



Infant Transport Device

Operating and Maintenance Manual

BabyPod 2™

Operating & Maintenance Manual

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Section 1.1 - Introduction

This manual contains instructions for initial set-up and inspection of BabyPod 2, proper operator use of the device, and care and maintenance of BabyPod 2.

Caution

Please read entire instruction manual prior to using BabyPod 2.

Warning

Patients may be harmed by the incorrect use of this device.

Section 1.2 - Warnings

- Only properly trained personnel who are aware of potential hazards or misuse should use BabyPod 2. Patients may be harmed by the incorrect use of this device.
- **DO NOT** leave baby unattended at any time while using BabyPod 2.
- **DO NOT** lean on BabyPod 2 or place weight on top of BabyPod 2's lid sections.
- **DO NOT** leave open containers of liquid on or near BabyPod 2. BabyPod 2's lid section will not prevent fluids from spilling onto the baby.

Section 1.3 - Cautions

- Always check the security of the Stretcher Fixing Straps prior to transport with BabyPod 2. Strap buckles make an audible click when fully engaged.
- **DO NOT** modify or make additions to any part of BabyPod 2.
- Only BabyPod 2 parts and accessories available through customer services and authorised representatives should be used to replace any components or accessories.
- Use only non-abrasive cleansers to clean BabyPod 2. Abrasive cleaners may damage the surface of BabyPod 2.
- Protect BabyPod 2 from the impact of sharp or hard objects that may cause internal damage that is not visible on the surface of the unit.
- BabyPod 2 should be inspected before each use for signs of damage to its carbon fibre Outer Shell. Remove Infant Positioning Straps, Vacuum Mattress and Shock Absorbent Foam and carefully inspect the inner surface of the carbon fibre shell for signs of stress, including cracks, pockmarks or irregularities. Discontinue use of BabyPod 2 if signs of stress or damage are present.
- Chips in the outer shell's surface due to normal wear and tear generally do not affect the performance of the BabyPod 2. Damage due to abrasive or rubbing actions may affect the performance and should be carefully inspected. Discontinue use of BabyPod 2 if signs of abrasive damage are present.

Section 2.1 - Product Description

BabyPod 2 consists of a lightweight carbon fibre outer shell, which is lined with a shock absorbent foam inner layer, and has a transparent lid for viewing the baby. BabyPod 2 contains a patient positioning vacuum mattress, stretcher fixing straps to secure the device for transport, and safety straps to position the infant inside the device during transport. BabyPod 2 is designed to provide safe conveyance of a patient whose weight is between 4.4-17.5 lbs. (2-8 kg)

Section 2.2 - Indications

BabyPod 2 is designed to safely convey a paediatric patient to or from a medical facility, between facilities or between departments within a single medical facility. BabyPod 2 is designed to provide safe conveyance of a patient whose weight is between 4.4-17.5 lbs. (2-8 kg)

BabyPod 2 has been designed to **exceed** the standard CEN 1789 (10g in six directions).

Section 2.3 - Components

| Part Number | Component Description |
|--------------------|-----------------------------------|
| BP2-001 | BabyPod 2 Infant Transport Device |
| BPOD2-002 | Vacuum Mattress |
| BPOD2-003 | Infant Positioning Strap Set |
| BP2-005 | Shock Absorbent Foam Set |
| BP20-006 | 9kN Stretcher Fixing Strap Set |
| BP2-007 | Viewing Lid Set |
| BP20-012 | Protective Storage Cover |

Section 2.4 - Accessories

USE ONLY BabyPod 2 approved accessories with this device. Patients may be harmed by the incorrect use of this device.

| Part Number | Description |
|--------------------|--|
| BP20-006-Aero | 9kN Stretcher Fixing Strap Set - Aero |
| BP20-013 | Protective Carry Bag |
| BP37-001 | BP37™ Infant Temperature Maintenance Kit |
| BPOD2-020 | Vacuum Pump |
| TRANS06 | TransWarmer® Infant Transport Mattress (Box of 6 pieces) |

Section 3.1 - Product diagram



Section 3.2 - Component descriptions

Outer Shell

The outer shell of BabyPod 2 is constructed of carbon fibre, producing a strong yet lightweight and durable material.

Shock Absorbent Foam

BabyPod 2's internal shock absorbent foam is constructed of polyurethane foam with a PUNL® removable cover, which remains breathable yet impervious to liquids and solutions. The foam interior surrounds the infant's head, feet and sides during transport and is designed to help protect the infant in event of impact, and reduce vibrations that might reach the patient from movements of the transporting vehicle. The covers can be removed and washed, allowing for increased infection control.

Vacuum Mattress

BabyPod 2's vacuum mattress is manufactured from a soft foil and is filled with flame-retardant polystyrene beads. Removal of the air from the vacuum mattress via the attached valve allows positioning of the baby within the BabyPod 2.

Infant Positioning Straps

BabyPod Infant Positioning Straps are manufactured from bands of soft foam which are attached using a hook and loop system. Each set is **SINGLE PATIENT USE ONLY**. BabyPods contains one set of 4 Infant Positioning Straps, 2 straps with pre-stitched hook tabs at each end and 2 straps with pre-stitched hook tab at one end only.

Stretcher Fixing Straps

The Stretcher Fixing Straps come in a set of two Side Straps, for fixing the BabyPod 2 width-wise to any stretcher or gurney, and one End Strap, for fixing the device length-wise to a stretcher or gurney. BabyPod 2's Stretcher Fixing Straps are composed of a high-tensile polyester webbing with attached metal quick-connect and release buckles.

Viewing Lid

The BabyPod 2's viewing lids are made from formed PETG with plastic hinges, allowing them to easily be cleaned and maintain durability. The large viewing area allows good visibility of the patient during transport. For additional access, there are four access ports on the top of the Viewing Lid. When stationary, the entire viewing lid can be opened, allowing total access to the entire patient compartment.

CO₂ Evacuation System

If concerned about CO₂ build-up in the patient compartment, this can be evacuated from the BabyPod 2. An air supply can be attached to the inlet on the 'front end' of the BabyPod 2, which, using only low pressure and jet flow and mixing principles, will draw the CO₂ from the BabyPod 2 interior and evacuate it via an outlet at the base of the BabyPod 2 'front end' section.

Section 4 - Environmental conditions

Environmental conditions may alter the use of BabyPod 2 slightly. Read the following specific instructions for more information.

Warning

- **DO NOT** leave BabyPod 2 in direct sunlight or near other radiant heat sources. Outside radiant heat sources may cause the baby to overheat.
- Secure BabyPod 2 to a stretcher or gurney when possible.
- BabyPod 2 may be hand-carried if no stretcher or gurney is available (e.g. Search and Rescue recovery). If BabyPod 2 is to be used in the absence of a stretcher or gurney, attach one Side Strap to both Stretcher Fixing Strap anchors on the same side of BabyPod 2. Repeat for the other Side Strap. Pull Side Straps up above the viewing area and hand-carry the device if necessary.

Please read the following instructions carefully and completely to minimise injury to BabyPod 2 operators and attendants.

Section 5.1 - Unpacking BabyPod 2

Carefully and completely remove the packing material surrounding the BabyPod 2 and place the device (in its protective storage cover) on a smooth surface for inspection.

Section 5.2 - Inspecting BabyPod 2

Careful inspection of BabyPod 2 prior to use is critical. Follow these steps in order to avoid overlooking important visual inspections.

Warning
Carefully inspect BabyPod 2 between each use. A damaged device may harm patient.

Warning
Patients may be harmed by the incorrect use of this device.

1. Place BabyPod 2 on a smooth surface for inspection.
2. Remove BabyPod 2 carefully from its protective storage cover and/or bag.
3. Release the black lid turn knob mechanism at the 'Front and Rear ends' of the BabyPod 2. Fully open the lids being careful not to bump the viewing lid on any surrounding objects.
4. Remove the loose contents and the accessories of the BabyPod 2.
5. Note: Infant Positioning Straps are already fastened into position and should not be removed until they require replacement for a new patient or during cleaning.
6. Inspect the Side and End Stretcher Fixing Straps for integrity, making sure that the metal buckle is securely attached to the straps. DO NOT use any component that does not pass visual inspection.
7. Remove Vacuum Mattress from BabyPod 2. Inspect the mattress for holes or other obvious flaws.
8. Remove Shock Absorbent Foam interior. Inspect covers for any cuts or abrasions. Lay foam aside for re-assembly later.
9. Inspect Outer Shell for cracks or abrasions. First, inspect the inner carbon fibre surface of BabyPod 2's Outer Shell.

Note: Smoothness is not a requirement. Natural irregularities in texture due to the nature of the manufacturing process and materials are normal. Second, inspect the outer surface of BabyPod 2. Look for signs of stress due to abrasions.

10. Check the security of the Stretcher Fixing Strap Anchors on each side of BabyPod 2 and at the rear end of the device (total of 5). Anchors should be firmly affixed to the device.
11. Carefully close Viewing Lids back over the BabyPod 2, checking operation of each hinge mechanism. Inspect Viewing Lid sections carefully for cracks or irregularities. When the BabyPod 2 is closed, the Viewing Lid should be evenly aligned along the lengthwise axis of the device.
12. Inspect the Access Covers checking that they open freely and locate securely when it's closed position. These friction hinges can be adjusted to users requirements.

Section 5.3 - Re-assembly of BabyPod 2

Once BabyPod 2 has been thoroughly inspected and cleared for use, the device must be re-assembled. Re-assemble BabyPod 2 according to the following instructions.

Place BabyPod 2 on a smooth surface for re-assembly.



Release the turn lock mechanism at both ends of BabyPod 2 and open both lid sections.



Section 5.3 - Re-assembly of BabyPod 2 - continued

Beginning with the 'Front end' and 'Rear end' sections, place Shock Absorbent Foam pieces inside the interior of BabyPod 2.



Attach the 4 Infant Positioning Straps, one at each end of each interior locating rail using the pre-stitched hook material, sliding under the rail and back onto itself.



Insert the "Side" foam panels, being sure to locate the end of each into the recesses in both the "Front end" and the "Rear end" sections already in place. When foam is properly located, secure "Side" foam to the BabyPod 2 interior with the attached loop to each side.



Section 5.3 - Re-assembly of BabyPod 2 - continued

Insert the “Base” foam section into the bottom of the BabyPod, making sure to keep the 4 Infant Positioning Straps Accessible. On top of this, place Vacuum Mattress with the vacuum port, where the feet of the baby will be (recommended), with the valve facing up. The valve should be in the open position (tubing sections fully engaged with the black “O” ring hidden from view) to allow air to enter the mattress. Spread the polystyrene bead contents of the mattress evenly by hand.



Pass each Infant Positioning Strap through its corresponding slot in the Vacuum Mattress. There are two available slots for each strap to cater for larger or smaller patients.



At this stage, the Vacuum Mattress should be tested according to the instructions in Section 5.4.

Once the Vacuum Mattress has been tested, any thermal support accessories can be put in place and activated if required.



Section 5.3 - Re-assembly of BabyPod 2 - continued

Attach one End, and two Side Stretcher Fixing Straps to BabyPod 2. Insert male latch into female anchor buckle. Listen for the click to indicate a secure connection.



Carefully close Viewing Lid back over the BabyPod 2, and close turn knobs, checking that the mechanism is fully engaged and the Viewing Lid secure.

BabyPod 2 is now ready for use.

Section 5.4 - Testing the Vacuum Mattress

The Vacuum Mattress valve consists of one long tubing section, and one short tubing section (marked by a black "O" ring).

To open the valve prior to vacuum suctioning, press the short tubing section into the long section. An audible click will sound when the sections are properly engaged and the "O" ring will no longer be visible. Vacuum may be applied once the two sections are engaged.

Valve open = Black "O" ring **NOT** visible

Valve closed = Black "O" ring visible

Check the integrity of the Vacuum Mattress valve by applying vacuum to the open valve (long and short tubing sections properly engage with the black "O" ring hidden from view) to suction air from inside the mattress.

If operating properly, the Vacuum Mattress should lose its mouldability and become stiff. Once the Vacuum Mattress has been suctioned successfully, depress grey tab on the Vacuum Mattress valve to close valve. Check mattress to see that it does not re-inflate but retains its moulded shape. Re-connect the valve sections (listen for the click to indicate successful engagement) to open the vacuum valve and allow air to re-enter the mattress. This will prepare the mattress for use.

Warning
Do not use the Vacuum Mattress if it does not pass this inspection



Connect the two sections of tubing until an audible "click" is heard and the black "O" ring disappears from view. This opens the valve, allowing air to be removed from the mattress via suction.

Section 6 - Operating instructions

Warning

Carefully inspect BabyPod 2 between each use. A damaged device may harm patient.

Warning

Patients may be harmed by the incorrect use of this device.

Section 6.1 - Securing BabyPod 2 to Transport Stretcher or Gurney

The Side Straps attached to the Stretcher Fixing Strap Anchors are used to secure BabyPod 2 to the stretcher or gurney or to hand carry the device.

Position BabyPod 2 in the centre of the stretcher making sure that it is facing in the proper direction. The 'Front end' of BabyPod 2 should be placed at the head of the stretcher.

Note: See direction of travel arrow on the outer shell of BabyPod 2.



Side Stretcher Fixing Straps

Connect male connector of side stretcher strap to Side Stretcher Fixing Strap Fixing Anchor at 'front end' of BabyPod. Feed second male connector on Side Stretcher Fixing Strap underneath stretcher base and connect male connector to corresponding Stretcher Fixing Anchor on other side of BabyPod. **Connections are secure when a click is heard.** Pull strap to tighten. Repeat for stretcher straps at 'rear end' of BabyPod.



End Stretcher Fixing Straps

Feed loop end of End Stretcher Fixing Strap underneath foot bar of stretcher with flat part of loop facing BabyPod. Feed male connector through loop. Pull stretcher strap until loop is taut. Connect male connector to female connector on 'end' Stretcher Fixing Anchor. **Connections are secure when a click is heard.** Pull strap to tighten.



Re-check the security of all Stretcher Fixing Straps to ensure patient safety before transport!

Section 6.2 - Opening BabyPod 2

Release the black turn knobs mechanism at both ends of the BabyPod 2, and open the viewing lids being careful not to bump the viewing lid on any surrounding objects.

Caution

Always use two hands to lift Viewing Lid and exercise extreme caution not to drop the lid onto the BabyPod 2 from its raised position.

Warning

Improper handling and use of the Viewing Lid mechanism risks harm to the device and to the patient.

Section 6.3 - Place thermal support accessories if required

Refer to any relevant information for use leaflets for operating instructions of any accessories.

Note: To order accessories, contact our Customer Service Department at:

Tel: +44 (0)1992 535933

Email: sales@babypod.com

Section 6.4 - Placing baby inside BabyPod 2

Place the baby in the BabyPod 2 with either head or feet in 'front end' section of the BabyPod 2. The orientation of the baby shall be determined by the clinician based on the monitoring and medical aid requirements of the baby during transportation and the layout of the transport vehicle.

Warning

Patients may be harmed by the incorrect use of this device.

Section 6.5 - Operating Vacuum Mattress

Check to see that the Vacuum Mattress valve is at the baby's feet. Valve should be open with the long and short tubing sections engaged (black "O" ring hidden).

Check to see that the baby is in the desired position for transport.

Place vacuum source into short tubing section on Vacuum Mattress valve and slowly suction air from the mattress while hand shaping the mattress around the baby. As air is removed, the Vacuum Mattress acts as a positioning and retaining shell for the baby.

Warning

Improper use of the Vacuum Mattress may cause injury to the patient during transport.

Once the Vacuum Mattress is in the desired position, remove the vacuum source and close the mattress valve by depressing the grey tab and disengaging the long and short tubing sections. Once disengaged, the short tube's black "O" ring is visible.

Section 6.6 - Securing baby inside BabyPod 2

Once the baby is properly positioned and the air removed from the Vacuum Mattress, position the baby in the BabyPod 2 using the Infant Positioning Straps.

Making sure that the straps have been passed through its corresponding slot on the Vacuum Mattress, take one Infant Positioning Strap from the 'rear end' of the BabyPod 2 and the strap from the 'front end' on the opposite side and cross them over the baby's torso. Secure the straps together using the pre-stitched hook tab.

Warning

Patients may be harmed by the incorrect use of this device.

Repeat this procedure with the corresponding front and rear straps on the opposite side. The two Infant Positioning Straps, when properly engaged, should form an "X" across the baby's torso. Infant Positioning Straps should be snug across the baby's torso, but not apply undue pressure. Improper use of the Infant Positioning Straps may cause injury to the patient during transport.

Warning

Each set of Infant Positioning Straps are **SINGLE PATIENT USE ONLY**



Section 6.7 - Closing BabyPod 2 with baby enclosed

Check baby's positioning before closing BabyPod 2. Re-check the security of the Infant Positioning Straps before closing the device.

Carefully close Viewing Lids back over the BabyPod 2 Outer Shell, using two hands at all times. Take care at all times that any ventilator or IV tubing passing through the Tubing Access Ports on the ends of the BabyPod 2 do not become trapped under the Viewing Lid.

DO NOT transport a baby without verifying the security of the Viewing Lid.

Re-check the security of the Stretcher Fixing Straps before transporting baby. If straps have become loose, tighten by grasping the webbing and pulling away from the slider buckles.

Re-check the security of BabyPod 2's closure to ensure patient safety.



Warning

Patients may be harmed by the incorrect use of this device.

Section 6.8 - Monitoring baby inside BabyPod 2

Monitor baby visually while using BabyPod 2.

To minimise heat loss during transport, leave patient access port in Viewing Lid in the closed position during transport unless the baby requires active care.

Section 6.9 - Removing baby from BabyPod 2

To remove baby from BabyPod 2, release the black lid lock turn knobs at both ends of BabyPod 2 and open lids, being careful not to bump the viewing lid on any surrounding objects.

Remove Infant Positioning Strap from across the baby's torso, being careful not to disturb any ventilator or IV tubing.

Open the Vacuum Mattress vacuum valve by pressing the two valve sections together. The click indicates proper engagement. The mattress should fill with air and become soft and mouldable.

Carefully lift the baby from BabyPod 2, making sure that any ventilator or IV tubing clears the patient compartment.

Warning

Patients may be harmed by the incorrect use of this device.

Section 7 - Cleaning BabyPod 2

Caution

BabyPod 2 should be thoroughly cleaned and inspected after each patient use.

See Section 5 for Step-by-step Safety Inspection Instructions

Abrasive, harsh or non water-based cleansers may damage BabyPod 2's carbon fibre Outer Shell. **USE ONLY** mild water-based, non-abrasive cleansers and a soft, absorbent cloth to clean the Outer Shell. Dry BabyPod 2 with a soft, absorbent cloth.

Clean BabyPod 2's internal component using only mild water-based cleansers in accordance with hospital protocol.

Section 8 - Maintenance of BabyPod 2

Follow cleaning instructions in Section 7 for general care of BabyPod 2. Special care is needed for both the carbon fibre Outer Shell and the Vacuum Mattress as noted below:

- **Outer Shell**

BabyPod 2 should be inspected at regular intervals for signs of damage to its carbon fibre Outer Shell (see Section 5.2 for step-by-step instructions). For best results, remove Infant Positioning Straps, Vacuum Mattress and Shock Absorbent Foam and carefully inspect the inner surface of the carbon fibre shell for signs of stress, including cracks, pockmarks or irregularities.

Discontinue use of BabyPod 2 if signs of damage are present.

BabyPod 2's Outer surface does not affect the integrity of the carbon fibre shell. Chips or scratches to BabyPod 2's finished outer surface due to normal wear and tear do not affect the performance of the unit.

Inspect BabyPod 2's Outer Shell for cracks and abrasions. First, inspect the inner carbon fibre surface of BabyPod 2's Outer Shell.

Note: Smoothness is not a requirement. Natural irregularities in texture due to the manufacturing process are normal.

Note: Cracks in the carbon fibre Outer Shell may not be apparent by visual inspection of the outer surface. Always check the inside surface of the Outer Shell for accurate visual assessment.

DO NOT use any component that does not pass visual inspection.

Inspect the integrity of the carbon fibre rods inside BabyPod 2's Outer Shell. Check the security of the attached Infant Positioning Straps before re-inserting the Shock Absorbent Foam interior panels. Infant positioning straps should be connected at an angle so that straps secure in a cross-wise "X" fashion over the baby's torso.

Warning

Each set of Infant Positioning Straps are **SINGLE PATIENT USE ONLY**

Protect BabyPod 2 from the impact of sharp or hard objects that may cause internal damage that is not visible on the surface of the unit.

Section 8 - Maintenance of BabyPod 2 - continued

Under **NO** circumstances should modifications or additions be made to BabyPod 2.

Clean BabyPod 2's Outer Shell with only a soft, absorbent cloth or wipe.

- **Vacuum Mattress**

BabyPod 2's Vacuum Mattress is constructed of a soft foil material which can be easily damaged by sharp objects. Keep all sharp objects away from the Vacuum Mattress to protect its internal components.

Test the Vacuum Mattress between each patient use. See **Section 5.2** for step-by-step safety inspection instructions and **Section 5.4** for testing procedures.

Note: Only genuine BabyPod 2 parts and accessories should be used to replace any components or accessories. For replacement or additional parts, contact our customer service department at:

Tel: +44 (0)1992 535933

Email: sales@babypod.com

Warranty Statement

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 9 - Storage of BabyPod 2

BabyPod 2 should be stored in its protective storage cover or protective carry bag when not in use. BabyPod 2 should be stored at room temperature in an area that is clean, dry and not exposed to direct sunlight.



Section 10 - Troubleshooting

Basic troubleshooting for BabyPod 2 appears below. If there are questions or concerns not addressed below, take BabyPod 2 out of service and contact our Customer Service Department.

| Problem | Possible cause | Correction | Section |
|--|---|--|---------|
| Visual damage to BabyPod 2 Outer Shell | Damaged due to sharp objects or blunt force. | Inspect inside of carbon fibre Outer Shell for cracks, replace if necessary. | 8 |
| Buckle not fully engaged | Inadequate connection. | Listen for audible click to engage fully. | 6.1 |
| Baby not secure within patient compartment | Vacuum Mattress not correctly suctioned. | Suction air from Vacuum Mattress with baby in place. | 6.6 |
| Baby not secure within patient compartment | Infant Positioning Straps not properly secured. | Secure Infant Positioning Straps. | 6.6 |
| Lid opens during transport | BabyPod 2 Viewing Lid not properly secured. | Check that viewing lid turn knobs are properly engaged. | 6.7 |

Section 11 - Summary

The following summary is not intended to take place of the full Operating Instructions for use of BabyPod 2.

BabyPod 2 Product Description and Indication for Use

BabyPod 2 is designed to safely convey a paediatric patient to or from a medical facility, between facilities or between departments within a single medical facility. BabyPod 2 consists of a lightweight carbon fibre outer shell which is lined with a shock absorbent foam inner layer, and has transparent shields for viewing the baby. BabyPod 2 contains a patient positioning vacuum mattress, stretcher fixing straps to secure the device for transport, and safety straps to position the baby inside the device during transport.

Safety Inspection Steps Prior to operating BabyPod 2

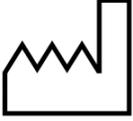
1. Unpack BabyPod 2
2. Inspect BabyPod 2
3. Re-assemble BabyPod 2
4. Test the Vacuum Mattress

BabyPod 2 Operating Instructions

1. Secure BabyPod 2 to transport stretcher or gurney
2. Open BabyPod 2
3. Place thermal support accessories if required
4. Place baby inside BabyPod 2
5. Operate the Vacuum Mattress
6. Secure baby inside BabyPod 2
7. Close BabyPod 2 with baby enclosed
8. Monitor baby inside BabyPod 2

Section 12 - Regulatory Information

Symbols:

| | |
|---|--|
|  | <p>CE Marking of Conformity</p> |
|  | <p>Authorized Representative in the European Community</p> |
|  | <p>Catalogue Number</p> |
|  | <p>Serial Number</p> |
|  | <p>Consult Instructions for use</p> |
|  | <p>Medical Device</p> |
|  | <p>Manufacturer</p> |
|  | <p>Date of Manufacture</p> |
|  | <p>Unique Device Identifier</p> |

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.

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