HOVERTECH International

SITASSIST™ PRO

Positioning Device

User Manual

MD

CE

Visit www.HoverMatt.com for other languages

TABLE OF CONTENTS

Symbol Reference

CE	CE MARKING OF CONFORMITY
UKCA	UK MARKING OF CONFORMITY
EC REP	AUTHORIZED REPRESENTATIVE
UK REP	UK RESPONSIBLE PERSON
CH REP	SWITZERLAND AUTHORIZED REPRESENTATIVE
	CAUTION / WARNING
	MANUAL CLEANING
	DISPOSAL
	IMPORTER
	OPERATING INSTRUCTIONS
LATEX	LATEX FREE
	MANUFACTURER
	DATE OF MANUFACTURE
MD	MEDICAL DEVICE
REF	MODEL NUMBER
SN	SERIAL NUMBER
	DO NOT LAUNDER
UDI	UNIQUE DEVICE IDENTIFIER
	PATIENT WEIGHT LIMIT

Intended Use and Precautions

INTENDED USE

The SitAssist™ Pro Positioning Device is used to pneumatically lift the upper body of a patient from a supine position to an upright seated position without manual effort. The device may also be used to controllably lay a patient from an upright seated position down to a supine position without manual effort. The device is intended for patients who need mid-to-moderate assistance.

INDICATIONS FOR USE

The radiolucent, MRI-compatible SitAssist Pro can be used for patients who require assistance to achieve a fully seated, reclined, and/or supine position.

CONTRAINDICATIONS

Patients who are experiencing thoracic, cervical or lumbar fractures that are deemed unstable should not use the HoverMatt unless a clinical decision has been made by your facility.

INTENDED CARE SETTINGS

Hospitals, long term/extended care facilities, diagnostic centers.

Radiology (Imaging) use, including but not limited to X-Ray, MRI, CT, Fluoroscopy, and Ultrasound.

PRECAUTIONS – SITASSIST PRO

- Ensure the SitAssist Pro meets the patient's needs before using. A clinical assessment should be carried out by a qualified medical professional before positioning patients using the SitAssist Pro.
- Make sure the patient is centered on the SitAssist Pro before inflating or deflating.
- Always support the patient's head when sitting up or lying down.
- Caregiver(s) must ensure the patient is attended and stabilized while on the SitAssist Pro.
- More than one caregiver may be necessary when operating the SitAssist Pro.
- Product should only be used by trained personnel.
- Only use attachments and/or accessories that are authorized by HoverTech International.
- The device may periodically need additional air to maintain full inflation.
- A caregiver must always attend to the patient while device is inflated.

For "totally dependent patients" in addition to the caregiver managing the SitAssist Pro and air supply, a dedicated caregiver is required to support the patient.

PRECAUTIONS - HOVERTECH'S HTAIR AIR SUPPLY

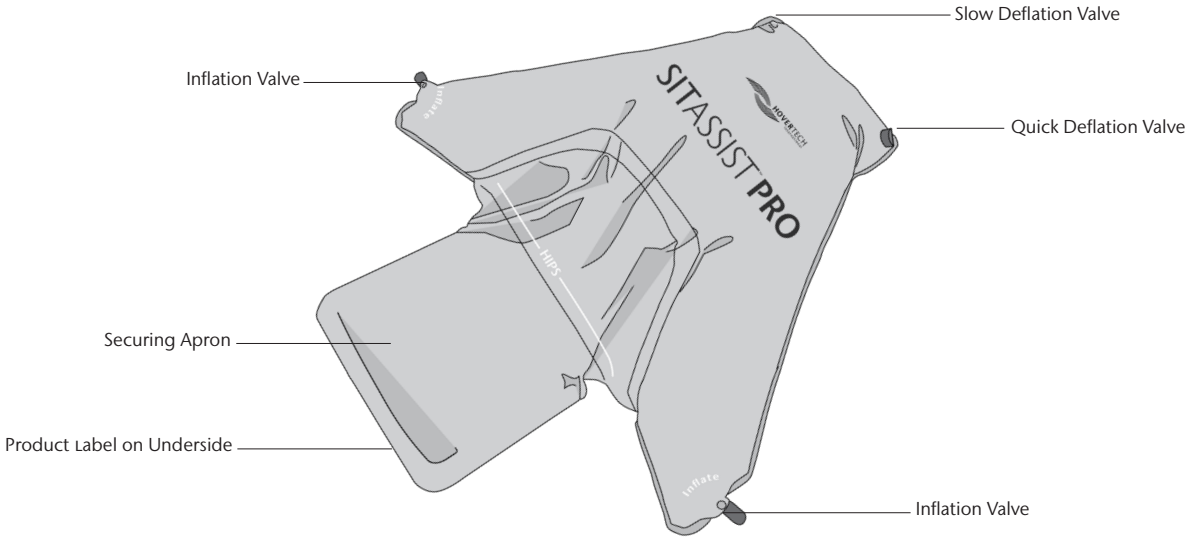
- Not for use in the presence of flammable anesthetics, in a hyperbaric chamber or oxygen tent.
- Route the power cord in a manner to ensure freedom from hazard.
- Avoid blocking the air intakes of the Air Supply.
- Use this product only for its intended purpose as described in this manual.
- Please use your facility's clinical protocol when transferring a patient on/off the table.
- When using the SitAssist Pro in the MRI environment, a 25 ft. specialty MRI hose is required (available for purchase).

Avoid electric shock. Do not open HoverTech International Air Supply.

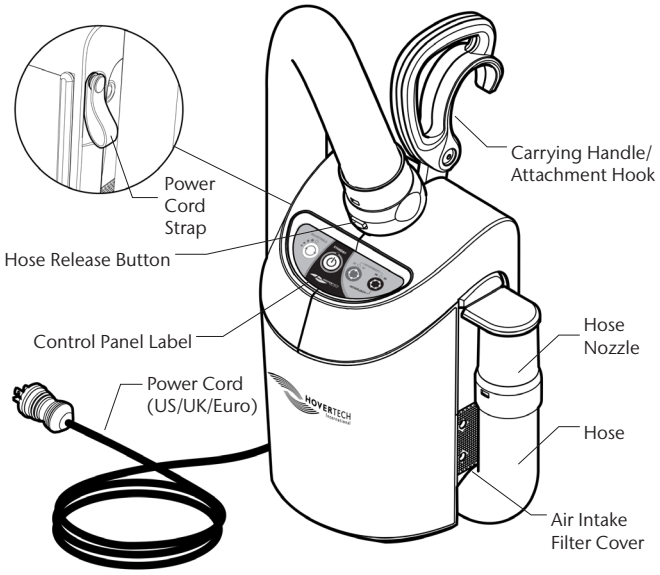
Reference product specific user manuals for operating instructions.

For use with the HoverTech HT-AIR. Do not use Air200G or Air400G.

Part Identification – SitAssist™ Pro Positioning Device

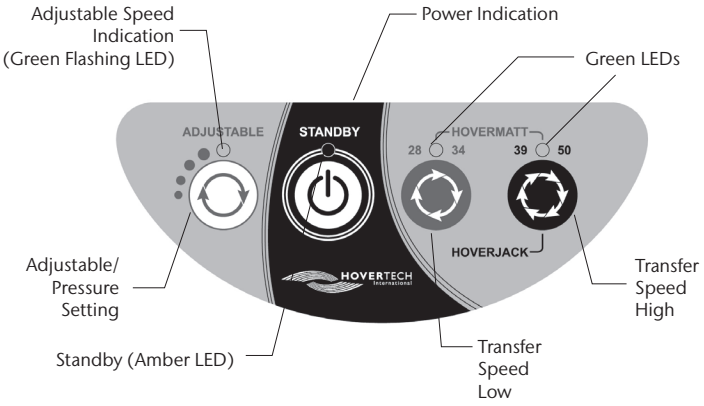


Part Identification – HT-Air® Air Supply



WARNING: The HT-Air is not compatible with DC power supplies.
The HT-Air is not for use with the HoverJack Battery Cart.

HT-Air® Keypad Functions



The ADJUSTABLE keypad function has four different settings. Each press of the button increases the air pressure and rate of inflation. The Green Flashing LED will indicate the inflation speed by the number of flashes (i.e. two flashes equals the second inflation speed).

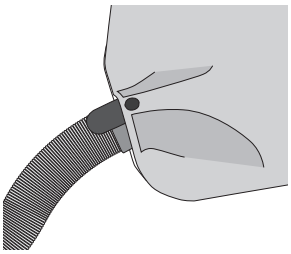
STANDBY: Used to stop inflation/air flow (Amber LED indicates STANDBY mode).

Instructions for Use

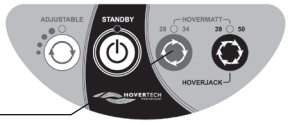
Laying Patient Down:

1. Center the SitAssist Pro on the surface with logo side facing up. Confirm both deflation valves are closed.

2. Using the HT-AIR Air Supply, insert hose nozzle into one of the two inflation valves located near the patient's hip on the sides of the device. Attach the snap to secure the hose to the device.



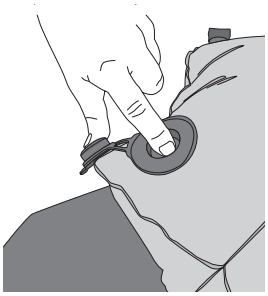
3. Press the 34" HoverMatt button to inflate the device.



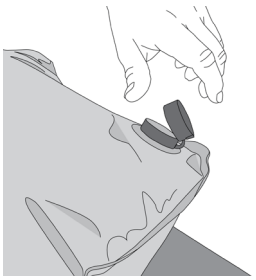
4. When the device is fully inflated, press STANDBY button to stop air flow. Remove the hose if necessary.

5. Center patient on SitAssist Pro using the centering line and align patient's hips to the edge of the device using the hip placement line.

6. Deflate the SitAssist Pro (see deflation options below) to lower the patient from the seated position to supine position, supporting the patient's head during deflation.



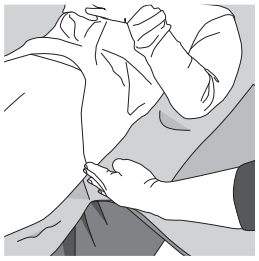
7. <u>For deflation:</u>
   a) Open the clear deflate valve and depress the inside flap. The device will deflate gradually and slowly.
   b) For a rapid deflation, open the red quick deflate valve cap. The device will deflate quickly.



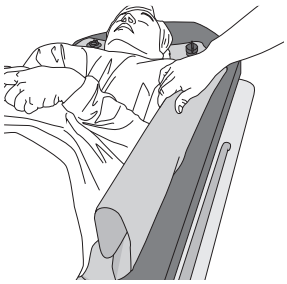
Sitting Patient Upright:

NOTE: If patient is already on a surface, use a log-rolling technique to place device under the patient. Make sure the securing apron is extended and flat underneath the patient.

1. Center the SitAssist Pro on the surface with logo facing up. Confirm both deflation valves are closed.

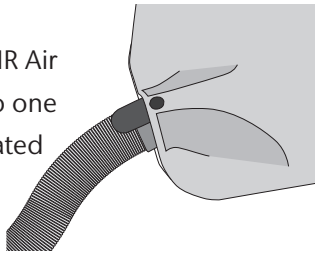


2. Center patient on SitAssist Pro using the centering line and align patient's hips with lower edge of the device using the hip placement line.

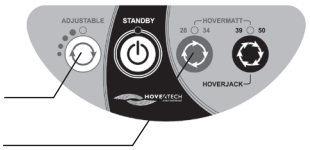


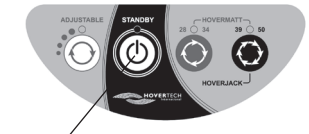
3. To ensure deflated device does not interfere with medical equipment during procedures, fold wings inward toward patient and secure patient to the table with a standard patient securing strap, if necessary.

4. After imaging, using the HT-AIR Air Supply, insert hose nozzle into one of the two inflation valves located near the patient's hip. Attach the snap to secure the hose to the device.



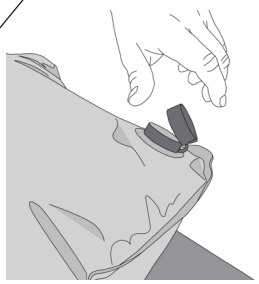
5. Press the ADJUSTABLE button on the air supply four times to gradually inflate the device. Ensuring the patient is centered, fully inflate by pressing the 34" HoverMatt button. Support the patient's head as the patient moves to a seated position.





6. When the device is fully inflated, press STANDBY button to stop airflow. Remove hose.

7. To deflate the device after the patient is removed, open the red quick deflate valve cap.



Product Specifications/Required Accessories

SITASSIST PRO POSITIONING DEVICE

Material:	210D Nylon Tarpaulin: 0.13mm Clear Ether; TPU double laminated
Construction:	RF Welded
Width:	48" (121 cm)
Length:	53.5" (136 cm) with Apron

Model #: SAP-200

Limit: 600 LBS/272 KG

REQUIRED ACCESSORY: AIR SUPPLY

Model #: HTAIR1200 (North American Version) – 120V~, 60 Hz, 10A
Model #: HTAIR2300 (European Version) – 230Vac, 50Hz, 6A

ADDITIONAL ACCESSORY: 25' MRI HOSE

Model #: HTA-MRI (Each) - for HT-AIR

Cleaning & Preventive Maintenance

Between patient uses, the SitAssist Pro should be wiped down with a cleaning solution used by your hospital for medical equipment disinfection. A 10:1 bleach solution (10 parts water: one part bleach) or disinfectant wipes can also be used. It is important to follow the cleaning solution manufacturer's instructions for use, including dwell time and saturation.

NOTE: Cleaning with bleach solution may discolor fabric.

Do not launder the SitAssist Pro.

INFECTION CONTROL

A sheet may be placed on top of the SitAssist Pro to help keep it clean.

If the SitAssist Pro is used on an isolation patient, the hospital should employ the same protocols/procedures it utilizes for the bed mattress and/or for linens in that patient room.

PREVENTIVE MAINTENANCE

Prior to use, a visual inspection should be performed on the SitAssist Pro to ensure that there is no visible damage that would render the SitAssist Pro unusable.

The SitAssist Pro should be periodically inspected to ensure the following:

- No tears or holes that would prevent the SitAssist Pro from inflating.
- The caps for both the slow and quick deflation valves are attached by the tethers and are secure.
- The inflation valve snaps are in working order.

If any damage is found that would cause the SitAssist Pro not to function as intended, the SitAssist Pro should be removed from use and returned to HoverTech International for repair.

When a product reaches the end of it's lifetime, it should be separated by material type so that the parts can be recycled or disposed of properly in accordance with local requirements.

Transportation and Storage

This product does not require any special storage conditions.

Returns and Repairs

All products being returned to HoverTech International (HTI) must have a Returned Goods Authorization (RGA) number issued by the company. Please call (800) 471-2776 and ask for a member of the RGA Team who will issue you an RGA number. Any product returned without an RGA number will cause a delay in the repair time.

Returned products should be sent to:

HoverTech International
Attn: RGA # _____
4482 Innovation Way
Allentown, PA 18109

For European companies, send returned products to:

Attn: RGA #_____
Kista Science Tower
SE-164 51 Kista, Sweden

For product warranties, visit our website:
https://hovermatt.com/standard-product-warranty/

HoverTech International

4482 Innovation Way
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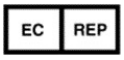
These products comply with the standards applicable for Class 1 products in the Medical Device Regulation (EU) 2017/745 on medical devices.



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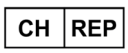

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In case an adverse event in relation to the device, incidents should be reported to our authorized representative. Our authorized representative will forward information to the manufacturer.

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