

# **Neonatal Transport Device**

**Operating and Maintenance Manual** 

## <u>NeoPod</u>®

**Operating & Maintenance Manual** 

Page

Section 1	<b>General warnings and cautions</b>	3
1.1	Introduction	3
		3
1.2	Warnings	
1.3	Cautions	3
Section 2	Indications for use	4
2.1	Product description	4
2.2	Indications	4
2.3	Components	4
2.4	Accessories	4
<b>2</b> .7	Accessones	•
Section 3	<u>Getting to know NeoPod</u>	5-6
3.1	Product diagram	5
3.2	Product components and descriptions	6
Section 4	Environmental conditions	7
Section 5	Safety inspection of NeoPod	8-13
5.1	Unpacking NeoPod	8
5.2	Inspecting NeoPod	8
5.3	Re-assembly of NeoPod	9-12
5.4	Testing the vacuum mattress	13
3.4	lesting the vacuum mattless	15
Section 6	Operating instructions	14-17
6.1	Securing NeoPod to stretcher or gurney	14
6.2		14
	Opening NeoPod	
6.3	Activating the Transwarmer Mattress	15
6.4	Placing baby inside NeoPod	15
6.5	Operating the vacuum mattress	15
6.6	Securing baby inside NeoPod	16
6.7	Closing NeoPod with baby inside	17
6.8	Monitoring baby inside NeoPod	17
6.9	Removing baby from NeoPod	17
012		.,
Section 7	Cleaning NeoPod	18
Section 8	Maintenance of NeoPod	19
<u>beenon o</u>	<u>Maintenance of field ou</u>	
Section 9	Storage of NeoPod	19
Section 10	Troubleshooting	20
	<b>_</b>	-
Section 11	<u>Summary</u>	21
Section 12	Regulatory Information	22
Section 13	<u>User Notes</u>	23



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#### AHT-F-114 v1.1 12/24 NeoPod<sup>®</sup> - Operating & Maintenance

NeoPod<sup>®</sup> - Operating & Maintenance Manual

#### Section 1.1 - Introduction

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

Caution Please read entire instruction manual prior to using NeoPod. 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 NeoPod. Patients may be harmed by the incorrect use of this device.
- **DO NOT** leave baby unattended at any time while using NeoPod.
- **DO NOT** place a baby directly onto the printed side of the TransWarmer Infant Transport Mattress. TransWarmer's soft, non-woven surface is designed to be easy on baby's skin and provide nesting during transport.
- **DO NOT** lean on NeoPod or place weight on top of NeoPod's lid sections.
- **DO NOT** leave open containers of liquid on or near NeoPod. NeoPod's lid section will not prevent fluids from spilling onto the baby.
- **DO NOT** activate the TransWarmer Infant Transport Mattress in ambient temperatures greater than 28.0 degrees Celsius. Ambient temperatures greater than 28.0 degrees Celsius may cause the mattress to become too hot and cause injury to the baby.

#### Section 1.3 - Cautions

- Always check the security of the Stretcher Fixing Straps prior to transport with NeoPod. Strap buckles make an audible click when fully engaged.
- DO NOT modify or make additions to any part of NeoPod.
- Only NeoPod 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 NeoPod. Abrasive cleaners may damage the surface of NeoPod.
- Protect NeoPod from the impact of sharp or hard objects that may cause internal damage that is not visible on the surface of the unit.
- NeoPod 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
  NeoPod 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 NeoPod. Damage due to abrasive or rubbing actions may affect the performance and should be carefully inspected. Discontinue use of NeoPod if signs of abrasive damage are present.

## Section 2.1 - Product Description

NeoPod 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. NeoPod 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. Accessories available for NeoPod include the Single-use TransWarmer Infant Transport Mattress. NeoPod is designed to provide safe conveyance of a patient whose weight is between 2.2-11 lbs (1-5 kg.)

#### Section 2.2 - Indications

NeoPod is designed to safely convey a neonatal patient to or from a medical facility, between facilities or between departments within a single medical facility. NeoPod is designed to provide safe conveyance of a patient whose weight is between 2.2-11 lbs (1-5 kg.)

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

Section	2.3 -	Com	ponents

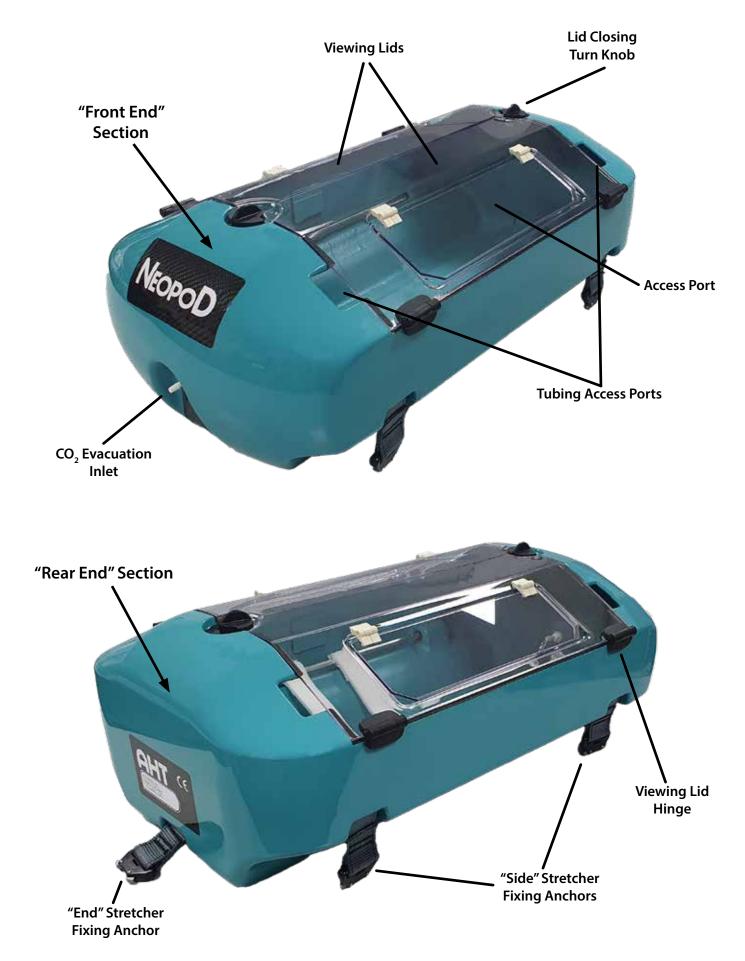
Part Number	Component Description
NPOD-001	NeoPod Neonatal Transport Device
NPOD-002	Vacuum Mattress
BPOD2-003	Infant Positioning Strap Set
NPOD-005	Shock Absorbent Foam Set
BP20-006	9kN Stretcher Fixing Strap Set
NPOD-007	Viewing Lid Set
NPOD-012	Protective Storage Cover
TRANS01	TransWarmer Infant Transport Mattress - Single

#### Section 2.4 - Accessories

**USE ONLY** NeoPod 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
NPOD-013	Protective Carry Bag
BPOD2-020	Vacuum Pump
TRANS06	TransWarmer Infant Transport Mattress (Set of 6pieces)

## Section 3.1 - Product diagram



#### Section 3.2 - Component descriptions

#### **Outer Shell**

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

#### **Shock Absorbent Foam**

NeoPod'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 baby's head, feet and sides during transport and is designed to help protect the baby 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

NeoPod'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 NeoPod.

#### TransWarmer Infant Transport Mattress (Accessory)

NeoPod incorporates the Transwarmer Infant Transport Mattress which is designed to provide radiant heat and shock absorption to the baby during transport. TransWarmer is manufactured using the patented WarmGel technology, which provides even heating via non-migrating gel in a non-electric infant transport mattress. Babies may be placed directly on the TransWarmer's soft, non-woven surface.

#### **Infant Positioning Straps**

NeoPod 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**. NeoPods 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 NeoPod width-wise to any stretcher or gurney, and one End Strap, for fixing the device length-wise to a stretcher or gurney. NeoPod's Stretcher Fixing Straps are composed of a high-tensile polyester webbing with attached metal quick-connect and release buckles.

#### **Viewing Lid**

The NeoPod's viewing lids are made from formed PETG with non-metallic 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 two 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.

#### CO, Evacuation System

If concerned about  $CO_2$  build-up in the patient compartment, this can be evacuated from the NeoPod. An air supply can be attached to the inlet on the "front end" of the NeoPod, which, using only low pressure and jet flow and mixing principles, will draw the  $CO_2$  from the NeoPod interior and evacuate it, via an outlet at the base of the "front end" section.

#### Section 4 - Environmental conditions

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

#### Warning

- **DO NOT** leave NeoPod in direct sunlight or near other radiant heat sources. Outside radiant heat sources may cause the baby to overheat.
- **DO NOT** use the TransWarmer Infant Transport Mattress in ambient temperatures greater than 28.0 degrees Celsius.
- **DO NOT** place a baby directly on the printed side of the TransWarmer mattress. A baby should be placed on TransWarmer's soft, non-woven surface.
- Secure NeoPod to a stretcher or gurney when possible.
- NeoPods may be hand-carried if no stretcher or gurney is available (e.g. Search and Rescue recovery). If NeoPod 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 NeoPod. 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 NeoPod operators and attendants.

#### Section 5.1 - Unpacking NeoPod

Carefully and completely remove the packing material surrounding the NeoPod and place the device on a smooth surface for inspection.

#### Section 5.2 - Inspecting NeoPod

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

**Warning** Carefully inspect NeoPod between each use. A damaged device may harm patient.

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

- 1. Place NeoPod on a smooth surface for inspection.
- 2. Remove NeoPod carefully from its protective storage bag and/or cover.
- 3. Release the black lid turn knob mechanism at the "Front and Rear" ends of the NeoPod. Fully open the lids being careful not to bump the viewing lids on any surrounding objects.
- 4. Remove the loose contents of the NeoPod, including the TransWarmer Mattress and loose Stretcher Fixing Straps.
- 5. Note: Infant Positioning Straps are already fastened into position and should not be removed until they require replacement for a new patient and 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 NeoPod. 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 reassembly later.
- 9. Inspect Outer Shell for cracks or abrasions. First, inspect the inner carbon fibre surface of NeoPod'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 NeoPod. Look for signs of stress due to abrasions.

- 10. Check the security of the Stretcher Fixing Strap Anchors on each side of NeoPod 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 NeoPod, checking operation of each hinge mechanism. Inspect Viewing Lid sections carefully for cracks or irregularities. When the NeoPod lids are 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 it's closed position. These friction hinges can be adjusted to users requirements.

#### Section 5.3 - Re-assembly of NeoPod

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

Place NeoPod on a smooth surface for re-assembly.



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



#### Section 5.3 - Re-assembly of NeoPod continued

Beginning with the "Front end" and "Rear end" sections, place Shock Absorbent Foam pieces inside the interior of the NeoPod.



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 NeoPod interior with the attached loop to each side.



#### Section 5.3 - Re-assembly of NeoPod 2 continued

Insert the "Base" foam section into the bottom of the NeoPod, 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.



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

Once the Vacuum Mattress has been tested, 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 so that the soft, non-woven side faces up. **DO NOT** place a baby directly on the printed side of the TransWarmer Infant Transport Mattress.



#### Section 5.3 - Re-assembly of NeoPod continued

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



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

NeoPod 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).

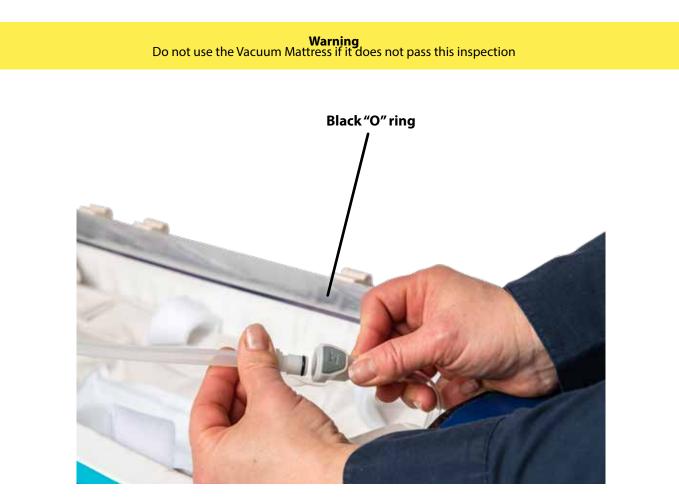
To open the valve prior to vacuum suctioning, press the short tubing section into the long section. An audible click will sound when the sections are properly engaged and the "O" ring will no longer be visible. Vacuum may be applied once the two sections are engaged.

#### 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.



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 NeoPod 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 NeoPod to Transport Stretcher or Gurney

The Side Straps attached to the Stretcher Fixing Strap Anchors are used to secure NeoPod to the stretcher or gurney or to hand carry the device. The End Strap is used to secure the NeoPod to either end of the stretcher or gurney.

#### **Side Stretcher Fixing Straps**

Connect male connector of side stretcher strap to Side Stretcher Fixing Strap Fixing Anchor at "front end" of NeoPod. 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 NeoPod. <u>Connections are secure when a</u> <u>click is heard.</u> Pull strap to tighten. Repeat for stretcher straps at "rear end" of NeoPod.



#### **End Stretcher Fixing Straps**

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



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

#### Section 6.2 - Opening NeoPod

Release the black turn knobs mechanism at both ends of the NeoPod, 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 NeoPod 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 - Activating the TransWarmer Infant Transport Mattress

**Warning** DO NOT use the TransWarmer Infant Transport Mattress in ambient temperatures greater than 28.0 degrees Celsius. Ambient temperatures greater than 28.0 degrees Celsius may cause Warmer Mattress to become too hot and cause injury to the baby.

- 1. Locate metal disc and grasp with thumb and forefingers of both hands.
- 2. Flex (bend) disc rapidly until crystals begin to form.
- 3. Massage pack to soften and to increase the activation rate.
- 4. After pack is fully activated, indent centre with palm to form a small nest.
- 5. Lay baby in nest on fabric surface.
- 6. Check baby's skin for redness and monitor core temperature regularly.

Note: The TransWarmer Infant Transport Mattress is a single-use, disposable product. Discard after each patient use. To order more TransWarmer Infant Transport Mattress, contact our Customer Service Department at:

Tel: +44 (0)1992 535933

Email: sales@babypod.com

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

#### Section 6.4 - Placing baby inside the NeoPod

Place the baby in the NeoPod with either head or feet in "front end" section of the NeoPod. 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.

Place baby face-up on the non-woven surface of the TransWarmer Infant Transport Mattress. **DO NOT** place a baby directly onto the printed side of the TransWarmer mattress.

#### 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 NeoPod

Once the baby is properly positioned and the air removed from the Vacuum Mattress, position the baby in the NeoPod 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 NeoPod 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. <u>Improper use of the Infant Positioning</u> <u>Straps may cause injury to the patient during transport.</u>

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





## Section 6.7 - Closing NeoPod with baby enclosed

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

Carefully close Viewing Lids back over the NeoPod's 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 NeoPod 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 the baby. If straps have become loose, tighten by grasping the webbing and pulling away from the slider buckles.

Re-check the security of NeoPod's Viewing Lids closure to ensure patient safety.



NEOPOD.

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

#### Section 6.8 - Monitoring baby inside NeoPod

Monitor baby visually while using NeoPod.

Check baby's skin occasionally for redness or irritation while TransWarmer Infant Transport Mattress is in use.

Monitor baby's temperature while TransWarmer Infant Transport Mattress is in use.

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 NeoPod

To remove baby from NeoPod, release the black lid lock turn knobs at both ends of NeoPod 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 NeoPod, 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 NeoPod

Caution

NeoPod 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 NeoPod's carbon fibre Outer Shell. **USE ONLY** mild water-based, non-abrasive cleansers and a soft, absorbent cloth to clean the Outer Shell. Dry NeoPod with a soft, absorbent cloth.

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

#### Section 8 - Maintenance of NeoPod

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

Outer Shell

NeoPod 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 NeoPod if signs of damage are present.

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

Inspect NeoPod's Outer Shell for cracks and abrasions. First, inspect the inner carbon fibre surface of NeoPod'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 rods inside NeoPod'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 NeoPod 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 NeoPod continued

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

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

#### Vacuum Mattress

NeoPod'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 NeoPod 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 NeoPod

NeoPod should be stored in its protective storage cover or protective carry bag when not in use. NeoPod 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 NeoPod appears below. If there are questions or concerns not addressed below, take NeoPod out of service and contact our Customer Service Department.

<u>Problem</u>	Possible cause	<u>Correction</u>	<u>Section</u>
Baby too cold	Disposable warming mattress not in use.	Activate TransWarmer Mattress before placing baby in NeoPod.	6.3
Baby too cold	Disposable warmer mattress used in excess of 2 hours.	Activate new TransWarmer Mattress after 2 hours of transport.	6.3
Baby too hot	NeoPod used outside prescribed environmental conditions.	DO NOT use the TransWarmer Mattress in ambient temperatures greater than 28.0 degrees Celsius.	6.3
Visual damage to NeoPod 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	NeoPod 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 NeoPod.

## NeoPod Product Description and Indication for Use

NeoPod is designed to safely convey a neonatal patient to or from a medical facility, between facilities or between departments within a single medical facility. NeoPod 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. NeoPod 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 NeoPod

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

## **NeoPod Operating Instructions**

- 1. Secure NeoPod to transport stretcher or gurney
- 2. Open NeoPod
- 3. Activate the TransWarmer Infant Transport Mattress
- 4. Place baby inside NeoPod
- 5. Operate the Vacuum Mattress
- 6. Secure baby inside NeoPod
- 7. Close NeoPod with baby enclosed
- 8. Monitor baby inside NeoPod

## Section 12 - Regulatory Information

## Symbols:

CE	CE Marking of Conformity
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
SN	Serial Number
i	Consult Instructions for use
MD	Medical Device
	Manufacturer
	Date of Manufacture
UDI	Unique Device Identifier

#### **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	<u>13 - User Notes</u>	
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## EC REP

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