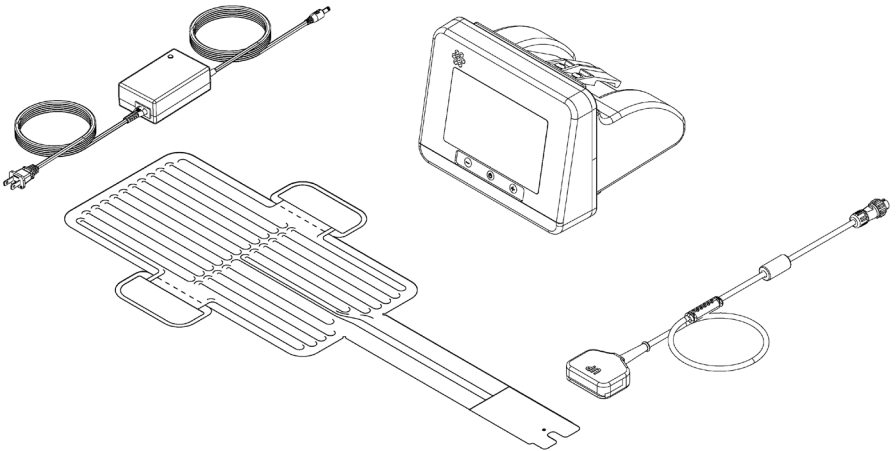


BP37™

Infant Temperature Maintenance Kit








Instructions For Use

BP37 is a patented product

BP37™ - Instructions for use

	Page
<u>Section 1</u> Precautions Before Use	1
<u>Section 2</u> Introduction	3
2.1 General Description	4
2.2 Description of Parts	4
2.3 BP37™ Infant Temperature Maintenance Kit Components	5
<u>Section 3</u> Symbols	6
<u>Section 4</u> Safety	7
4.1 Intended Use	8
4.2 Indication for use	8
4.3 Contraindications	8
4.4 Warnings	9
4.5 Disclaimers	10
4.6 User Profile	10
<u>Section 5</u> Kit Description / Application – Overview	11
5.1 Overview of how the kit is used	11
<u>Section 6</u> Kit Description / Application Detailed	12
6.1 BP37™ Battery Charger	12
6.2 BP37™ Controller	13
6.3 BP37™ Thermal Support Matrix	14
<u>Section 7</u> Using BP37™ Controller	18
<u>Section 8</u> Alarms, User Alerts and User Actions	22
<u>Section 9</u> Storage	28
<u>Section 10</u> Service and Maintenance	28
<u>Section 11</u> Infection Control and Cleaning	29
<u>Section 12</u> Disposal	29
<u>Section 13</u> Technical Description and Specification	30
<u>Section 14</u> BP37™ Performance	31
<u>Section 15</u> Serious Incidents	33
<u>Section 16</u> Warranty Statement	33
<u>Section 17</u> Temperature Conversion	34
<u>Section 18</u> User Notes	35

Section 1 - Precautions before use

	<p>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.</p>
	<p>Certain components of the BP37™ Kit can be recycled.</p>
	<p>Although the BP37™ Controller has some shock resistance it is advisable not to let your controller drop and to avoid any shocks.</p>
	<p>Your BP37™ has some limited protection against water. However It is best to avoid water or high level of humidity.</p>
	<p>Avoid continually charging batteries. When batteries are charged unplug charger.</p>
	<p>Only use BP37™ Charger. There is risk of damage to battery if you use alternative chargers.</p>

Before using BP37™ ensure:

- BP37™ Controller is sufficiently charged to provide thermal support for the expected use. Switch Controller on to check battery %.
- Thermal Support Matrix Cable & Clamp (TSMC) is in good order with no signs of damage.
- New unused Thermal Support 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	TS Matrix
BP37™ Thermal Support Matrix Cable & Clamp	TSMC
BP37™ Infant Temperature Maintenance Fitting Kit	Fitting Kit

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 4 hours (dependent on ambient temperature).

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

The TS Matrix is designed to be adhered via adhesive pads. When the TS Matrix is no longer required, the flanges where the adhesive pads are located are designed to tear along perforated sections which break the electrical circuit ensuring the TS Matrix can only be used for single patient multiple use. The adhesive pads can simply be peeled from the surface and discarded with the used TS Matrix. The non-woven fabric and adhesive used for the TS Matrix is biocompatible and is compatible for use on skin.

The TS Matrix is connected to a previously charged low voltage Li-ion battery operated Controller to provide a surface temperature of 37°C (99°F).

The useful life of the Battery Charger is 3 years, the Controller and TSMC is 5 years under normal use conditions. The TS Matrices 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™ Kit.

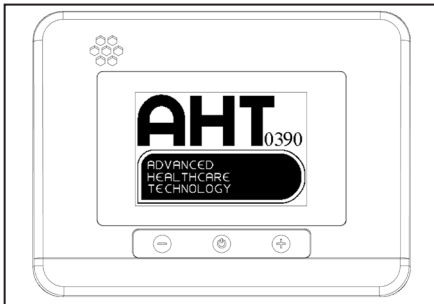


Figure 1 - Controller

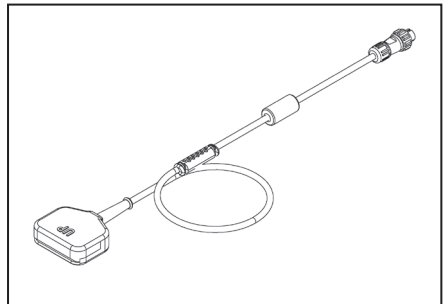


Figure 2 - TSMC

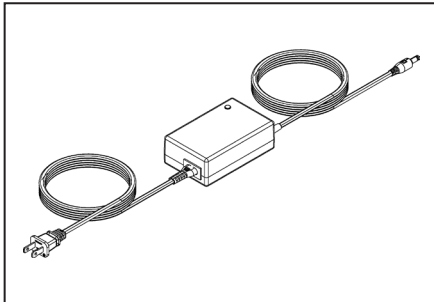


Figure 3 - Battery Charger & Associated Cables

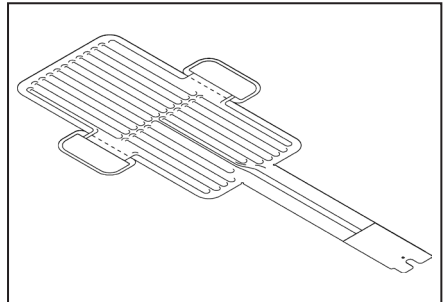


Figure 4 - TS Matrix











Section 2.2 - BP37 Infant Temperature Maintenance Kit Components













Part Number	Part Description
BP37-001	Complete BP37™ Infant Temperature Maintenance Kit including: <ul style="list-style-type: none"> • BP37-002 BP37™ Infant Temperature Maintenance Kit Controller • BP37-003 Battery Charger and power cord applicable to geographical region of use • BP37-008 BP37™ Thermal Support Matrices (x 10) • BP37-009 BP37™ Thermal Support Matrix Connecting Cable & Clamp (TSMC) • BP37-010 Fitting Kit for attachment to AHT Infant Transport Devices
BP37-002	BP37™ Infant Temperature Maintenance Kit Controller
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
BP37-008	BP37™ Thermal Support Matrices (x 10)
BP37-009	BP37™ Thermal Support Matrix Connecting Cable & Clamp (TSMC)

Accessories

Part Number	Part Description
BP37-008	BP37 Thermal Support Matrices (x 10)
BP37-010	BP37 Infant Temperature Maintenance Fitting Kit - Fitting Kit for attachment to AHT Infant Transport Devices
BP37-012	12v Charger
BP37-013	C14 Connector Cable

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
	Authorized representative in the European Community/European Union
	Product complies with the provisions of the Medical Device Regulations (2017 / 745)
	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
	Batch code
	Catalogue number
	Serial number
	Unique device identifier
	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
	Controllers are rated to a degree of Ingress Protection (IP)X4
	TS Matrix are rated to a degree of Ingress Protection (IP)X2

Section 4 - Safety**Section 4.1 - Intended Use**

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

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

An independent device should be used to regularly measure the infant's core body temperature whilst the system 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 during healthcare activities.

**Section 4.3 - Contraindications**

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



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

Some components within the BP37™ 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 TS 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.

If materials are used with high thermal conductivity such as water, gels or similar substances, these materials may lower the patient's body temperature.

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 manufacturer's 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 TS Matrix is safely positioned.

TS Matrix is not to be wrapped around the infant.

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

Partial covering of the TS 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™ Kit if it is not used correctly as a kit with approved components and accessories authorised for use by AHT.

AHT makes no warranty of any kind with any other manufacturer controllers, thermal support matrix, accessories or applications that are created to be used in conjunction with the BP37™ Kit by users.

This document contains confidential and proprietary information that is protected by copyright. All rights are reserved. Any unauthorised copying, storage, reproduction or translation of this document in any form is strictly prohibited.

Section 4.6 - User Profile

The BP37™ 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™ Kit components should be stored together, at room temperature.



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

OVERVIEW OF USING THE BP37™ KIT

1. Charge up Controller.
2. Connect TSMC to Controller.
3. Remove TS Matrix from pouch and position on mattress.
4. Attach TS Matrix to mattress by removing release paper from adhesive flanges and gently rubbing flanges down.
5. Connect TSMC to TS Matrix tail.
6. Switch on Controller in Stand By Mode (**SB**).
7. Lay infant on top of mattress.
8. If thermal support is required, switch Controller to **37**.
9. If thermal support is not required, leave Controller in Stand By (**SB**).

When healthcare activity of infant complete.

10. Switch Controller to Stand By Mode (**SB**), then turn off Controller.
11. Unclamp TS Matrix.
12. Tear off TS Matrix from mattress and remove adhesive flanges and dispose of.
13. Put Controller on charge in readiness for next healthcare activity, if required.

Section 6.1 - Battery Charger

Refer to the Battery Charger IFU before use.

Voltage is supplied to the Battery Charger via an IEC socket and IEC mains lead.
Battery Charger is connected to the batteries in 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.

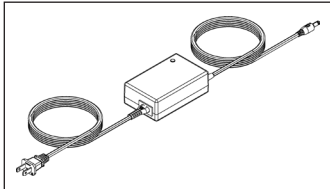
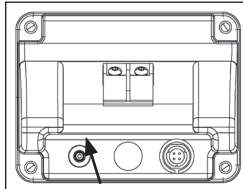
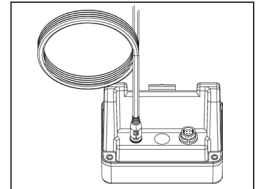


Figure 5 -Battery Charger



*Figure 6 - Battery
Charger Socket*



*Figure 7 - Connect Battery Charger
to Controller*

Battery Charger Status

See separate Battery Charger IFU.

Under normal conditions, the batteries in the Controller shall be fully charged after connecting to the Battery Charger after four hours.

Section 6.2 - Controller

The Controller is a temperature controller to be used only in conjunction with AHT branded TS Matrix.

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

Connecting TSMC to Controller.

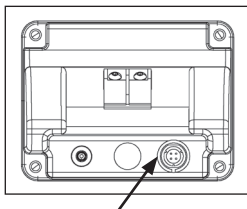


Figure 8 - TSMC Socket

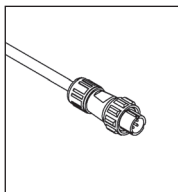


Figure 9 - TSMC cable end

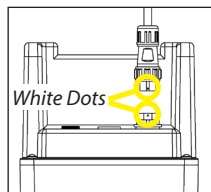


Figure 10 - Line up white dots

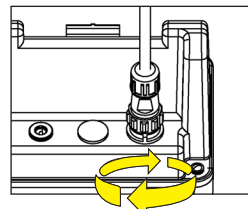


Figure 11 - Screw cable to socket

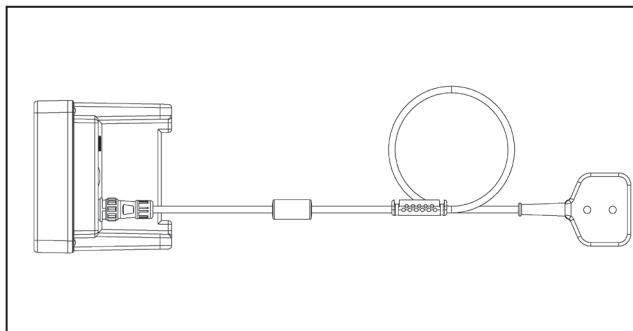


Figure 12 - Controller with TSMC connected.
(View from below)

Section 6.3 - TS Matrix

The TS Matrix consist 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 operational mode when connected to a charged Controller. Placing the Controller in standby mode will reduce the current flow to the TS Matrix and the TS Matrix will passively cool. This means that if thermal support from the TS Matrix is no longer required to maintain the infant's temperature, the TS Matrix can remain in position and the infant does not have to be disturbed.

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



The TS Matrix provides an even temperature over the whole surface and are flexible. The materials used for the TS Matrix have been tested for biocompatibility to allow skin contact during use.

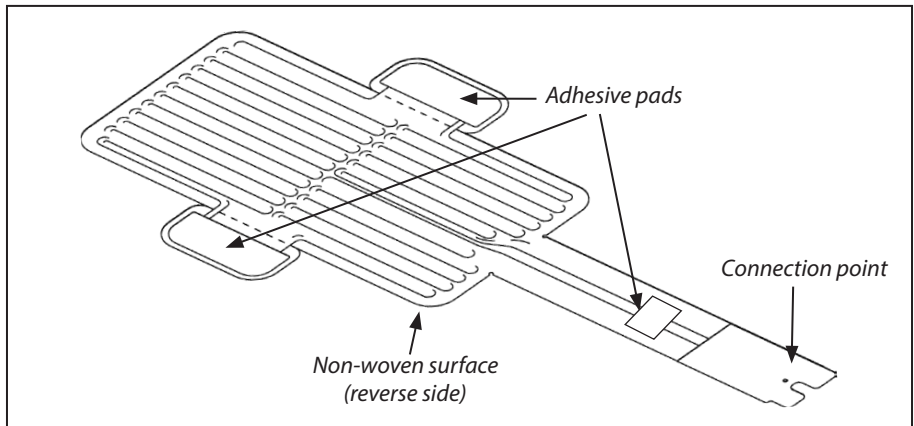


Figure 13 - TS Matrix

Using TS Matrix

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

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



Place TS Matrix on top of mattress.

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

When satisfied with position of the TS Matrix, peel of release paper from adhesive flanges and adhere to mattress. (Figure 15)

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

Consolidate the bond of the adhesive to the mattress by gently rubbing non-woven fabric on flanges of TS Matrix. (Figure 16)

Matrix is now secure to mattress. (Figure 17)

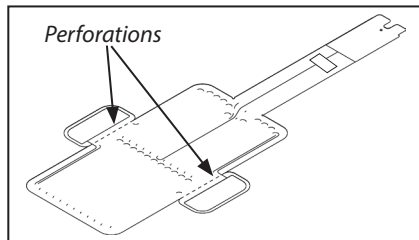


Figure 14 - Perforations

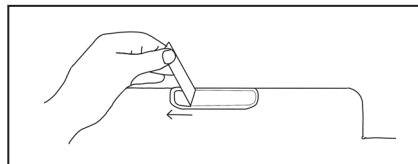


Figure 15- Removal of release paper from adhesive pads

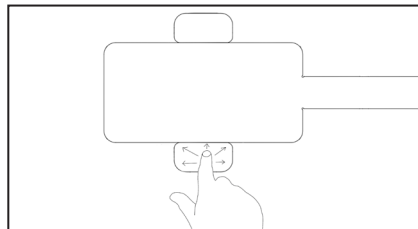


Figure 16 - Rub down adhesive flanges

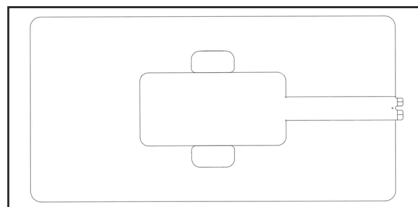


Figure 17 - Matrix secured to mattress

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

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

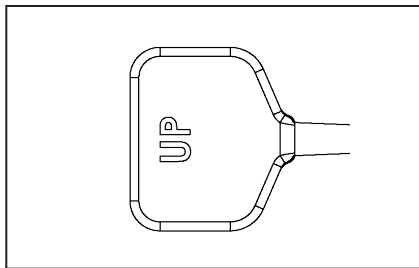


Figure 18 - TSMC marked 'UP' on one side

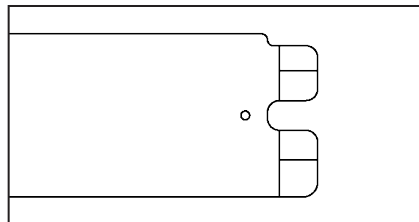


Figure 19 - TS Matrix connecting tail has asymmetrical cut outs and a guide hole to enable correct connection

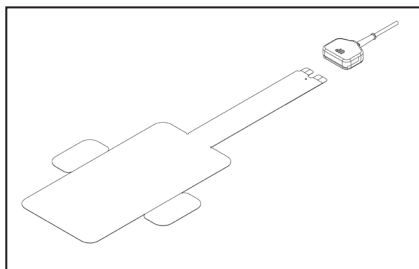


Figure 20 - Non-woven side up

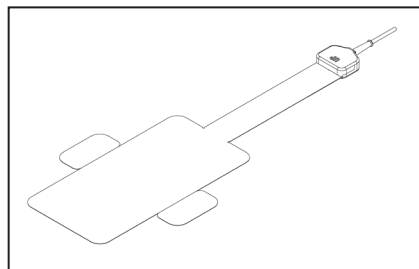


Figure 21 - Push TSMC onto TS Matrix

On completion of infant's healthcare activity, take off clamp, tear off TS Matrix (*Figure 22*). This will break the heater circuit.

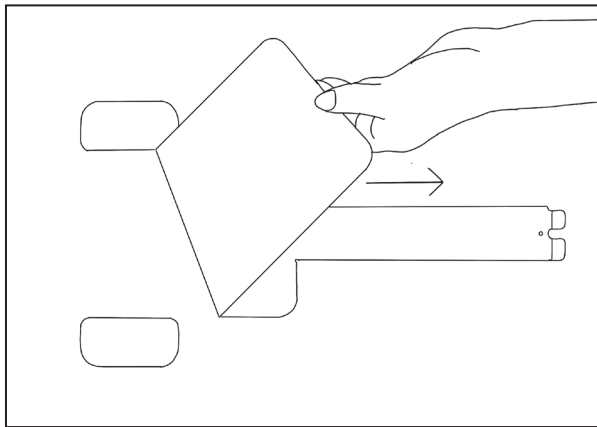


Figure 22

Adhesive flanges will be left in place. (*Figure 22*)

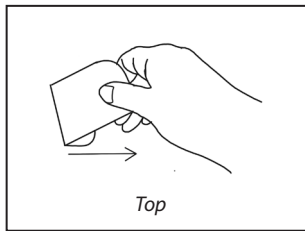


Figure 23

These flanges can be peeled off.
(*Figure 23 & 24*)

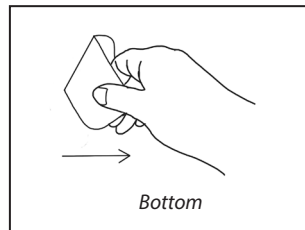


Figure 24

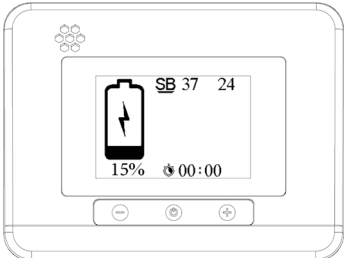
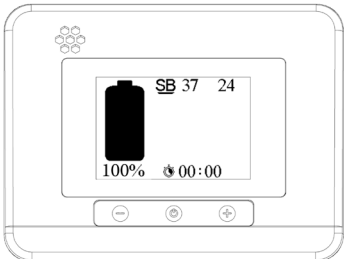
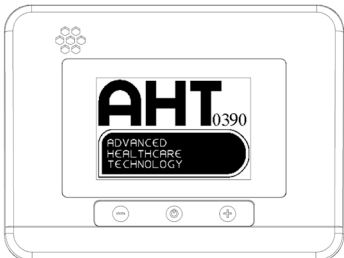
Remove adhesive flanges from mattress.

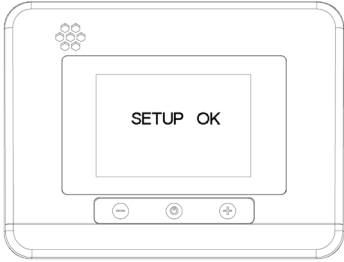
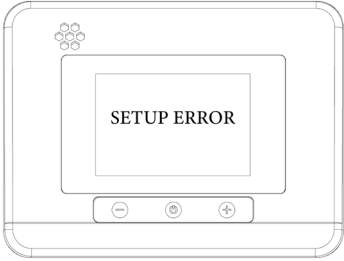
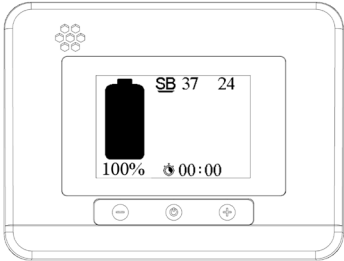
Note: If the TS Matrix flanges do not tear off on removal, then the TS Matrix must still be disposed, as they are single patient multiple use.

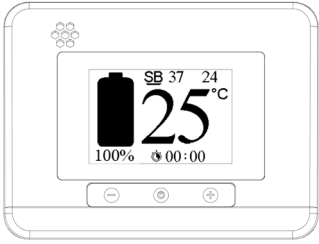
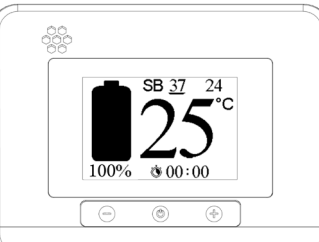
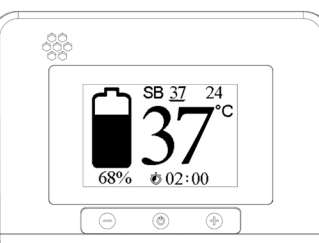
TS Matrix can be used with direct infant contact or separated with a layer of fabric.

Section 7 - Using the Controller

Screen shots showing Controller Graphic User Interface (GUI) and description of information displayed.

Mode	Description	Screen
<p>Charging batteries in Controller</p>	<p>Pressing On/Off for 3 Seconds whilst controller is being charged. Shows 'Lightning' Symbol indicating batteries are being charged and % battery charge (15% in this instance)</p>	
<p>Charging batteries in Controller</p>	<p>Battery now 100% charged. Disconnect Controller from Battery Charger.</p>	
<p>Start Up</p>	<p>Pressing On/Off for 3 Seconds. Shows AHT Screen and clicks 3 times.</p>	

Mode	Description	Screen
Start Up (TS Matrix connected)	SETUP OK, means that the TS Matrix is functional and okay to use.	 <p>The image shows a controller screen with a central display area. At the top left of the screen is a small icon of a flower-like symbol. The text 'SETUP OK' is centered on the screen. Below the screen are three buttons: a minus sign, a power button, and a plus sign.</p>
Start Up (TS Matrix not connected)	If a TS Matrix has not already been connected to the Controller this screen will appear temporarily. Attach TS Matrix.	 <p>The image shows a controller screen with a central display area. At the top left of the screen is a small icon of a flower-like symbol. The text 'SETUP ERROR' is centered on the screen. Below the screen are three buttons: a minus sign, a power button, and a plus sign.</p>
<u>SB</u> (TS Matrix not connected)	This shows Controller is in Standby (<u>SB</u>) Mode. This screen shows % Battery Charge (100% in this example, Ambient Temperature (where Controller is situated. 24°C in this example).	 <p>The image shows a controller screen with a central display area. At the top left of the screen is a small icon of a flower-like symbol. The screen displays a battery icon on the left, followed by 'SB 37 24'. Below the battery icon is '100%' and below the temperature is a clock icon followed by '00:00'. Below the screen are three buttons: a minus sign, a power button, and a plus sign.</p>

Mode	Description	Screen
<p><u>SB</u> (TS Matrix connected)</p>	<p>This shows Controller is in Standby (<u>SB</u>) Mode. This screen shows % battery charge (100% in this example), ambient temperature where Controller is situated (24°C in this example).</p>	
<p><u>37</u></p>	<p>This shows Controller in <u>37</u> Mode.</p>	
<p><u>37</u></p>	<p>Whilst operating in <u>37</u> mode the screen will show: % battery charge left (68% in this example); the temperature at the surface of the TS Matrix (37°C in this example); the ambient temperature where Controller is situated (24°C in this example) and time elapsed by a rotating clock face (2 hours in this example).</p>	

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

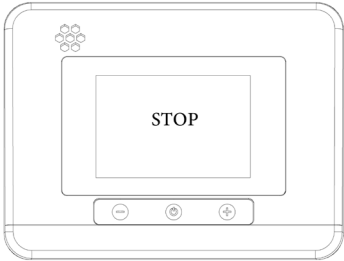
Note: If a TS Matrix is connected to the Controller during charging and an attempt is made to activate the TS Matrix whilst charging by pressing (+) to activate 37 mode, the Controller will stay in SB Mode until the Battery Charger is disconnected from mains electricity.

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

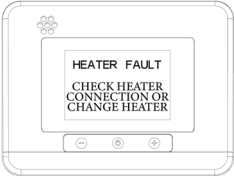
Note: Pressing (-) and hold until a beep is heard, Controller goes into standby (SB) mode. Elapsed time since initial activation will be retained but battery % will slowly discharge whilst in this mode.

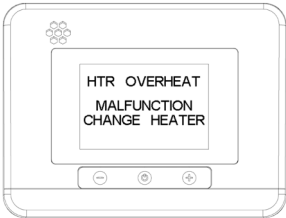
Note: If Controller is switched off, and then restarted the % battery will be indicated but the time elapsed will start at 00:00.


Note: If TS Matrix is disconnected and then reconnected the % battery will be indicated but the time elapsed will start at 00:00.

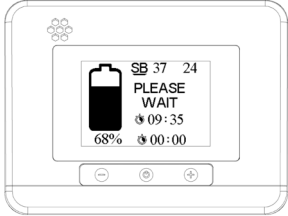
Mode	Description	Screen
<p><u>37</u></p>	<p>When battery has fully depleted screen will show 'STOP'.</p> <p>The Controller internal batteries will need to be charged before it can be used again.</p>	

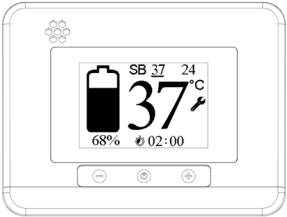
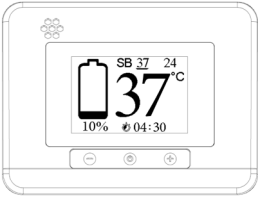
Section 8 - Alarms, User Alerts and User Actions

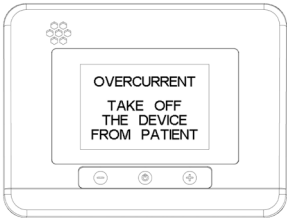

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	Heater Fault
<p><u>Actions to Clear / Silence</u></p> <p>Replace TS Matrix</p>	<p><u>Cause(s)</u></p> <p>Non-standard matrix connected to Controller</p>	<p><u>Actions</u></p> <p>Replace with approved AHT TS Matrix</p>

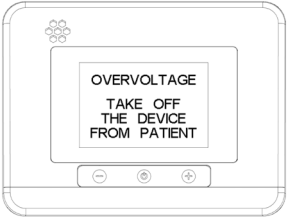
Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	<p>Temperature of TS Matrix >41°C. Controller will shut down.</p>
<p><u>Actions to Clear / Silence</u></p> <p>Resolve issue</p>	<p><u>Cause(s)</u></p> <p>Controller detects a resistance corresponding to a temperature above >41°C. (abnormal use, error, battery malfunction or non-standard matrix)</p>	<p><u>Actions</u></p> <p>Use only approved AHT TS Matrix. Where applicable, arrange repair of Controller.</p>


Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	TS Matrix disconnected during activation
<p><u>Actions to Clear / Silence</u></p> <p>Reconnect TS Matrix</p>	<p><u>Cause(s)</u></p> <p>Inadvertent or deliberate disconnection of TS Matrix when Controller is active in <u>37</u> mode.</p>	<p><u>Actions</u></p> <p>Correctly reconnect</p>

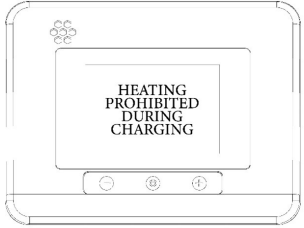
Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	TS Matrix has been disconnected when Controller is active in <u>37</u> mode.
<p><u>Actions to Clear / Silence</u></p> <p>Reconnect TS Matrix. Wait at least 10 minutes before reactivating. (Count down timer will indicate time remaining before system can be reactivated).</p>	<p><u>Cause(s)</u></p> <p>Inadvertent or deliberate disconnection of TS Matrix when Controller is active in <u>37</u> mode.</p>	<p><u>Actions</u></p> <p>After 10 minute countdown the Controller will default to <u>SB</u> mode. Activate system by pressing '+' to activate <u>37</u> mode.</p>

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	<p>2 second beep</p>	<p>Spanner symbol – Service required</p>
<p><u>Actions to Clear / Silence</u></p> <p>Arrange Service</p>	<p><u>Cause(s)</u></p> <p>300 Charge / Discharge Cycles</p>	<p><u>Actions</u></p> <p>Arrange service of Controller as soon as possible.</p>
Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	<p>2 second beep</p>	<p>Battery % = 10%</p>
<p><u>Actions to Clear / Silence</u></p>	<p><u>Cause(s)</u></p> <p>Battery now has 10% charge left.</p>	<p><u>Actions</u></p> <p>Review estimated time thermal support is required. Prepare additional thermal support if needed.</p>

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
 <p>OVERCURRENT TAKE OFF THE DEVICE FROM PATIENT</p>	2 second beep	<p>Battery safety. If the system detects an issue related to a larger than usual current value it shuts down to preserve the system</p>
<p><u>Actions to Clear / Silence</u> Ensure only AHT approved Battery Charger is being used</p>	<p><u>Cause(s)</u> Incorrect Battery Charger</p>	<p><u>Actions</u> Use only AHT approved Battery Charger</p>
Alarm On-Screen Message(s)	Audible Sound	Alarm Description
 <p>BATT OVERHEAT PLEASE WAIT</p>	2 second beep	<p>Battery safety. If the battery temperature reaches 50°C the system stops and waits for the battery temperature to go back down. If it reaches 80°C, the system automatically shuts off.</p>
<p><u>Actions to Clear / Silence</u> Ensure only AHT approved Battery Charger is being used</p>	<p><u>Cause(s)</u> Incorrect Battery Charger</p>	<p><u>Actions</u> Use only AHT approved Battery Charger</p>

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	<p>Battery safety.</p> <p>If the system detects an issue related to a larger than usual voltage value it shuts down to preserve the system.</p>
<p>Actions to Clear / Silence</p> <p>Ensure only AHT approved Battery Charger is being used</p>	<p>Cause(s)</p> <p>Incorrect Battery Charger</p> <p>Battery Malfunction</p>	<p>Actions</p> <p>Use only AHT approved Battery Charger</p> <p>Arrange repair</p>

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	<p>BRD means board. If the PCB board reaches 75°C the system stops thermal support and waits for the battery temperature to go back down. If temperature keeps rising, it will shut down automatically.</p>
<p>Actions to Clear / Silence</p> <p>Ensure only AHT approved Battery Charger is being used</p>	<p>Cause(s)</p> <p>Incorrect Battery Charger</p>	<p>Actions</p> <p>Use only AHT approved Battery Charger</p>

Alarm On-Screen Message(s)	Audible Sound	Alarm Description
	2 second beep	Whilst in <u>37</u> Mode, a mains connected battery charger has been connected to the Controller.
<p><u>Actions to Clear / Silence</u></p> <p>Disconnect the Battery Charger</p>	<p><u>Cause(s)</u></p> <p>Mains power connected battery charger has been connected to the Controller whilst in <u>37</u> Mode</p>	<p><u>Actions</u></p> <p>Do not use Controller when connected to a mains connected battery charger, whilst in <u>37</u> Mode</p>

Section 9 - Storage

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

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

Section 10 - Service & Maintenance

After 300 recharging cycles, the Controller can be serviced. A 'spanner' symbol will be displayed on GUI of Controller. This involves returning the Controller back to the manufacturer for review of battery condition and where applicable, fitting of replacement batteries and resetting the Controller.

A loan Controller will be made available during the servicing process.

If your Controller requires servicing then please contact:

Tel: +44 (0)1992 535933

Email: sales@babypod.com

Apart from cleaning there are no other maintenance or service requirements required.

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, TS Matrix should be disposed in accordance with local policies.

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

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	50kPa to 106kPa
Note	Higher storage temperatures will reduce the life of the internal battery
Use Conditions	
Temperature	0°C - 38°C
Humidity	10% to 70%RH
Pressure	50kPa to 106kPa
Settable Temperature Range	Fixed at 37°C (99°F)
Safety:	IEC 60601-1, IEC 60601-2-35
EMC Standards:	Emmissions - 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:	550g

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
Storage Conditions Temperature	5°C-35°C
Use Conditions Temperature	0°C-40°C

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

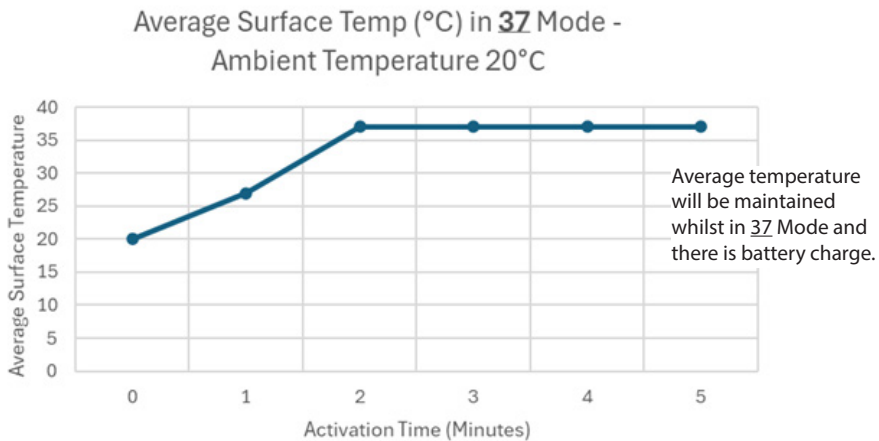
Section 14 – BP37 Performance

Figure 25 - Average surface temperature

Section 15 - Serious Incidents

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.

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 - Temperature Conversion

Celsius to Fahrenheit

°C	°F		°C	°F		°C	°F		°C	°F
20	68		26	79		32	90		38	100
20.5	69		26.5	80		32.5	91		38.5	101
21	70		27	81		33	91		39	102
21.5	71		27.5	82		33.5	92		39.5	103
22	72		28	82		34	93		40	104
22.5	73		28.5	83		34.5	94		40.5	105
23	73		29	84		35	95		41	106
23.5	74		29.5	85		35.5	96		41.5	107
24	75		30	86		36	97		42	108
24.5	76		30.5	87		36.5	98		42.5	109
25	77		31	88		37	99		43	109
25.5	78		31.5	89		37.5	100		43.5	110

Fahrenheit to Celsius

°F	°C		°F	°C		°F	°C		°F	°C
68	20		80	26.5		92	33.5		104	40
69	20.5		81	27		93	34		105	40.5
70	21		82	28		94	34.5		106	41
71	21.5		83	28.5		95	35		107	41.5
72	22		84	29		96	35.5		108	42
73	23		85	29.5		97	36		109	43
74	23.5		86	30		98	36.5		110	43.5
75	24		87	30.5		99	37		111	44
76	24.5		88	31		100	38		112	44.5
77	25		89	31.5		101	38.5		113	45
78	25.5		90	32		102	39		114	45.5
79	26		91	33		103	39.5		115	46

AHT

ADVANCED
HEALTHCARE
TECHNOLOGY

Manufactured in France on behalf of
Advanced Healthcare Technology Ltd.

Unit 6, The Mead Business Centre,
Mead Lane, Hertford, Herts. SG13 7BJ,
United Kingdom

Tel: +44(0)1992 535933

Email: sales@babypod.com

Web: www.babypod.com

EC

REP

Advanced Healthcare Technologies s.r.o.
Varšavská 715/36
120 00 Prague 2
Czech Republic



AHT-F-104 v2 01/25 BP37™ - Instructions For Use Manual
BP37 is a patented product.