in a "RF Fail" notification on the receiving equipment if Failsafe is enabled and any resulting alarm notifications will no longer be received.

2.4 Serious Incidents

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

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

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

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

3 INTRODUCTION

The P137 Advanced Pager is designed especially for local “plesiocare” in home and professional care settings.

The specific features for this are;

- Anti-microbial plastic & fascia, proven to kill MRSA & C Difficile.
- Medical Device Class 1 with Failsafe operation for life & health critical monitoring.
- Large character backlit screen with simple no interaction alarm indications.
- Cancel at source for total compliance with duty of care.
- Long radio range.
- Long battery life to cover over 80 hours continuous use on one charge.
- Three alarm severity levels (plus fault indication), configurable for individual or group use.
- Advanced loud audible tones indicating severity level and multiple alarm activity.
- Easy reprogramming of monitor name/location.
- Simple cloning for multi-pager environments.

This handbook assumes the pager has been fully configured by your supervisor to work with all the monitors in your “home” or “ward” and has the correct operational protocol enabled. This book gives details of a variety of standard protocols that may be relevant as well as more general control features accessible to the two levels of user

In normal use all caregivers have a very simply protocol:

- The pager will indicate the location and severity level of an alarm.
- The indication may be accompanied by audible alert and/or vibration.
- The caregiver can temporarily silence the sound/vibration with one key press.
- The caregiver attends to the patient and reset the alarm in their room.
- The pager automatically resets itself.

4 CONFIGURATION

There are some very simple basic parameters the caregiver can change, depending on the level authorised by the supervisor.

4.1 All Users

All users can:

- Rename the source of an alarm. This facilitates change of user or change of room.
- Change basic interface features such as allowing sounds or vibration (silent is only allowed at Supervisor level).
- The basic user cannot turn-off the pager, which ensures full duty of care compliance (which extends to warning message if the battery is removed to effect a turn-off).

4.2 Extended Users

As well as being able to turn the pager off, the default "extended" user mode allows for some simple housekeeping tasks, such a resetting alarms that may have become stuck if the monitor is damaged or no longer on site.

5 PAGER OPERATION

5.1 Turning the pager on

To turn the pager ON:

- Hold the bottom "MENU" button for 3 seconds.

Upon turning on, the display will show the PRODUCT name followed by 4 digits for the software Version/Issue and 4 digits for a security checksum.

5.2 Turning the pager off

To turn the pager OFF:

- Hold the bottom "MENU" button for 3 seconds, until "Setup & Edit" is displayed, followed by "List".
- If "Extended User Mode" is enabled, press the "Right" button until "Turn Off" is displayed, then press the "Up" button to turn off.
- OR if "Extended User Mode" is disabled, press the "Right" button until "Pass" is displayed, enter the password, then press the "Right" button until "Turn Off" is displayed, then press the "Up" button to turn off.

Warning: Do not remove the batteries to turn the device off, as this may damage the battery contacts.

5.3 Backlight

The displays backlight automatically illuminates for 15 seconds after an alarm is received or if any key is pressed. It is always enabled when in the settings menu.

5.4 Snoozing Alarms

Press the "Up" button when an alarm is received to temporarily silence the pager and/or stop vibrations. The alarms sounds and/or vibrations will automatically resume after 5 minutes.

Alarms must be cleared at source.

6 SUPERVISOR SETTINGS

Pagers are typically configured to one of the following states.

6.1 Individual Pagers (Typically care homes)

The supervisor can configure the pager so that:

- The pager only responds to some or all of the monitors in the home.
- The carer is not troubled by maintenance information (e.g. low battery in a monitor or a NEW monitor discovered on-site).
- Multiple alarms are queued behind the current alarm (unless of a higher severity level) until the carer resets the current alarm.
- The care staff can change the name/location of any monitor.
- Staff may be barred from turning the pager off.

6.2 Communal Pagers (Typically supporting a nursing group in a hospital)

The supervisor can configure the pager so that:

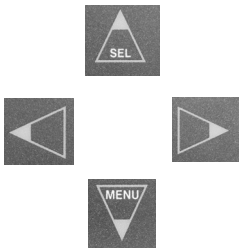
- The pager only responds to some or all of the monitors on the ward.
- The carer is not troubled by maintenance information (e.g. low battery in a monitor or a NEW monitor discovered on-site).
- A second alarm of the same severity as the current will overwrite the screen on the basis that the first is being attended already.
- The care staff can change the name/location of any monitor.
- Staff may be barred from turning the pager off.

6.3 Supervisor/Maintenance Pager

If the carer pagers are restricted to patient alarms only, then at least one pager in the system MUST:

- Indicate faults (such a battery low).
- Indicate NEW monitors in the area (optional).
- Can be set to SILENT provided it is regularly reviewed.

7 MENU CONTROL



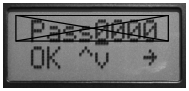
Press to display list of active alarms. In menu mode also used to scroll through numbers and letters or select an option.

Scroll back and forth through menus or select settings shown on the display above the key.

Hold down for 3 seconds to enter “Set-Up and Edit” menus. Press to abort menus, one level at a time also used to scroll through numbers & letters as required.

7.1 Example edit

Scroll through menu and select option. Menu drops back a level in the menu.

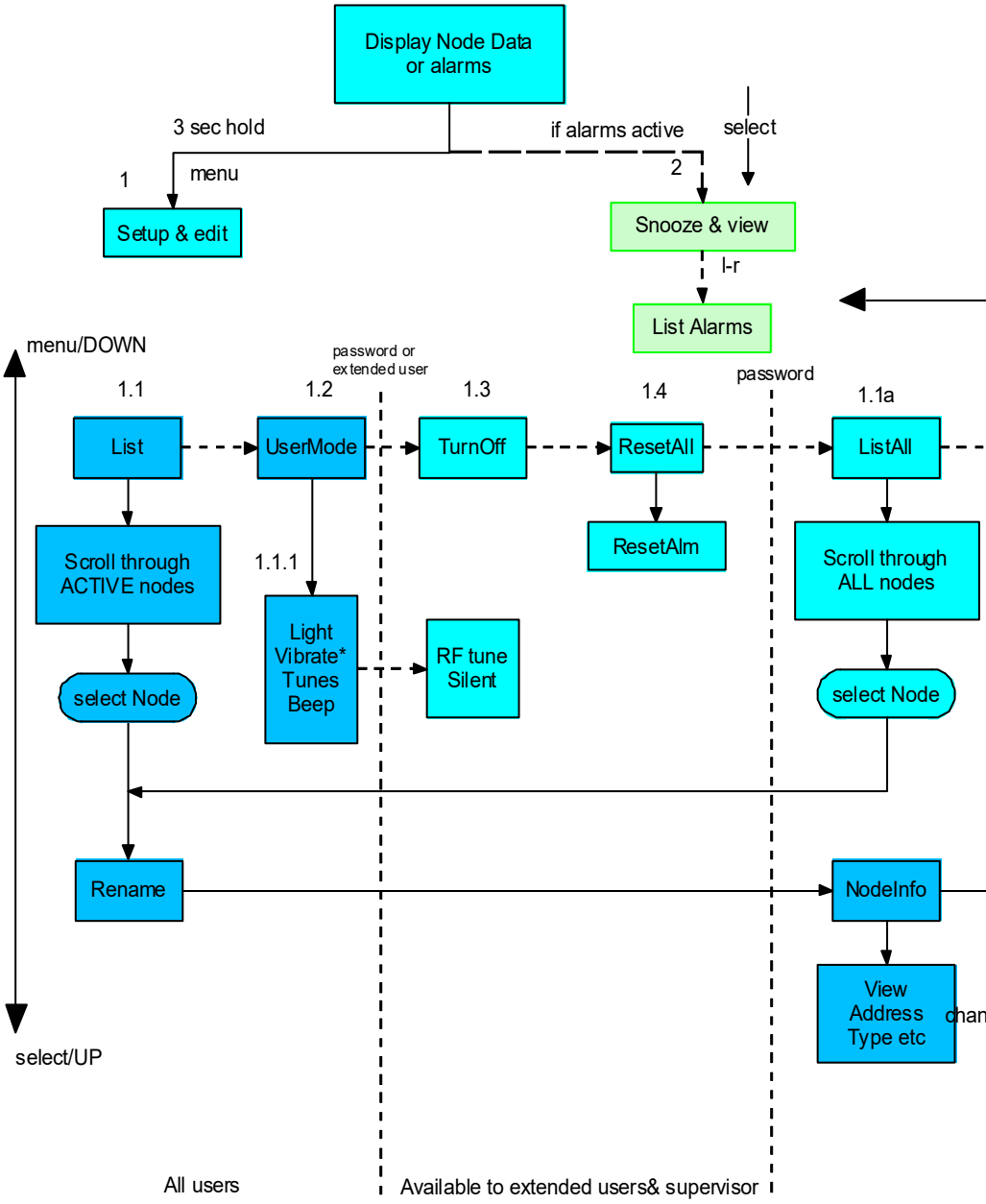


Select/Menu scrolls the number/letter over cursor. Left key accepts the value, right key selects next.

Next step will be to accept the value with left key, repeat entry with the left key or abort the process with the Menu key.

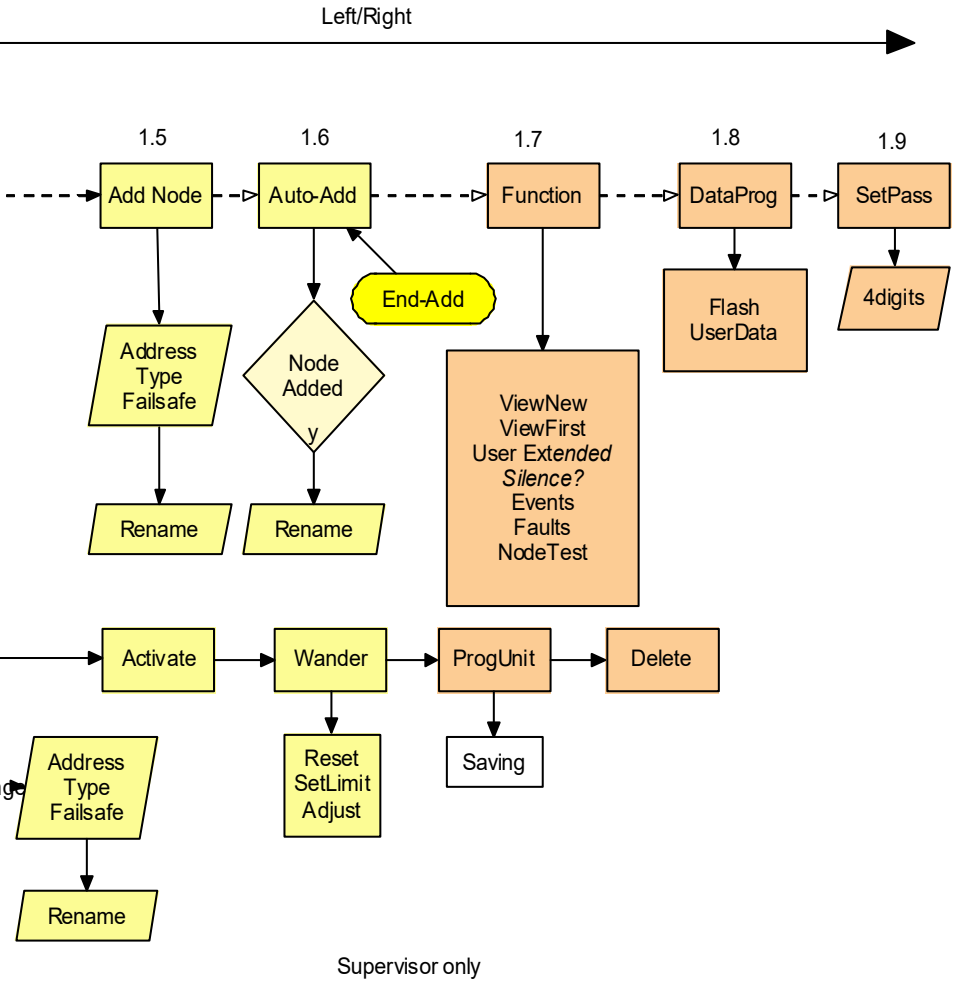
Left and right keys change the option. Select key to activate the selected option, menu key to abort leaving function unchanged.

8 USER MENU STRUCTURE



*Tunes automatically on if Vibrate off (unless Silence enabled by Superviusor in FUNCTION

9 SUPERVISOR MENU STRUCTURE



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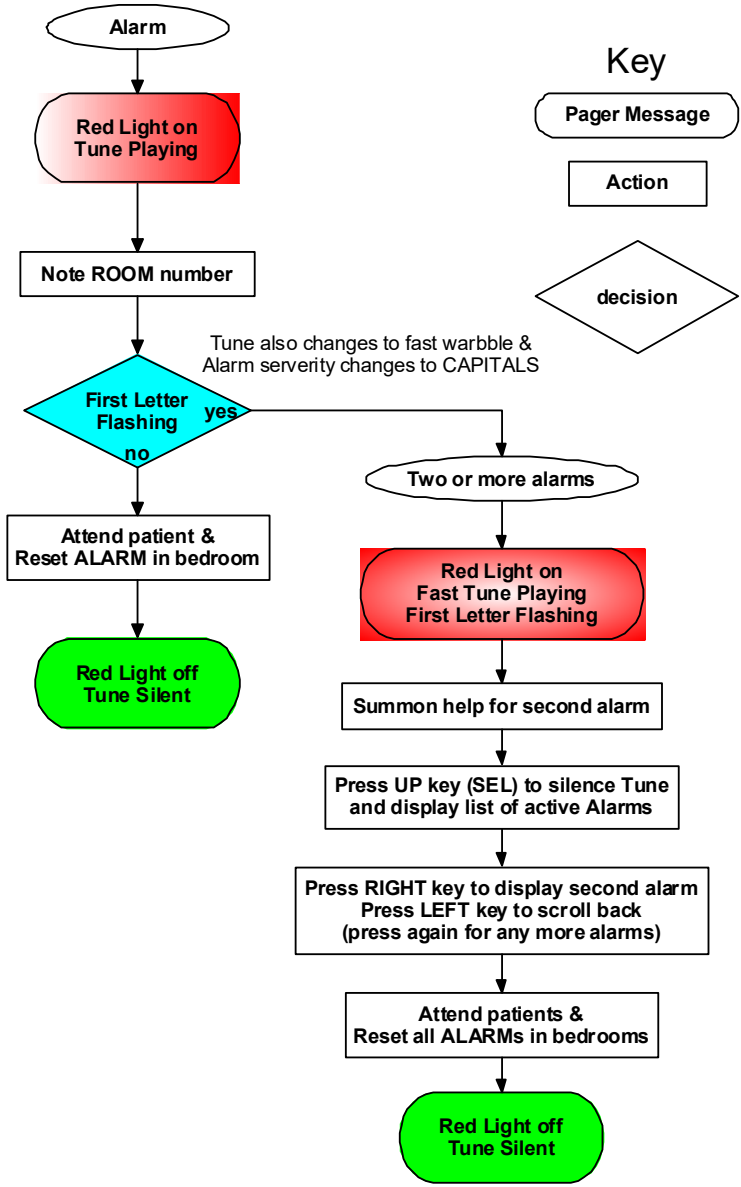
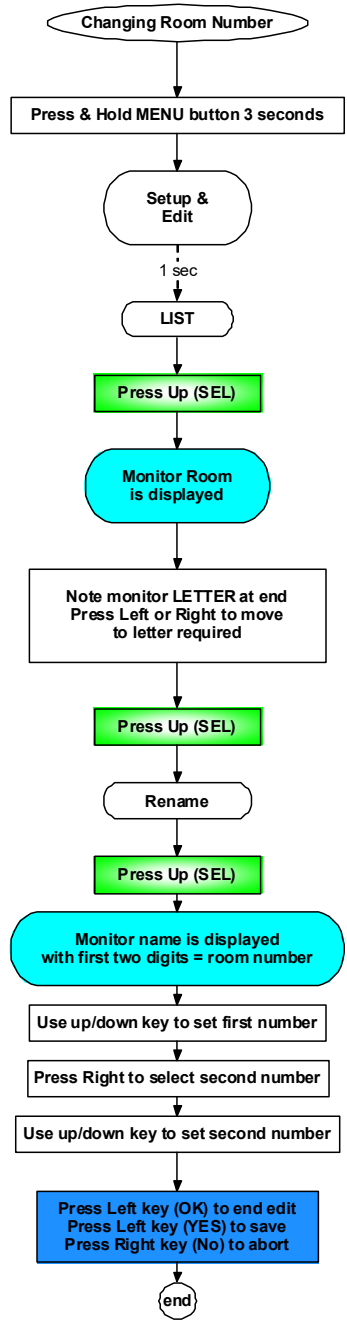
10 MENU FEATURES

Standby Operation			
1	Enter "Set-Up & Edit"	After pressing MENU for 3 seconds	See next Main Menu table
2	Snooze & View	Press select to silence any alarm for 5 minutes	Left/right will now list all active alarms. Menu returns to standby.
1. Main Menu			
1.1	List	List all the ACTIVE nodes with access to a sub-menu of features see 1.1	Only supervisor can see Deactivated nodes and reactivate them
1.2	User Mode	Change main user features see 1.2	E.g Light, sounds and vibration
	Password(bypassed for extended users)		
1.3	Turn off	Turns off the pager	Restart by pressing MENU key 3 seconds
1.4	Reset All	Reset all alarms	They will be reactivated if the node is still transmitting an alarm message
	Password		
1.2 User_mode sub-menu			
	Light	Turns backlight on/off	
	Vibrate	Turn on/off vibrate	Tunes automatically on if vibrate off unless SILENCE enabled in FUNCTION
	Tunes	Turn on/off Tunes	
	Key Beep	Silences the beep on key press	
	Password (bypassed for extended users)		
	RF Tune	Enables tune for RF Fail Alarms	Useful to silence alarm if equipment node off
1.1 List Function			
1.1	List	Scroll left & right through the list of nodes and press up to select one for detailed menu	List only shows activated nodes
	Rename	The node name can be changed	
	Password		

11 ANSWERING AND ALARM CALL



12 CHANGING A ROOM ALLOCATION



13 MAINTENANCE

13.1 Charging

The charger is plugged into the side connector and then into a mains power supply.

The display will then show “charging”.

A full charge takes 12 hours and the pager will feel warm to the touch if a boost charge is needed (indicated by the < symbol on the display).

Once a good level of charge is reached the symbol changes to #.

13.2 Battery Status

The display will show “battery” and the state of the charge will be indicated by the number of bars next to the battery symbol.

When the battery is getting low the display will change to “Bat<10%”. There will still be a few hours left, which may allow for a shift to end, but charging should be imminent.

When the battery gets critical the display changes to “Act Now” and an audible alert will sound that cannot be permanently silenced. There is only a short time left and charging must commence immediately or protection will be lost.

13.3 Cleaning

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

Avoid getting any liquid into the power socket or rear data connector.

Always disconnect the charging cable before cleaning the device. Dry all parts well after cleaning.

14 LIABILITY OF THE MANUFACTURER

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

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

15 DISPOSAL OF THE DEVICE AFTER USE

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

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

16 TECHNICAL SPECIFICATIONS

Equipment is for continuous operation.

16.1 Pager

Model:	P137.
Power:	9v DC @ 400mA.
Batteries:	2x AA Ni-MH 2400mAH Rechargeable (HR6).
Battery Life:	80 hours (100 Typical).
Charge Time:	12 hours.
Input and Output Connectors:	1.3mm 9V DC socket (Center +Ve). 10 pin Data Connector.
Signal Lights:	Red Alarm Light. Backlit Display.
Audible Alert:	52-63 dB @ 1m. 56-68 dB @ 0.3m.
Measurements:	120 x 70 x 20 mm (HxWxD).
Weight:	161g.
Colour:	White.
Casing:	ABS Plastic with Biomaster Anti-microbial Additive.
IP Rating:	IP52.
Service Life:	5 years.
Radio Frequency:	434.0750 MHz.
Radio Output Power:	< 10 mW.
Radio Range:	450 meters (line-of-sight).

16.2 Ambient Conditions

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

17 DECLARATIONS OF CONFORMITY

The manufacturer, iTs Designs Ltd., hereby declares that this product conforms with the relevant requirements of the Medical Device Directive 93/42/EEC as an accessory suitable to support a medical device.

The manufacturer, iTs Designs Ltd., hereby declares that this product is in compliance with 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/

ITs Designs Ltd,
T/A: Alert-iT Care Alarms
Fernie House (Unit 3)
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EC REP

Leisner ApS
Korsvangcentret
DK - 5610 Assens
Denmark

For support please contact your equipment provider.

EU Importer to add details here, where applicable.