



Remote Reset Button

User Manual

This document applies to;

Model: **P176B****

Product Version: **v9**

Firmware: **v1.*.***

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TABLE OF CONTENTS

	Page		Page
INTRODUCTION	4	MAINTENANCE	13
Product Description	4	Changing the batteries	13
INTENDED USE	4	Cleaning	13
Indications for Use	4	Reuse	13
Intended Users and Use Environment	4	Routine Checks	13
Intended Patient Population	4	DISPOSAL OF THE DEVICE AFTER USE	14
Contraindications	4	DECLARATIONS OF CONFORMITY	14
Device Lifetime	5	TECHNICAL SPECIFICATIONS	15
SAFETY	5		
Important Information	5		
Safety Definitions	5		
Serious Incidents	5		
Conformance with requirements for medical devices	5		
Unintended adjustment of settings	5		
Product Liability	6		
Safety Precautions	6		
Consultation with a healthcare professional	7		
Explanation of the markings used on the device and in the documentation	8		
PACKAGE CONTENTS	9		
Compatible Products	9		
SYSTEM OVERVIEW	9		
Status Light	9		
INITIAL SETUP	10		
Configuration	10		
Turning On	10		
Remotely Resetting Alarms	10		
Turning Off	10		
Positioning and Testing	10		
SYSTEM OPERATION	11		
Battery Level Warnings	11		
Radio Connection	11		
CHANGING SETTINGS ON THE RESET BUTTON	12		
Radio Address and Radio Type	12		
How to use profile editor	12		

1 INTRODUCTION

These 'instructions for use' describe the use of the Alert-iT **"Remote Reset Button"**.

The **"Product Version(s)"** these instructions apply to are shown on the front page of this document. This should be referred to and compared against the **"Product Version"** number shown on the product information sticker found on the top of your device. If this document is not suitable for your product please refer to the 'support' section of our website for alternative instructions.

- Follow all instructions provided in this document concerning the initial setup, use, cleaning and disposal of the device.
- The **"Remote Reset Button"** is a medical device accessory.

1.1 Product Description

The **"Remote Reset Button"** has been designed to work alongside compatible monitors to allow these devices to be reset remotely.

This can be useful in scenarios where it is acceptable for a caregiver to perform a visual check of the patient from a distance and not disturb the user by entering the room and pressing the reset button on the monitor.

2 INTENDED USE

2.1 Indications for Use

The product is intended to be used as a remote reset button for compatible monitors.

This device is designed and manufactured as a social aid intended only to be used as an aid for a caregiver.

The system does not monitor vital physiological processes and should not be expected to diagnose any disease or predict the onset of any symptoms.

2.2 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.

2.3 Intended Patient Population

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

2.4 Contraindications

There are no contraindications.

2.5 Device Lifetime

The typical expected life in normal home use is “5 years”.

Replace this device after this or earlier, if;

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

See “page 14” for recycling guidance. If any cracks or structural damage is observed, cease the use and replace the Companion mini immediately.

Note: the batteries must be replaced when the product does not start or if the status light is flashing red frequently.

3 SAFETY

3.1 Important Information

Before you use the product, read and understand the contents of this user manual.

3.2 Safety Definitions



WARNING: Risk of serious injury if the instructions are not followed.



CAUTION: Risk of damage to the product if the instructions are not followed.



NOTE: Information that is necessary in a given situation.

3.3 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.

3.4 Conformance with requirements for medical devices

The Alert-iT “**Remote Reset Button**” is marketed as a technical aid for caregivers. It complies with all necessary requirements, regulations and directives for medical devices.

3.5 Unintended adjustment of settings

Changing the radio address or type (without also changing it on the monitor and receiving equipment) will result in the reset signals not clearing alarms from the receiving equipment.

3.6 Product Liability

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 product is developed and risk-assessed according to ISO 14971. The manual and the technical specifications are made according to the safety assessments in the risk analysis. Always consider the safety when using the product. Alert-iT does not take responsibility for any consequences following incorrect use or installation of the product. Any form of damage or tampering with the product invalidates the warranty and disclaims the manufacturers liability. The estimated lifetime of the product applies when used in accordance with its intended use and maintenance instructions.

3.7 Safety Precautions



WARNING:

- The caregiver must never clear an alarm without checking the patient's condition.



WARNING: According to 60601-1-2 EMC

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Alert-iT products, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



WARNING: According to 60601-1 Safety

- No modification of this equipment is allowed.



CAUTION:

- Do not use if the device is broken.
- Do not use the equipment in strong electromagnetic fields.
- Do not use the product in environments with flammable anaesthetic mixtures, oxygen or nitrous oxide.
- Only use the device with accessories approved for use and only in accordance with instructions.
- Do not try to repair the device yourself.
- Remove the batteries when the device is not in use or when it is stored for an extended period.
- Do not use any rechargeable batteries or lithium-ion batteries. Lithium-ion batteries carry the risk of overheating and ruining the device.
- This product is for indoor use only in a dry environment, do not let the device get wet.
- Remove the batteries when the device is not in use or stored for an extended period. Alkaline batteries may become self-discharged and, start leaking and contaminate the device.

① NOTE:

- This device is only intended to be used as an aid by caregivers. The product must not replace human supervision.
- Make sure the instructions for use cover the device being used, i.e. the same part number stated on the front page.
- The device should only be used by knowledgeable caregivers and shall not be used by operators that do not understand the content in this manual.
- The caregiver is responsible for assessing the risks of using this equipment and any settings pertaining to it.
- Do not use this device for any purpose other than that specified by the manufacturer.
- Always test the device before using it and when the settings are adjusted.
- Regularly test the device as described in these instructions for use. Ensuring by testing, that the alarm notifications are received at the caregiver's location(s). See **page 13**.
- 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 patient's likelihood of tampering with the system.
- No maintenance of the product is allowed during use.
- Clean and disinfect each item as needed in accordance with information on **page 13**.
- 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.
- As with all electronic equipment there is potential for the equipment to interfere with or be affected by interference from other electrical or electronic devices. For this reason avoid placing the device, sensor or connecting 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.
- To maintain basic safety and essential performance with regard to electromagnetic disturbances for the expected service life, no instructions are required.



















3.8 Consultation with a healthcare professional

Call emergency services where immediate medical attention is required.

It is important to consult a healthcare professional:

- if you are unsure whether the device (or compatible monitor) is suitable for the patient's condition.
- if the patient experiences differences in their symptoms, for example symptom type or duration.

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

-  Refer to these instructions before use.
-  This is a Medical Device.
-  Unique Device Identification.
-  Batch Code.
-  Serial Number.
-  Catalogue Number
-  Manufacturer.
-  Date of Manufacture.
-  Authorized representative in the European Union.
-  Keep Dry.
-  Fragile, handle with care.
-  Temperature Limitation.
-  Humidity Limitation.
-  Atmospheric Pressure Limitation.
- IP20** Indicates the level of Ingress Protection for the device.
-  Caution : Consult safety information in these instructions for use.
-  Consult instructions for use. Refer to instructions for use.
- CE** CE Mark. (the product conforms with the general safety and performance requirements of the Medical Device Regulations (EU) 2017/745).
- UK CA** UKCA Mark. (the product conforms with the essential requirements of the UK Medical Device Regulations 2002).
-  Symbol of the European Waste Electrical and Electronic Equipment Directive (WEEE Directive) 2019/19/EU on waste electrical and electronic equipment.
- RoHS** Indicates that the product is in compliance with the European directive 2011/65/EU 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).
-  Importer Information.

4 PACKAGE CONTENTS

Your package will contain the following:

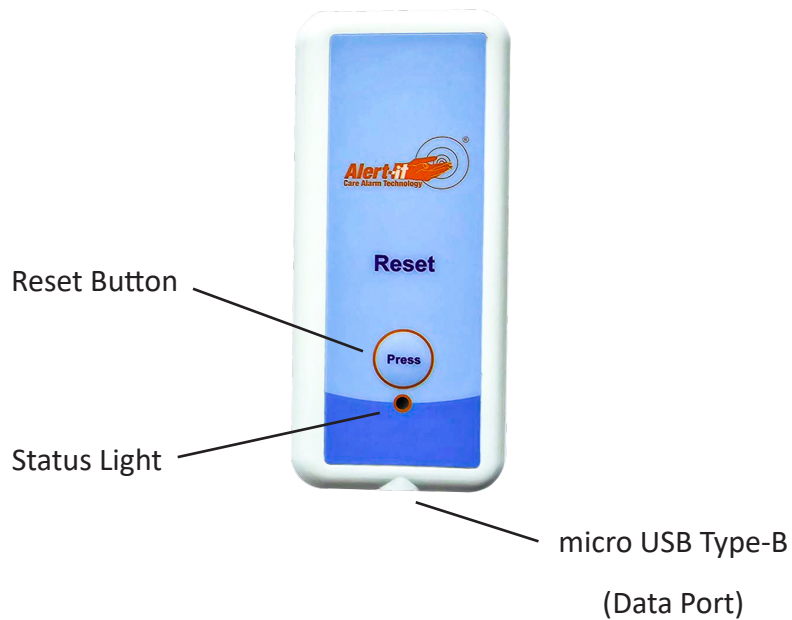
- 1x **Remote Reset Button** [Part #: P176B**]
- 2x **AAA Batteries [Alkaline LR03 1.5V]** (Fitted) [Part #: P160F]
- 1x **Mounting Kit** (2x Screws, 2x Sticky Pads)

4.1 Compatible Products

The device is compatible with all of Alert-iT's Safelink™ Radio receivers.

Note: For additional information please contact your equipment provider.

5 SYSTEM OVERVIEW



5.1 Status Light

The status light behaves as follows:

- **Sending Reset Signal** = Solid Green for 5 seconds.
- **Battery Low** = Blink Red every 6 seconds.
- **Battery Very Low** = Blink Red every 3 seconds.

6 INITIAL SETUP

6.1 Configuration

You must ensure that the devices “**Radio Address**” and “**Radio Type**” printed on the device label match that of the monitor that you wish to reset.

For help on how to change these settings, refer to **page 12**.

6.2 Turning On

The device turns on and is ready to be used as soon as batteries are inserted.

The “**Status**” light will illuminate green briefly upon battery insertion.

6.3 Remotely Resetting Alarms

Each time the “**Press**” button is pressed the device will transmit the reset signal to any paired receivers.

6.4 Turning Off

You cannot turn off this device.

The device consumes very little power, so batteries can be left fitted if the device is placed in storage for several months. Although it is still recommended to remove batteries if the device is to be stored for a long time (> 1 year) as alkaline batteries can leak if stored for a long time.

6.5 Positioning and Testing

The caregiver must check the user prior to clearing any alarm, therefore the “**Remote Reset Button**” should be installed near to the patient. For example just inside or outside of their door.

A wall mounting kit has been provided that can be used to fasten the reset button to a wall with sticky pads or screws.

To test;

1. Trigger an alarm on the matched monitor, ensure the receiving equipment receives the alarm.
2. Press the reset button and ensure the alarm clears from the receiving equipment.

7 SYSTEM OPERATION

7.1 Battery Level Warnings

The device regularly checks the battery state, however to avoid confusion with the battery state in the paired monitor, the “**Remote Reset Button**” will not transmit a battery low warning to the paired receiver.

A “**Battery Low**” warning will be raised when the batteries are nearing the end of their usable life. The “**Status**” light will begin to flash red every “**6 seconds**”.

A “**Battery Very Low**” warning will be raised when the batteries need changing immediately (See **page 13**), the “**Status**” light will start flashing red every “**3 seconds**”.

When the batteries are flat the device will turn off. Pressing the button will no longer make the status light illuminate green and the device will no longer send the reset signals.

Suspending Battery Low Warnings

When a “**Battery low**” warning has been raised, the fault will be temporarily suspended for 9 hours each time the “**Press**” button is pressed.

Once a “**Battery very low**” fault is triggered, it can no longer be suspended and the “**Status**” light will continue to flash red until the unit shuts down.

7.2 Radio Connection

If radio range is an issue, radio repeaters can be used to extend the radio range of the system.

Multiple radio repeaters can be “daisy-chained” to extend the range even further.

8 CHANGING SETTINGS ON THE RESET BUTTON

8.1 Radio Address and Radio Type

The “**Remote Reset Button**” needs to match the same radio “**Address**” and “**Type**” of the monitor its intended to reset.

You can configure both these settings using the “**Alert-iT Profile Editor**” as detailed below.

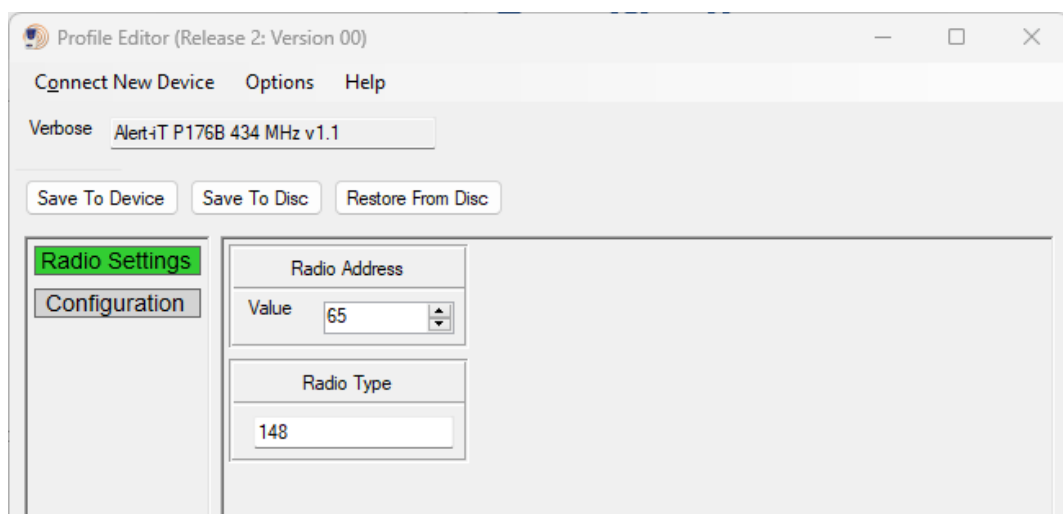
8.2 How to use profile editor

The “**Alert-iT Profile Editor**” can be downloaded from our website:

www.alert-it.co.uk/support/

Once installed:

- 1) Plug the USB cable into the Reset Button.
- 2) Ensure the Reset Button’s “**Status**” light is flashing green.
- 3) Launch “**Profile Editor**”. (Click “**Connect New Device**” if no device is found).
- 4) Ensure “**Radio Settings**” is selected on the left hand side.
- 5) Make any desired settings changes, then click “**Save to Device**”.
- 6) Test the device performs as expected (See **section 6.5**).



9 MAINTENANCE

The “Remote Reset Button” is maintenance free, however the batteries will need to be changed when required.

9.1 Changing the batteries

The device operates with 2 high quality AAA size 1.5V Alkaline Batteries that should last 3 years before they need replacing.

To change the batteries:

Step 1) Remove the back plate by inserting a small tool into the slot to depress the catch and release the case back (see **figure 1**).

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 2**).

Step 4) Insert the new batteries (see **figure 3**).

Batteries: 2x AAA Alkaline 1.5V. LR03. Non-rechargeable.

Step 5) Clip the rear case back into position.

Step 6) After changing batteries, the device will be turned on, replace the device back on the wall and test the device (see **section 6.5**).



Figure 1



Figure 2

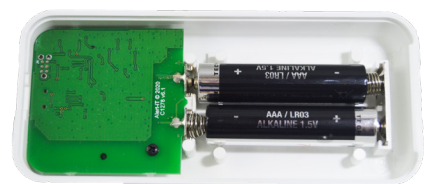



Figure 3

9.2 Cleaning

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

 Avoid getting any liquid into the USB connector.

9.3 Reuse

If the device is to be reused, the device should be restored to its default radio settings printed on the label if they have been modified.

9.4 Routine Checks

Weekly Checks

It is recommended to test the system weekly by triggering an alarm on the paired monitor the ensuring the reset button clears the alarm.

If the “**Status**” light is flashing red the batteries should be changed soon.

10 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.

11 DECLARATIONS OF CONFORMITY

The manufacturer, iTs Designs Ltd., hereby declares that this product conforms with the relevant requirements of the Medical Device Regulations (EU) 2017/745 and the UK Medical Device Regulations 2002.

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/

Electromagnetic Compliance

- Compliant to IEC 60601-1-2 clause 4.3, 7 and 8.
- Emission class IEC 55011: Class B.
- Immunity test level: 10V/M. Performance criteria: A.
- Emission limits and immunity test levels applied for IEC 60601-1-11 Home healthcare environment.

12 TECHNICAL SPECIFICATIONS

Equipment is for continuous operation.

Remote Reset Button

Model:	P176B**.
Batteries:	2x AAA 1.5V Alkaline (LR03).
Battery Life:	3 years.
Input and Output Connectors:	micro USB Type-B (Programming Port).
Switches and Controls:	1x Press Button.
Signal Lights:	Status Light (Red / Green)
Delay time from ALARM CONDITION to SIGNAL OUTPUT:	< 1s.
Maximum remote ALARM SIGNAL GENERATION DELAY:	< 1s.
Memory Retention:	All memory retained after power loss.
Measurements:	100 x 44 x 16 mm (HxWxD).
Weight:	80g (including batteries).
Colour:	White.
Casing:	ABS Plastic.
IP Rating:	IP20 (Not-waterproof).
Service Life:	5 years.

Radio Frequency:	434.0750 MHz.
Radio Output Power:	< 10 mW.
Radio Range:	450 meters (line-of-sight).
OR	
Radio Frequency:	869.2125 MHz.
Radio Output Power:	< 10 mW.
Radio Range:	450 meters (line-of-sight).

Ambient Conditions

Operating Temperature:	5°C to 40°C (Use Indoors).
Humidity Limit:	5% to 90% max. Non-condensing.
Atmospheric Pressure:	700 hPa to 1060 hPa.
Storage Temperature:	-30°C to 50°C.



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For support please contact your equipment provider.

EU Importer to add details here, where applicable.

