



Infant Transport Device

Operating and Maintenance Manual

SCANPOD®

Operating and Maintenance Manual

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Section 1.1 - Introduction

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



Caution

Please read entire instruction manual prior to using ScanPod.



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 of misuse should use ScanPod.
- **DO NOT** leave baby unattended at any time while using ScanPod.
- **DO NOT** lean on ScanPod or place weight on top of ScanPod's lid sections.
- **DO NOT** leave open containers of liquid on or near ScanPod. ScanPod's lid section will not prevent fluids from spilling onto the baby.
- If using a TransWarmer, **ALWAYS** read the instructions of the TransWarmer.
- Only use accessories approved by AHT for the ScanPod.
- The ScanPod must **ALWAYS** be carried by 2 people. Extra care must be taken when lifting and carrying the ScanPod by hand with an infant present inside.
- **DO NOT** transport a baby without securing the Viewing Lid in place.
- **DO NOT** use any component that does not pass visual inspection or tests.

Section 1.3 - Cautions



- Always check the security of the Stretcher Fixing Straps prior to moving the ScanPod on a trolley. Strap buckles make an audible click when fully engaged.
- **DO NOT** modify or make additions to any part of ScanPod.
- Only AHT approved parts and accessories should be used.
- Use only non-abrasive cleansers to clean ScanPod. Abrasive cleansers may damage the surface of ScanPod.
- Protect ScanPod from the impact of sharp or hard objects.
- ScanPod should be inspected before each use for signs of damage to its Outer Shell. Remove Infant Positioning Straps, Vacuum Mattress and Shock Absorbent Foam and carefully inspect the inner surface of the shell for signs of stress, including cracks, pockmarks or irregularities.
- Chips in the Outer Shell's surface due to normal wear and tear generally do not affect the performance of the ScanPod. Damage due to abrasive or rubbing actions may affect the performance and should be carefully inspected. Discontinue use of ScanPod if signs of abrasive damage are present.
- If using a gurney, stretcher or Dock always secure ScanPod prior to moving.
- Extra care should be taken, if positioning the focus coil receiver plate in place, when a baby is present.
- ScanPod should be thoroughly cleaned after each patient use.

Section 2.1 - Product Description

ScanPod consists of a lightweight composite shell, which is lined with a shock absorbent foam inner layer, and has a transparent lid for viewing the baby. ScanPod contains a patient positioning vacuum mattress, stretcher fixing straps to secure the device for transport in hospital to the MRI unit, and infant positioning straps to secure the infant inside the device during transport. ScanPod is designed to provide safe conveyance and imaging of a patient whose weight does not exceed 17.5 lbs (8 kg).

For a list of approved accessories and ancillary equipment contact AHT.

Non-clinical testing has demonstrated that the ScanPod is MR Conditional. There is no projectile risk. It can be safely scanned under the following conditions: static magnetic field of 3T or less.

**Section 2.2 - Indications**

ScanPod is designed to safely convey an infant within a single medical facility, and to provide a comfortable and protective environment for the patient during MRI. ScanPod is designed to provide safe conveyance of a patient whose weight does not exceed 17.5 lbs (8 kg). ScanPod's unique metal-free construction ensures that it is X-Ray, MRI & CT compatible.

Section 2.3 - Contraindications

The ScanPod is not designed to be used in Road or Air Transport.

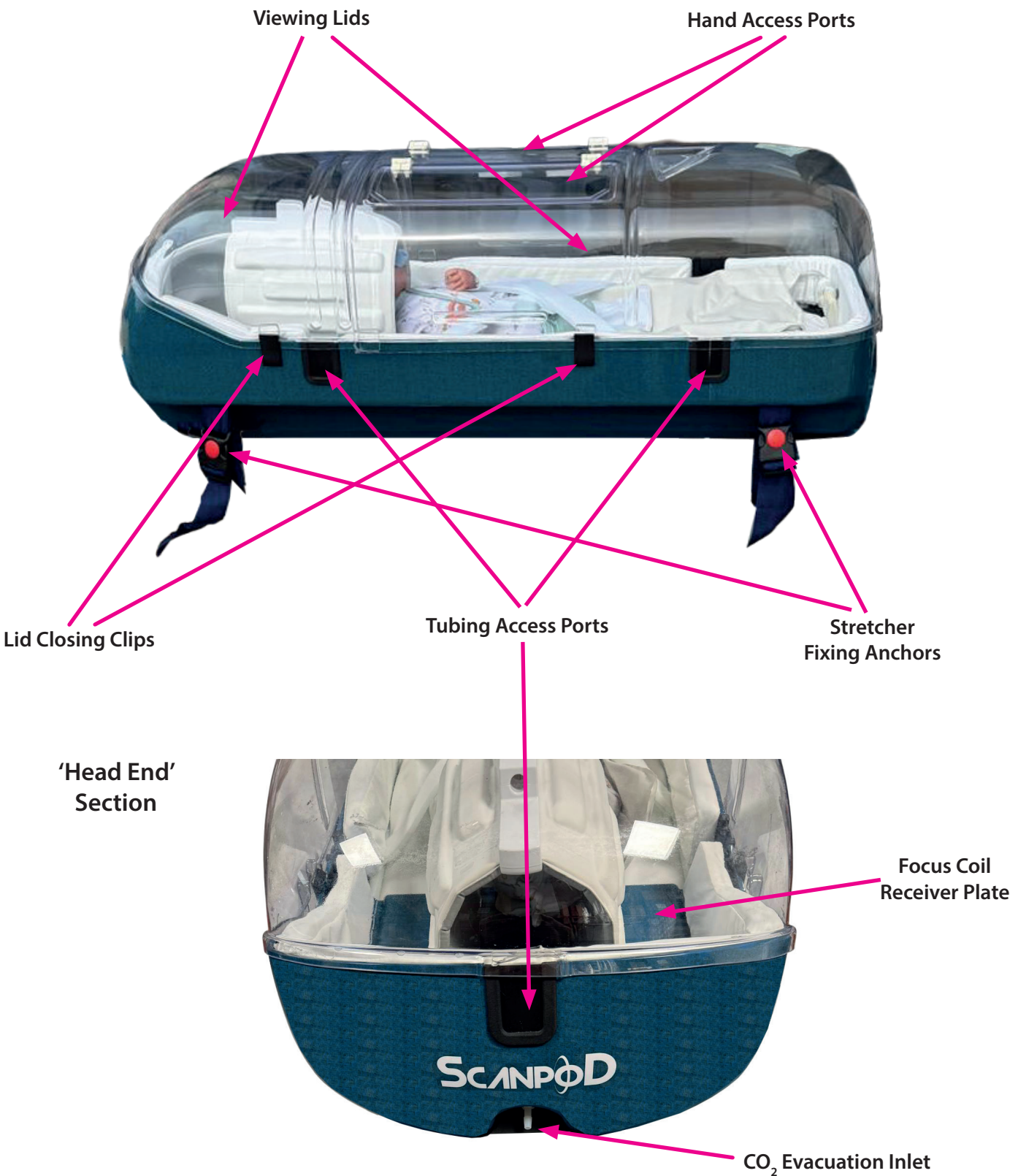
The ScanPod should not be used in MRI outside of the conditions stated in Section 9.

Section 2.4 - Components and Accessories

USE ONLY ScanPod approved accessories for this device.

Part Number	Description
SPOD-001	ScanPod Infant Transport Device
SPOD-002	ScanPod Vacuum Mattress
BPOD2-003	Infant Positioning Strap Set
SPOD-005	ScanPod Shock Absorbent Foam Set
SPOD-006	ScanPod Stretcher Fixing Strap Set
BPOD-012	Protective Storage Cover
SPOD-013	ScanPod MRI Dock and Fittings
TRANS06	TransWarmer® Infant Transport Mattress (Box of 6 pieces)

Section 3.1 - Product Diagram



Note: Images in this IFU are for illustrative purposes only. Some parts shown, may differ.

Section 3.2 - Component Descriptions

Outer Shell

The Outer Shell of ScanPod is constructed of epoxy resin composite material to produce a strong, lightweight and durable material, suitable for use in MRI, CT and X-Ray environment.

Shock Absorbent Foam Set

ScanPod's internal Shock Absorbent Foam Set is constructed of polyurethane foam with a PUNL® removable cover. ScanPod's internal Shock Absorbent Foam surrounds the infant during transport and is designed to help protect the patient from vibration and noise.

Vacuum Mattress

ScanPod's Vacuum Mattress is manufactured from soft PVC and is filled with flame-retardant, polystyrene beads. Removal of air from the Vacuum Mattress via the attached valve allows positioning of the baby within the ScanPod.

TransWarmer® Infant Transport Mattress (Accessory)

The TransWarmer® may be used to provide warmth for the infant to lie on. Always read the instructions of the TransWarmer prior to use.

Infant Positioning Straps

ScanPod's Infant Positioning Straps are manufactured from bands of soft foam, which are attached using a hook and loop system. Each set is **single patient multiple use**.

Stretcher Fixing Straps

The Stretcher Fixing Straps are used for fixing the ScanPod to a stretcher, gurney or Dock. ScanPod's Stretcher Fixing Straps are composed of thick nylon webbing with attached quick-release nylon latches.

Closure Clips

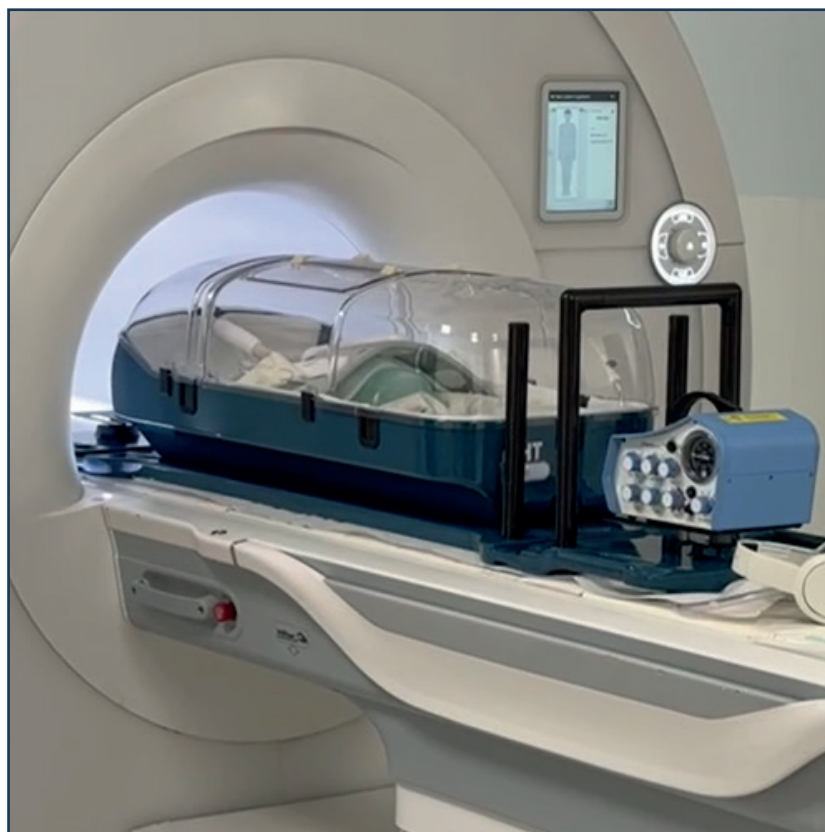
The Closure Clips are permanently affixed to the Outer Shell and are used to secure the Viewing Lid sections in place.

CO₂ Evacuation System

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

Section 4 - Environmental Conditions for Use and Storage

- **DO NOT** leave ScanPod in direct sunlight or near other radiant heat sources for long periods.
- The ScanPod is designed to be used and stored in a single healthcare facility.
- The ScanPod should be used and stored at room temperature between 18°C and 24°C.
- The ScanPod should be stored in its protective cover.



Section 5.1 - Unpacking ScanPod

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

Section 5.2 - Inspecting ScanPod

Always inspect the ScanPod prior to use following these steps.

1. Place ScanPod on a smooth, flat surface for inspection.
2. Carefully remove ScanPod protective storage cover.
3. Unclip Closure Clips from the ScanPod to release Viewing Lids.
4. Carefully remove ScanPod Viewing Lid and place on smooth surface.
5. Remove Vacuum Mattress from ScanPod. Inspect the mattress for holes or other obvious flaws.
6. Remove Shock Absorbent Foam. Inspect foam for cuts or abrasions. Lay foam aside for re-assembly later.
7. Inspect Outer Shells inner and outer surfaces for cracks, or signs of stress due to abrasions.

Note: Smoothness is not a requirement.

Natural irregularities in texture due to the manufacturing process are normal.

8. Inspect the integrity of the rods inside ScanPod's Outer Shell. Check the security of the attached Infant Positioning Straps before reinserting Shock Absorbent Foam.
9. Check the security of the Stretcher Fixing Strap Anchors on each side of ScanPod. Anchors should be firmly affixed to the device and that the latches are securely attached to the straps.
10. Attach Viewing Lid sections carefully by placing onto the ScanPod shell, inspecting for cracks or irregularities. When ScanPod Viewing Lids are attached, the lid sections should be secured with the Closing Clips.

Section 5.3 - Re-assembly of ScanPod

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

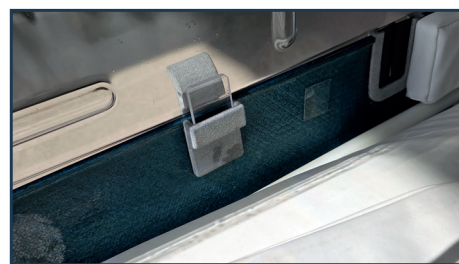
1. Place ScanPod on a smooth, flat surface for reassembly.
2. Attach Infant Positioning Straps to the rods.
3. Place Shock Absorbent Foams (side / bottom pieces) into ScanPod being careful to position Infant Positioning Straps under the Side foam pieces.



4. Place Vacuum Mattress with the vacuum port at the foot of the ScanPod with the valve facing up. The valve should be in the open position (tubing sections fully engaged with black "O" ring hidden from view) to allow air to enter the mattress. Spread the contents of the mattress evenly by hand.
5. Test Vacuum Mattress according to the instructions in Section 5.4.



6. If using a TransWarmer, place the TransWarmer Infant Transport Mattress with the printed side up so that it is ready to be activated. Once activated, the TransWarmer should be turned over, so that the soft non-woven side faces up and placed on the Vacuum Mattress.
7. Attach Side Stretcher Fixing Straps to the ScanPod. Insert male latch into female (anchor) buckle. Listen for the click to indicate a secure connection.
8. Replace the Viewing Lids carefully over the patient compartment, using the clips and guide to secure.
9. Secure the larger rear lid first, slotting into the clips and rear guide. Then, place the front section, overlapping the front section, also slotting into their relevant clips.



ScanPod 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.



Section 6.1 - Securing ScanPod to Transport Stretcher / Gurney / Dock

The Side Straps attached to the Stretcher Fixing Strap Anchors are used to secure ScanPod to the stretcher, gurney or Dock. If using a Dock be sure to fix the ScanPod to the Dock before attaching to the stretcher or gurney.

Position ScanPod in the centre of the stretcher.

Connections are secure when a click is heard. Pull on the webbing strapping downwards and away from the slider buckle to tighten straps.

Re-check the security of all Stretcher Fixing Straps to ensure patient safety before moving.

Section 6.2 - Opening ScanPod

Open ScanPod carefully by unclipping the Closure Clips of the ScanPod. Remove the Viewing Lids and carefully place on a flat surface.

Section 6.3 - Placing Baby inside ScanPod

Check Vacuum Mattress valve is at the 'feet end' of the ScanPod.

If a TransWarmer is being used, ensure it is activated and it is in the centre of the Vacuum Mattress with the non-woven side upwards. Always read the Instructions for Use of the TransWarmer before use.

Place baby into ScanPod making sure that the baby's head is nearest the "Head" end.

Section 6.4 - Operating the Vacuum Mattress

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 on Vacuum Mattress valve and slowly suction air from the mattress while hand shaping the mattress around the baby.

As the air is removed, the Vacuum Mattress acts as a positioning and restraining shell for the baby. 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 6.5 - Securing Baby inside ScanPod

Once the baby is properly positioned in the Vacuum Mattress, secure the baby in the ScanPod using the Infant Positioning Straps.

Take one Infant Positioning Strap from the foot end of the ScanPod and the strap from the head end on the opposite side and cross them over the baby's torso.

Secure the straps together using the hook tab.

Repeat this procedure with the corresponding head and foot straps on the opposite side.

The Infant Positioning Straps, when properly engaged, should form an "X" across the baby's torso, as shown below.

Infant Positioning Straps should be snug across the baby's torso.

Improper use of the Infant Positioning Straps may cause injury the patient during transport.

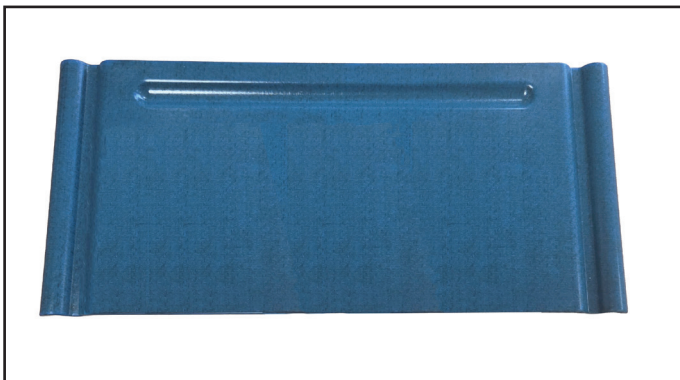


Section 6.6 - Attaching Accessories to ScanPod MRI Focusing Coil

ScanPod is designed to house an MRI focusing coil inside the patient compartment.

The focus coil receiver plate will secure the MRI focus coil from various manufacturers in the base of the ScanPod, preventing lateral and vertical movement of the coil. The base plate of the coil may need to be temporarily removed and the coil slid carefully into position.

Once the coil is on the receiver plate, carefully place back in the ScanPod and whilst gently lifting the baby, slide the coil into position.



Section 6.7 - Closing ScanPod with the Baby inside

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

Replace the ScanPod Viewing Lids carefully, making sure that any cable and tubing are unobstructed by the Viewing Lids.

Tubing should pass through the ports in the Outer Shell section of the ScanPod.

Secure the Viewing Lids in place for transport, by clipping the Closure Clips of the ScanPods' Outer Shell into the recess sections on the Viewing Lids.

Re-check the security of the Stretcher Fixing Straps before transporting the baby.

If Stretcher Straps have become loose, tighten by pulling the straps away from the slider buckles. Re-check the security of ScanPod's Viewing Lids to ensure patient safety.

Close hand access ports in ScanPods' Viewing Lids to minimise heat loss during use.

Leave hand access ports in the closed position during use unless the baby requires active care.

Section 6.8 - Monitoring Baby inside ScanPod

Monitor baby visually while using ScanPod. If using the TransWarmer refer to its Instructions for Use regarding monitoring.

Section 6.9 - Removing Baby from ScanPod

To remove baby from ScanPod, carefully unclip the Closure Clips to release the Viewing Lids and carefully remove the lids, placing them on a flat surface.

Remove Infant Positioning Straps from across the baby's torso.

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 ScanPod, making sure that any cables or ventilator tubing clears the patient compartment.

Optional Accessories and Ancillary Equipment

The ScanPod Dock is designed to allow a ventilator or oxygen therapy unit and other such ancillary equipment such as syringe drivers to be moved with the ScanPod, but positioned outside of the bore of the MRI.

The Dock, is complete with various poles to allow equipment to be attached. Always check with the equipment supplier about its suitability with MRI.

For details of mounting the bracket to an approved third-party ventilator, please contact AHT.

To order accessories for ScanPod, contact AHT at:

Tel: +44 (0)1992 535933

E-mail: sales@babypod.com

or your local AHT supplier.



Section 7 - Cleaning ScanPod

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

Dry ScanPod with a soft, absorbent cloth.

Clean ScanPod's internal components using only mild, water-based cleansers in accordance with hospital protocol.

Section 8 - Maintenance of ScanPod

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

Outer Shell

ScanPod should be inspected at regular intervals for signs of damage to its composite 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 Outer Shell for signs of stress, including cracks, pockmarks or irregularities.

Discontinue use of ScanPod if signs of damage are present.

ScanPod's outer surface does not affect the integrity of the composite shell. Small defects in ScanPod's outer surface due to normal wear and tear generally do not affect the performance of the unit.

Inspect ScanPod's Outer Shells inner and outer surface for cracks or abrasions as per Section 5.2

Note: Smoothness is not a requirement.

Natural irregularities in texture due to the manufacturing process are normal.

Note: Cracks in the composite Outer Shell may not be apparent by visual inspection of the outer surface. Always check the inside surface of the Outer Shell.

Inspect the integrity of the rods inside the ScanPod.

Check the security of the attached Infant Positioning Straps before re-inserting Shock Absorbent Foam Set.

Infant Positioning Straps should be connected at an angle so that straps secure in a cross-wise fashion over the baby's torso.

Protect ScanPod from the impact of sharp or hard objects that may cause damage.

Vacuum Mattress

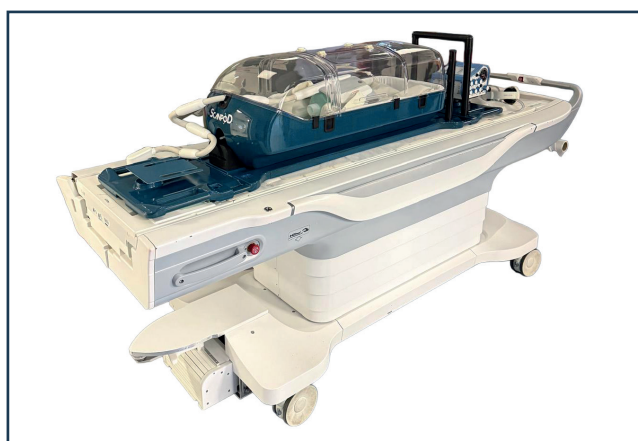
ScanPod's Vacuum Mattress is constructed of a soft PVC material, which can be easily damaged by sharp objects. Keep all sharp objects away from the Vacuum Mattress.

Clean the Vacuum Mattress with warming soapy water and mild disinfectants using a soft non-abrasive cloth. 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.

Section 9 - Specification

Item	Material
Viewing Lid	Polycarbonate lids with plastic hinges
Outer Shell	Epoxy Resin
Shock Absorbent Foam	Polyurethane foam with a PUNL® removable cover
Vacuum Mattress	PVC outer with internal polystyrene beads
Focus Coil Receiver Plate	Epoxy Resin
Stretcher Rods	Glass Fibre
Dock	Epoxy Resin
Patient Positioning Straps	Nylon Velour, Polyurethane Foam with hook tabs
Closure Clips	Polyamide
Tubing Ports	Neoprene Rubber
Weights and Dimensions	
ScanPod Complete Dimensions Weight	1032mm x 431.3mm x 355mm 8.25kg
Maximum Patient Weight	8kg
Dock Dimensions Weight	1789mm x 421.6mm x 50mm (without accessories attached) 6kg (without accessories)





Non-clinical testing has demonstrated that the ScanPod is MR Conditional. There is no projectile risk.
It can be safely scanned under the following conditions: static magnetic field of 3T or less.

Parameter	Condition
MR Safety Status	MR Conditional
Static Magnetic Field Strength	Upto 3 T
Other conditions	No additional conditions apply

Section 10 - 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.

For full details of our warranty please see our website.

Section 11 - 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 12 - Regulatory Information

Symbols:

	CE Marking of Conformity
	Authorized Representative in the European Community
	Catalogue Number
	Serial Number
	Consult Instructions for use
	Medical Device
	Manufacturer
	Date of Manufacture
	Unique Device Identifier
	MR Conditional
	Warning
	Caution

Section 13 - User Notes

Serial no.: _____

Purchase date: _____

Purchased from: _____

Service contact tel.:

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

This image shows a blank sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



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