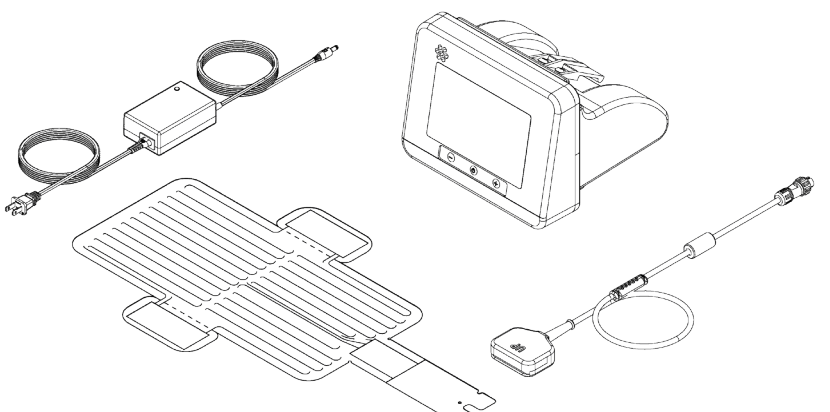
BP37™

Infant Temperature Maintenance Kit



Instructions For Use

BP37™ is a patented product

BP37™ - Instructions for use

Section 1 - Precautions before use

	Your BP37 is an electronic device. The product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. Your BP37 Controller contains Li-ion batteries and must not be discarded as standard waste.
	Certain components of the BP37 TM Kit can be recycled.
	Although the BP37 **Controller** has some shock resistance it is advisable not to let your controller drop and to avoid any shocks.
	Your BP37 has some limited protection against water. However It is best to avoid water or high level of humidity.
	Avoid continually charging batteries. When batteries are charged unplug charger.
	**Only use the provided BP37 Charger. There is risk of damage to battery if you use alternative chargers.**

Before using the BP37 ensure:

- Controller and accessories are in good working order with no signs of damage.
- New unused Matrix is available.

Section 2 - Introduction

Throughout this manual, abbreviations for various components of the BP37™ Infant Temperature Maintenance Kit will be made.

Full Description	Abbreviation
BP37 Infant Temperature Maintenance Kit	BP37 TM Kit
BP37 Controller	Controller
BP37 Battery Charger	Battery Charger
BP37 Thermal Support Matrix	Matrix
BP37 Thermal Support Matrix Cable & Clamp	TSMC
BP37 Infant Temperature Maintenance Fitting Kit	Fitting Kit

The BP37 is a patented product. BP37 is a trademark of Advanced Healthcare Technology Ltd.

Section 2.1 - General Description

The Advanced Healthcare Technology BP37 TM Kit is designed for use to provide a portable source of thermal support that does not require connection to mains electricity. When fully charged the BP37 TM Kit is expected to provide thermal support for up to 6 hours (dependent on ambient temperature).

During use of the BP37 TM Kit the infant's core temperature must be regularly monitored.

The Matrix is designed to adhere to a surface via adhesive pads. When the Matrix is no longer required, the wings where the adhesive pads are located are designed to tear along perforated sections which break the circuit. The wings can then be peeled from the mattress and discarded with the used Matrix. The non-woven fabric and adhesive used for the Matrix is biocompatible and can be in direct contact with skin.

The Matrix is connected to a previously charged low voltage Controller to provide a surface temperature of 37 °C (99 °F).

Note: This IFU covers the use of the generic BP37 TM Kit. Specific additional IFUs in the form of addendums are supplied with each kit variant.

The useful life of the Controller and accessories are 5 years under normal use conditions. The Matrix are designed and intended for single patient multiple use.

Section 2.2 - Description of Parts

Figures 1-4 shown below are images of the components that make up the BP37 TM Kit.

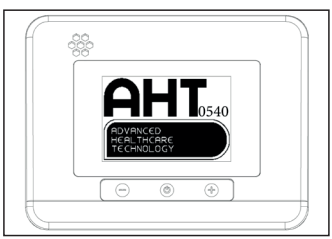


Figure 1 - Controller

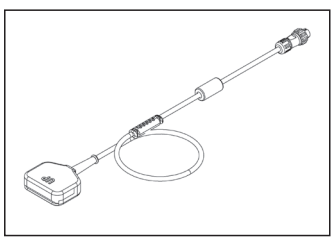


Figure 2 - TSMC

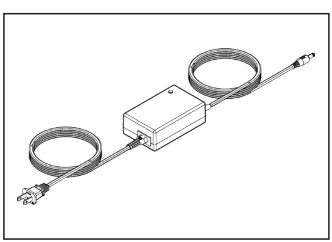


Figure 3 - Battery Charger & Associated Cables

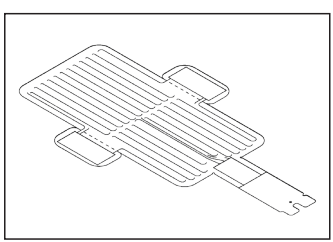


Figure 4 - Matrix

Note: Images in this IFU are for illustrative purposes only and are not to scale. Parts used in variants may be different, see relevant addendum for relevant images.

Section 2.3 - BP37 Infant Temperature Maintenance Kit Components

Part Number	Part Description
BP37-001 **(or Variants)**	Complete BP37 Infant Temperature Maintenance Kit Starter Pack **(Variant)** including: • BP37 Infant Temperature Maintenance Kit Controller **(Variant)** • Battery Charger and power cord applicable to geographical region of use • BP37 Thermal Support Matrix (x 10) • BP37 Thermal Support Matrix Connecting Cable & Clamp (TSMC) **(Variant)** • Fitting Kit or Rail Clamp
BP37-002 **(or Variants)**	BP37 Infant Temperature Maintenance Kit Controller **(Variant)** including: • BP37 Infant Temperature Maintenance Kit Controller **(Variant)** • Battery Charger and power cord applicable to geographical region of use • BP37 Thermal Support Matrix Connecting Cable & Clamp (TSMC) **(Variant)** • Fitting Kit or Rail Clamp
BP37-003	Battery Charger
BP37-004	UK Power Cord for Battery Charger
BP37-005	EU Power Cord for Battery Charger
BP37-006	USA Power Cord for Battery Charger
BP37-007	AU Power Cord for Battery Charger
BP37-009 **(or Variants)**	BP37 Thermal Support Matrix Connecting Cable & Clamp (TSMC) **(Variant)**
See variant addendum	BP37 Thermal Support Matrix (x 10) **(Variant - See relevant addendum)**

Accessories (see variant addendum)

Part Number	Part Description
See variant addendum	BP37 Infant Temperature Maintenance Fitting Kit / Rail Clamp **(Variant - See relevant addendum)**
BP37-012	12V Charger
BP37-018	Universal rail clamp

Section 3 - Symbols

Symbol	Title/Definition
	General warning sign
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Consult instructions for use or consult electronic instructions for use
EU REP	Authorized representative in the European Community/European Union
CE	Product complies with the provisions of the Medical Device Regulations (2017 / 745)
UK CA	Product complies with the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)
	Manufacturer
	Date of manufacture FR – Manufactured in France
	Dangerous Goods - Lithium Batteries contained
	Fragile - Handle with care

Symbol	Title/Definition
	Temperature Limit (0 °C to 40 °C)
	Single patient multiple use
	Use by date
LOT	Batch code
REF	Catalogue number
SN	Serial number
UDI	Unique device identifier
MD	Medical Device
	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. The WEEE marking must appear on any electrical and electronic equipment placed on the EU market.
	Do not use if package is damaged and consult instructions for use
IPX4	Controllers are rated to a degree of Ingress Protection (IP)X4
IPX2	Matrix are rated to a degree of Ingress Protection (IP)X2

Section 4 - Safety

Section 4.1 - Intended Use

The BP37 TM Kit is a set of components and devices that, when connected and activated, provide battery operated portable thermal support.

The BP37 TM Kit is intended to provide a nominal surface temperature of 37 °C (99 °F) on the mattress where an infant is lying.

An independent device should be used to regularly measure the infant's core body temperature whilst the BP37 TM Kit is in use.

Section 4.2 - Indication for use

To support the maintenance of normothermia in infants who may become at risk of temperature loss in healthcare settings.

Section 4.3 - Contraindications

It is the responsibility of the user to determine whether temperature support is appropriate for each individual infant.

The BP37 TM Kit should not be used on infants where clinical considerations indicate that the thermal support provided by the BP37 TM Kit is not advisable.

Some components within the BP37 TM Kit are ferromagnetic and therefore are not MRI compatible.

Avoid direct patient contact where patient's skin is compromised.

Section 4.4 - Warnings

The user should carefully read the Instruction for Use before using the BP37 TM Kit consisting of Battery Charger, Controller, TSMC and Matrix to become familiar with the function and use of the equipment. Failure to do so may affect safety of user and patient.

Do not use the BP37 TM Kit with any components other than those approved by Advanced Healthcare Technology Limited (AHT).

Do not use the BP37 TM Kit if there is any sign of damage.

The user should not attempt any repairs of the BP37 TM Kit if damage is identified. The Controller, TSMC and Battery Charger can only be repaired or replaced by qualified service personnel.

The BP37 TM Kit has visual alarm systems (and 2 second audible beep). See Section 8 - Alarms, User Alerts and User Actions, for details.

It is important to ensure that the Matrix is safely positioned.

The Matrix is not to be wrapped around the infant.

The BP37 TM Kit components and accessories are not supplied sterile.

Partial covering of the Matrix with items that have good insulating properties may impair the thermal support of the device.

Section 4.5 - Disclaimers

AHT assumes no responsibility for the use of the BP37 TM Kit if it is not used correctly in line with this IFU.

Section 4.6 - User Profile

The BP37 TM Kit is designed for use by trained and competent healthcare professionals involved in the medical care of infants.

Section 5.1 - Overview of how the kit is used

It is important to follow these steps in order.

For optimum performance, all BP37 TM Kit components should be stored together, at room temperature.

When used, the Controller, TSMC, Matrix and the mattress where the infant is laid, should be at the same ambient temperature before activation.

OVERVIEW OF USING THE BP37 TM KIT

1. Ensure the Controller has adequate charge.
2. Unscrew protective dust cover and connect TSMC to Controller.
3. Remove Matrix from pouch and position on mattress.
   Note: Do not put the baby on the plastic / silver side of the Matrix.
4. Secure Matrix to mattress by removing release paper from wings and gently rubbing wings down.
5. Connect TSMC to Matrix tail.
6. Switch on Controller (Push and hold ⏻).
7. Lay baby / infant on top of Matrix.
8. When thermal support is required, switch Controller to **37** Mode (Push and hold +).
9. If thermal support is not required, switch Controller to Standby (**SB**) (Push and hold -).

When thermal support is no longer required.

10. Switch Controller to Standby Mode (**SB**), then turn off Controller.
11. Unclamp Matrix.
12. Tear off Matrix from mattress and remove remaining wings and dispose of.
13. Put Controller on charge as required.

Note: If **37** Mode is activated when no infant present, it is recommended to place an insulating layer over the Matrix. This will help to achieve a surface temperature of 37 °C (99 °F) on the Matrix. Otherwise, dependent on ambient temperature, the surface temperature may not reach 37 °C (99 °F) until an infant is laid on the Matrix.

Section 6.1 - Battery Charger

Refer to the Battery Charger IFU before use.

Mains power is supplied to the Battery Charger via an IEC socket and IEC mains lead.
Battery Charger is connected to the Controller with an IEC socket and lead.

Charging Controller

Connect cable from Battery Charger to socket in the back of the Controller.
Connect Battery Charger to mains electricity using the IEC lead provided.

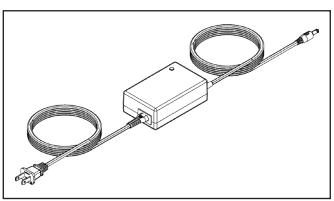


Figure 5 - Battery Charger

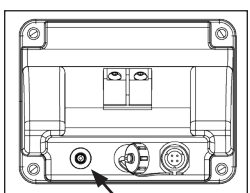


Figure 6 - Battery Charger Socket

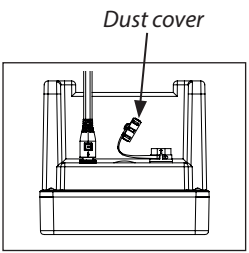


Figure 7 - Connect Battery Charger to Controller

Battery Charger Status

See separate Battery Charger IFU.

Under normal conditions, it can take up to 3 hours to fully charge the Controller from 0 %.

Section 6.2 - Controller

The Controller is only to be used with the BP37 Matrix.

The Controller has a display which shows the status of the batteries, the surface temperature of the Matrix and the ambient temperature.

Connecting TSMC to Controller

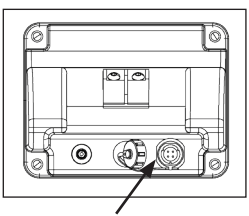


Figure 8 - TSMC Socket & protective dust cover

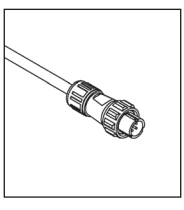


Figure 9 - TSMC cable end

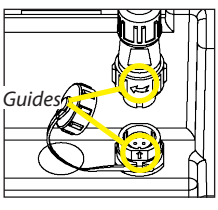


Figure 10 - Line up guides

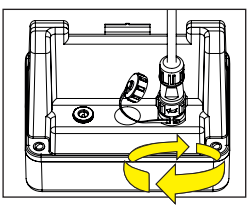


Figure 11 - Screw cable to socket

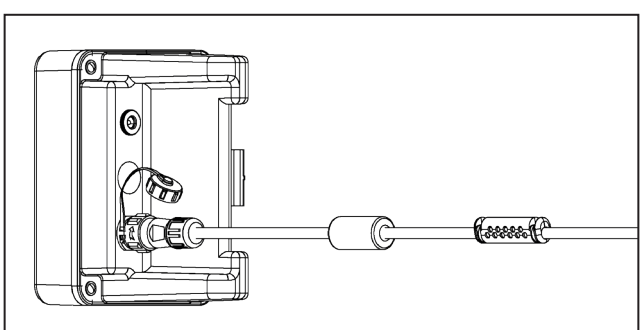


Figure 12 - Controller with TSMC connected.

Section 6.3 - Matrix

The Matrix consists of a printed aluminium circuit laminated between a polyester and non-woven fabric. The printed aluminium circuit has been designed to provide a surface temperature of 37 °C (99 °F) when in operation. If thermal support from the Matrix is no longer required, place the Controller in Standby Mode (**SB**). The Matrix can remain in position and will passively cool.

The Matrix must be used with the non-woven fabric surface uppermost.

The Matrix is designed to provide an even temperature over the whole surface. The materials used for the Matrix have been tested for biocompatibility to allow direct contact with unbroken skin during use.

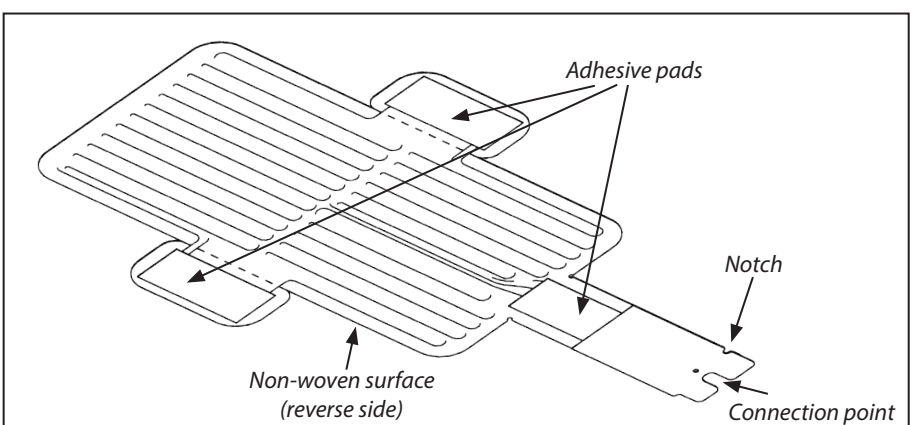


Figure 13 - Matrix

Using Matrix

Remove Matrix from pouch. If any sign of damage on the Matrix, do not use.

Ensure surface of mattress is clean and free from contamination that may compromise the adhesion properties of the Matrix.

Place Matrix on top of mattress.

Note: Non-woven fabric must be upper most. Ensure connecting tail is not between the Matrix and mattress.

Note: Take care that the perforated wings are not damaged. If they are, there is risk that the circuit might be broken and the Matrix will require replacement. (*Figure 14*)

When satisfied with position of the Matrix, peel of release paper from adhesive pads on the wings and adhere to mattress. (*Figure 15*)

Gently rub the non-woven fabric on the wings of the Matrix to ensure the adhesive pads are properly secure. *(Figure 16)*

Matrix is now secure to mattress. *(Figure 17)*

Note: Matrix can be used with direct infant contact or separated with a thin layer of fabric.

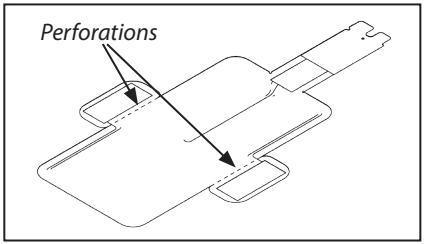


Figure 14 - Perforations

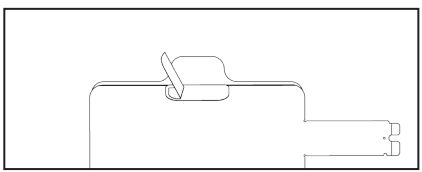


Figure 15 - Removal of release paper from adhesive pads

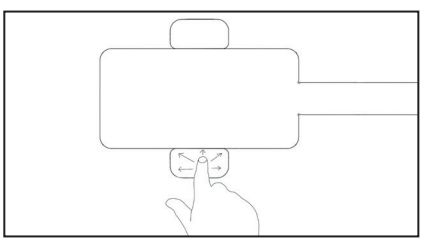


Figure 16 - Rub down wings

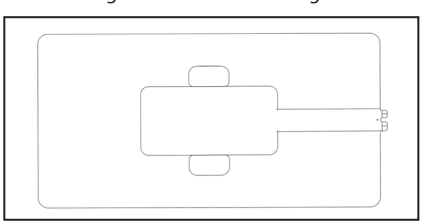


Figure 17 - Matrix secured to mattress

Connect TSMC to the Matrix. The TSMC is marked 'UP' (*Figure 18*) on one side and this should be presented to the Matrix with 'UP' uppermost.

Locate printed circuit connection points on the tail of the Matrix. The Matrix connecting points have asymmetrical cutouts which are designed to match the asymmetrical contact points in the TSMC (*Figure 19*) and also have a notch to enable correct contact area. Ensure non-woven side of the Matrix is facing up. Push printed circuit connection points firmly into the TSMC until notch is no longer visible.

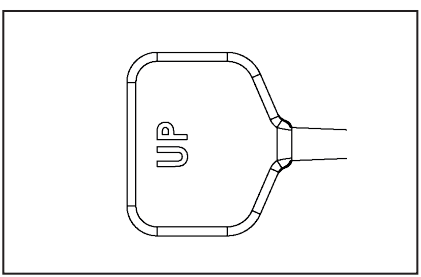


Figure 18 - TSMC marked 'UP' on one side

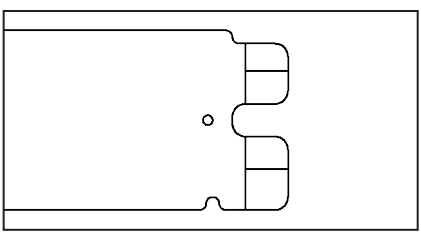


Figure 19 - Matrix connecting tail has asymmetrical cut outs, and a notch to enable correct connection

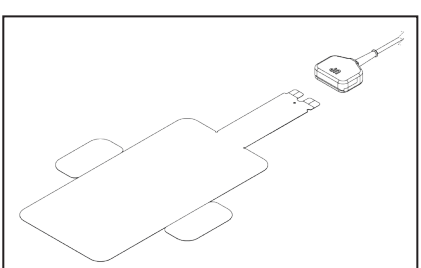


Figure 20 - Non-woven side up

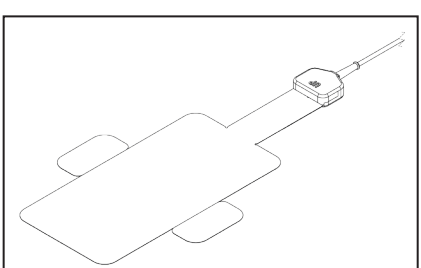


Figure 21 - Push TSMC onto Matrix

When thermal support is no longer needed and the infant has been removed, take off the clamp and tear off the Matrix *(Figure 22)*. This will break the Matrix circuit.

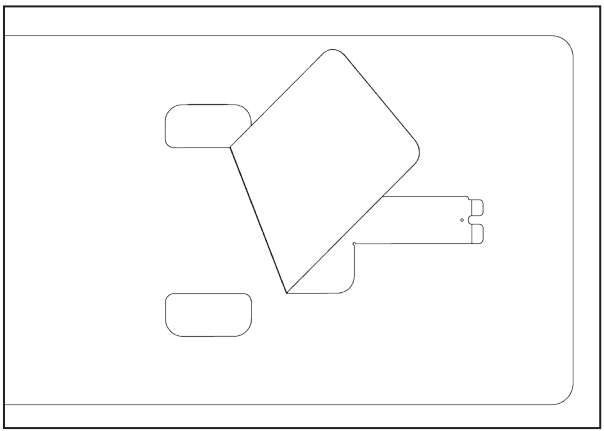


Figure 22

Wings will be left in place.
(Figure 22)

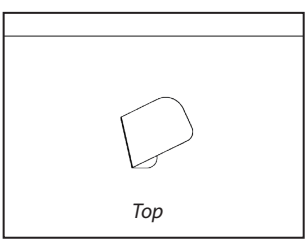


Figure 23

The wings
can be peeled off.
(Figure 23 & 24)

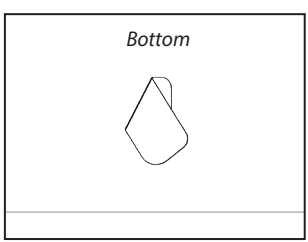
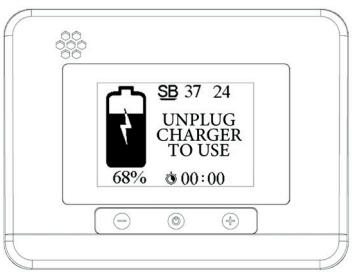
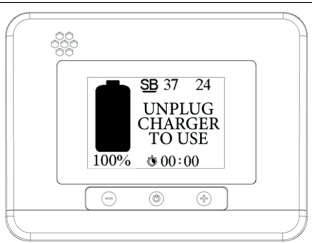
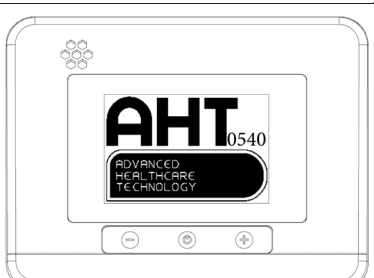


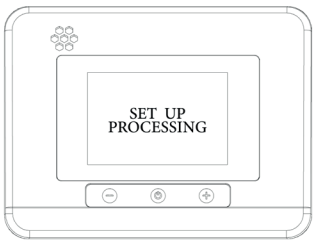
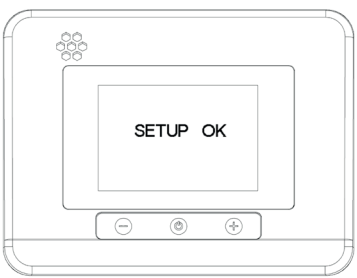
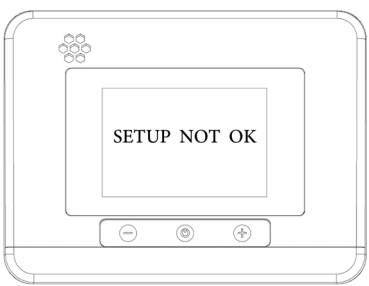
Figure 24

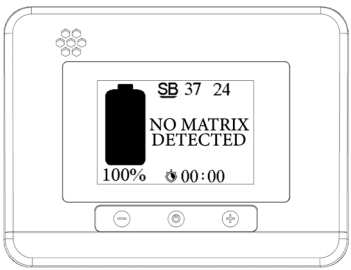
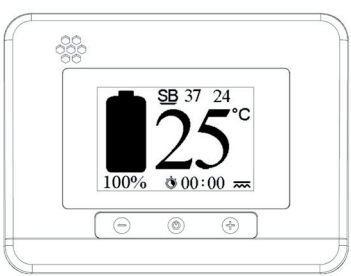
Note: If the Matrix wings do not tear off on removal, then the Matrix must still be disposed of.

Section 7 - Using the Controller

Controller Graphic User Interface (GUI) descriptions and examples of information displayed are shown below.

Mode	Description	Screen
Charging batteries in Controller	Pressing On/Off for 3 seconds whilst Controller is being charged. Shows 'Lightning' Symbol indicating batteries are being charged and % battery charge.	
Charging batteries.	Battery now 100 % charged. Disconnect Controller from Battery Charger.	
Start Up	When Controller is not being charged. Pressing On/Off for 3 seconds. Shows AHT Screen and 'clicks' 3 times.	

Mode	Description	Screen
Start Up	Screen temporarily shows.	
Start Up (Matrix attached)	SETUP OK, Controller, TSMC and Matrix are ready to use.	
Start Up (Matrix not attached)	Matrix has not been connected / incorrectly connected, or Matrix is faulty. This screen will appear temporarily.	

Mode	Description	Screen
SB (Matrix not attached)	Matrix has not been connected or Matrix is faulty.	
SB (Matrix attached)	% Battery charge (100 %), ambient temperature (24 °C) and temperature of Matrix surface (25 °C).	
SB (Matrix attached)	Controller ready to start by pressing '+' to activate **37** Mode.	

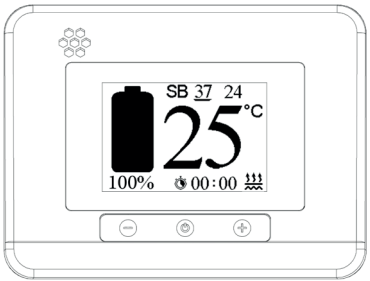
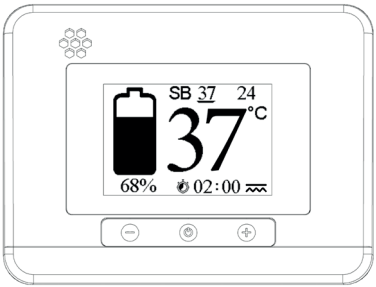
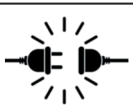
Mode	Description	Screen
37	Thermal support is being provided.	
37	% Battery charge; temperature of Matrix surface; the ambient temperature (24 °C) and time elapsed (2 hours).	

Table below shows different symbols and their meanings.

Symbol	Controller activity.
	Matrix attached to Controller.
	Matrix attached to Controller. Thermal Support being provided.
	Hardware safety activated. No thermal support provided .
	Software safety activated. No thermal support provided .
	Matrix disconnected when Controller is in **37** Mode

Note: The BP37 TM Kit can not be operated and charged at the same time.

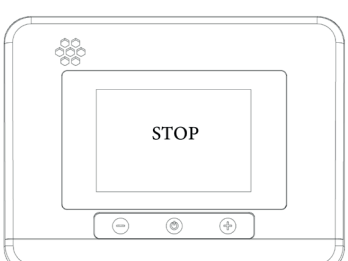
Note: If a Matrix is connected to the Controller and an attempt is made to activate **37** Mode whilst charging by pressing (+), the Controller will stay in **SB** Mode until the Battery Charger is disconnected from mains electricity.

Note: When switching the Controller off, the system needs at least 10 seconds to shut down correctly. Wait at least 10 seconds before switching Controller on again.

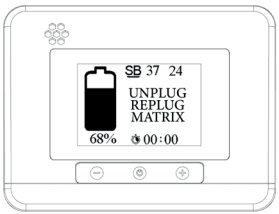
Note: Press (-) and hold until a beep is heard, Controller goes into Standby (**SB**) Mode. Elapsed time since initial activation will be retained but battery % will slowly discharge.

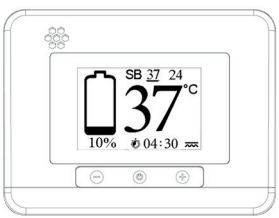
Note: If Controller is switched off, and then restarted the % battery will be indicated but the time elapsed will start at 00:00.

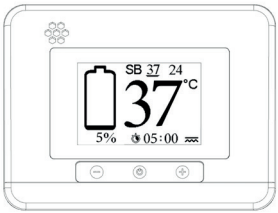
Note: Matrix should only be disconnected from TSMC when Controller is switched off, or is in **SB** Mode. Disconnecting the Matrix when in **37** Mode will cause the Controller to reset and it may take several minutes before surface temperature of 37 °C shows on screen.

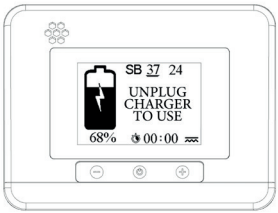
Mode	Description	Screen
37	When battery has fully depleted screen will show 'STOP'. The Controller batteries will need to be charged before it can be used again.	

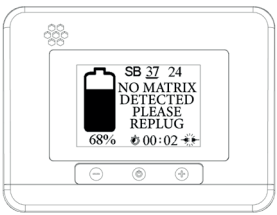
Section 8 - Alarms, User Alerts and User Actions

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	Controller detecting insufficient contact between Matrix and TSMC.
Cause(s) Contamination on contact points of Matrix.	**Actions** Disconnect, ensure contact points are clean and dry, reconnect Matrix. If message remains, change Matrix.	

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	Battery % = 10 %.
Cause(s) Battery now has 10 % charge left.	**Actions** Review estimated time thermal support is required. Prepare additional thermal support if needed.	

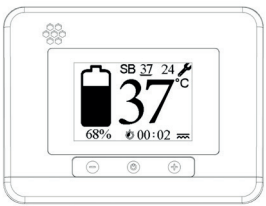
Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	Battery % = 5 %.
Cause(s) Battery now has 5 % charge left.	**Actions** Review estimated time thermal support is required. Prepare additional thermal support if needed.	

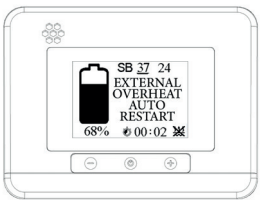
Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	Controller connected to mains connected battery charger when in **37** Mode. **No thermal support will be provided.**
Cause(s) Attempting to charge Controller when in **37** Mode.	**Actions** Disconnect battery charger from Controller.	

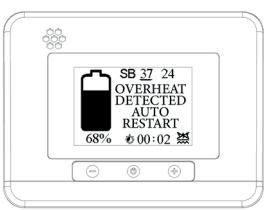
Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	3 beeps every several seconds - continues until Matrix is reconnected.	Matrix disconnected when Controller in **SB** or **37** Mode.
Cause(s)	**Actions**	
Inadvertent or deliberate disconnection of Matrix when Controller in **SB** or **37** Mode.	Reconnect Matrix.	
Circuit on Matrix damaged / broken.	Replace Matrix.	

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	Battery safety. Battery temperature reaches 50°C.
Cause(s)	**Actions**	
Incorrect Battery Charger.	Replace with AHT approved Battery Charger.	

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	Internal overheat.
Cause(s) Incorrect Battery Charger.	**Actions** Replace with AHT approved Battery Charger. If error persists contact your local supplier.	

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	Spanner symbol
Cause(s) 1000 on/off cycles.	**Actions** Contact AHT or your local supplier. **Note:** Controller can still be used.	

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	Temperature of Matrix > 39 °C.
Cause(s) External factor causing temperature of Matrix > 39 °C.	**Actions** Check the temperature of the infant. Put Controller in **SB** Mode.	

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	External source of heat detected on Matrix.
Cause(s) External source of heat detected on Matrix e.g. radiant heater used, Matrix exposed to sunlight etc.	**Actions** Remove external source of heat.	

Section 9 - Storage

Store all components and accessories of the BP37 TM Kit at room temperature in a dry and clean area not exposed to direct sunlight.

Keep Matrix in their pouches until they are required for use.

Section 10 - Service & Maintenance

After 1,000 on-off cycles, the Controller may need to be serviced.
A 'spanner' symbol will be displayed on the Controller.

If your Controller requires servicing then please contact AHT:

Tel: +44 (0)1992 535933 **Email: sales@babypod.com**

or your local AHT supplier.

Section 11 - Infection Control and Cleaning

Clean the Controller and associated components with care using a surface cleaner or disinfectant wipes (pH neutral or alkaline).

Where a higher level of decontamination is required, use Sodium Hypochlorite (bleach) solution.

Do not immerse any part of the BP37 TM Kit in fluids.

Do not process in an autoclave, steriliser or automatic washer-disinfector.

Do not use phenolic based products, abrasives or harsh chemicals for cleaning.

Section 12 - Disposal

The single patient use Matrix should be disposed in accordance with local policies for contaminated medical waste protocols.

At end of life, the Battery Charger, Controller and TSMC should not be disposed as unsorted waste, but should be sent to separate collection facilities for recovery and recycling in accordance with local policies.

Section 13 - Technical Description and Specification

BP37 Controller	
Characteristic	**Description**
Power Input	15W
Max Power Output per channel	15W
Internal Battery	16.8V DC / 2A
Maximum Alert Sound Pressure	77 dB
Storage Conditions Temperature	15 °C - 30 °C
Humidity	10 % to 70 % RH
Pressure	50 kPa to 106 kPa
Note	Higher storage temperatures will reduce the life of the internal battery
Use Conditions: Temperature Humidity Pressure	 0 °C - 38 °C 10 % to 70 % RH 50 kPa to 106 kPa
Operating Temperature	37 °C (99 °F)
Safety:	IEC 60601-1, IEC 60601-2-35
EMC Standards:	Emmisions - EN 55011/02 Immunity - EN 60601-1-2/A/21
IP Rating	X4
Construction Materials	Body - PA66 Screen - Stalinate TSMC Cable - PVC TSMC Clamp - PA66
Dimensions:	125 x 95 x 115mm
Weight (Controller and TSMC):	710g (LS-Variant - 730g) (C-Variant - 765g)

Thermal Support Matrix	
Characteristic	**Description**
IP-Rating	X2
Thermal Support Matrix Construction Materials	Top surface - Non-woven Spun bond PP Adhesive Pads - Acrylic solvent on a PE carrier Backing - Polyester Printed Circuit - Aluminium
Weight:	18g (C-Variant 25g)
Storage Conditions Temperature	5 °C - 35 °C
Use Conditions Temperature	0 °C - 40 °C
Safety:	ISO 10993-5, IEC 60601-2-35

Li-Ion Battery Charger (4 cell)
Refer to separate Battery Charger IFU for information

Section 14 – BP37 Performance

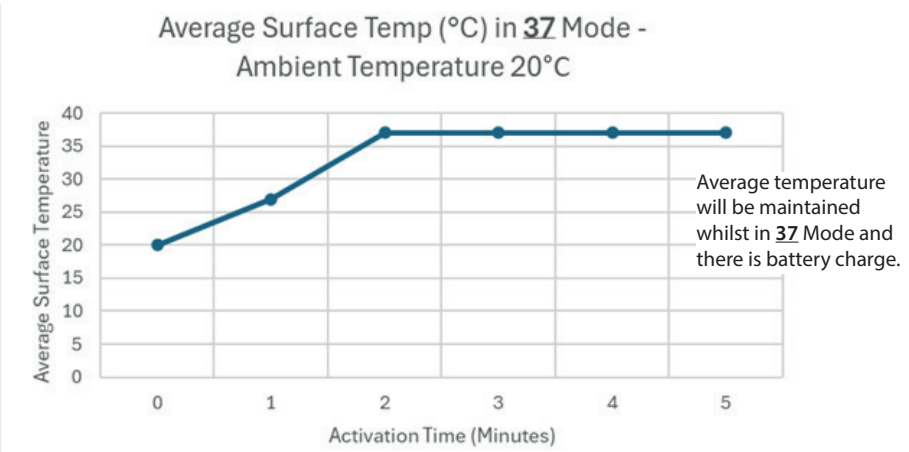


Figure 25 - Average surface temperature

Section 15 - Serious Incident / Serious Adverse Event

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established (EU) or in the case of a serious adverse event, the relevant regulatory authority in the country where the event happened.

Section 16 - Warranty

We provide free rework or free replacement for materials or manufacturing defects found within 12 months from the date of delivery. Excluded from this is damage caused by mechanical or chemical influences during use or storage as well as normal wear and tear as they arise during use.

We are not liable for direct or indirect damage of any kind to persons or objects resulting from improper use, disregard of the instructions for use or the inability to use due to necessary repairs not being carried out.

Section 17 - User Notes

Please register your product at: https://babypod.com/register-a-product/

Manufactured in France
on behalf of:

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Herts., EN8 8YD, United Kingdom
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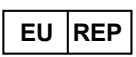

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