



Vapotherm Transfer Unit

for use with Vapotherm Precision Flow

Instructions for Use



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Intended Use

The Vapotherm Transfer Unit (VTU) allows the mobile delivery of high-flow humidified respiratory therapy within a hospital environment. With a fully charged battery module and filled gas supply tanks, the duration of available mobile therapy depends on 2 factors:

- Tank gas supply: mobile run time will vary depending on the O₂/air blend and flow rate settings on the Precision Flow.
- Battery life: Up to 1-hour

The VTU consists of the

- · Precision Flow Roll Stand
- Astrodyne-TDI MedipowerTM Mobile Medical Power System
- Medical Air and Oxygen Manifold
- Cylinder Bottle Holder





Indications, Warnings and Cautions

For ease of assembly and to avoid injury when handling the heavy power components, the VTU should be assembled by a minimum of 2 trained professionals.

The Astrodyne-TDI Medipower[™] has been validated for use with the Vapotherm Precision Flow. Precision Flow may refer to both Precision Flow and Precision Flow Plus. Using a power supply not validated by Vapotherm for use with the Precision Flow may result in inadequate device performance.

Before assembly and use of the system, please refer to the following indications, warnings and cautions:

- Vapotherm Precision Flow: Indications, Warnings and Cautions, as published in the Precision Flow Instructions for Use (see Referenced Documents, below).
- MedipowerTM Medical Mobile Power System: Important Safety Instructions, as published in the Owner's Manual (see Referenced Documents, below).

To understand the alarm behavior of the system, please refer to the description of alarms in the following documentation:

- Vapotherm Precision Flow Products Instructions for Use, excluding Precision Flow Heliox (see Referenced Documents, below).
- MedipowerTM Medical Mobile Power System: Owner's Manual (see Referenced Documents, below).

The VTU may be used to transfer patients within acute-care medical environments for which the Precision Flow is cleared.

The VTU and Precision Flow are not MRI compatible.

Transfer Unit Components

Before assembling the Vapotherm Transfer Unit, make sure that you have the following system components:

| Item Description | |
|--|---|
| Precision Flow Roll Stand: | |
| Roll Stand Post, 36" | 1 |
| Roll Stand Base with 10lb Counterweight | 1 |
| • 5/16-18 x 1" Hex Head Cap Screw (HHCS) | 1 |
| 5/16 Flat Washer | 1 |
| 5/16 Split Lock Washer | 1 |
| Utility Basket (with mounting hardware) | 1 |
| Handle (with mounting hardware) | 1 |
| IV/Device Post | 1 |
| #10-32 x 3/4" Socket Head Cap Screw (SHCS) | 3 |
| • 5/32" Hex Wrench | 1 |
| 1/2" Socket Wrench | 1 |
| Medipower [™] Medical Mobile Power System: | |
| Battery Module | 1 |
| Power Supply Module | 1 |
| Remote User Interface | 1 |
| DC Power Cable | 1 |
| Manifold & Start-up Kit: | |
| Air and O₂ Gas Manifold | 1 |
| Dual Cylinder Holder | 1 |
| Power Extension Cord | 1 |
| Communication Cable | 2 |
| Bracket Kit | 1 |
| Instructions for Use | 1 |
| Quick Reference Guide | 1 |



Transfer Unit Assembly

Tools required but not supplied: Phillips screwdrivers PH1, PH2.

For ease of assembly, Vapotherm recommends the following assembly sequence ("from-the-ground-up"):

1. Insert the Roll Stand POST into the Roll Stand BASE and fasten (see Roll Stand Installation Guide in Roll Stand box). Return Roll Stand to upright position.



2. Assemble and install the MedipowerTM Medical Mobile Power System (battery – Box 2, power supply – Box 3, and remote user interface – in Box 1). Please refer to fully assembled unit on Page 3.





- Assemble brackets onto the Battery and Power Supply. Ensure the metal plates are flush and secure.
- b. Loosen the clamps so they can slide down the Roll Stand pole while attached to the Power Supply and Battery (starting with the Battery)
- c. Ensure at least 1" spacing from the BASE of the stand to the bottom of the Battery.

Warning: Not following these spacing requirements may cause damage to the battery.

- d. Tighten the clamp to secure the Battery to the Roll Stand pole (For easier assembly, one assembler can hold the battery while the other tightens)
- e. Slide the Power Supply down on the opposite side of the Battery until the bottom of the clamp reaches the top of the Battery
- f. Tighten the clamp to secure the Power Supply to the Roll Stand pole (For easier assembly, one assembler can hold the Power Supply while the other tightens)
- g. Loosen Cylinder Holder bracket enough so it slides down Roll Stand pole.
- h. Ensure there is a 2" space between the top of the Power Supply and the bottom of the Cylinder Holder.
- Tighten the clamp block to secure the Cylinder Holder to the Roll Stand pole (For easier assembly, one assembler can hold the basket while the other tightens). Tighten the screws with the Hex wrench.









- j. Attach the Front Basket clamps to the basket and loosen clamps.
- k. Slide the basket down the Roll Stand pole until the bottom of the Basket is just above the top of the Power Supply.
- I. Tighten the clamps to secure the Basket to the Roll Stand pole



m. Screw the components of the Gas Manifold together so that they are still loose enough to slide down the Roll Stand pole



- n. Ensure the Air side of the Manifold is on the same side as the PF Unit when it is attached
- o. Line up the bottom of the Gas Manifold to the top of the E-Tank Holder and tighten the Gas Manifold to secure the Manifold to the Roll Stand pole (For easier assembly, one assembler can hold the manifold while the other tightens)





- p. Remove the back plate of the Remote User Interface (RUI). Attach the back plate to the third clamp with the supplied screws. Loosen the clamp so it slides down the Roll Stand pole.
- q. Tighten the clamp to secure the Remote User Interface (RUI) to the Roll Stand pole approximately 6 inches from the top of the pole.
- Complete the assembly of the Roll Stand, including handle and IV/Device Post (see GCX Roll Stand Installation Guide).
- Move the handle assembly to a position 36" (inches) from the top of the Roll Stand. The handle will be towards the front of the Roll Stand.
- 5. Attach the 18-inch air hose to the VT Unit connector on the air manifold.
- 6. Attach second 18-inch air hose to the Tank connector on the air manifold.
- 7. Attach the 10-foot air hose to the Wall connector on the air manifold.
- 8. Attach the 18-inch oxygen hose to the VT Unit connector on the oxygen manifold.
- 9. Attach second 18-inch oxygen hose to the Tank connector on the oxygen manifold.
- 10. Attach the 10-foot oxygen hose to the Wall connector on the oxygen manifold.

Note: Hoses to the wall and to the tank are not supplied by Vapotherm. Photos are for reference use only.

11. Connect the communication cables from the Power Supply to the Battery and from the Power Supply to the Remote User Interface. Use ties to ensure that cables are organized and positioned to prevent disconnection.



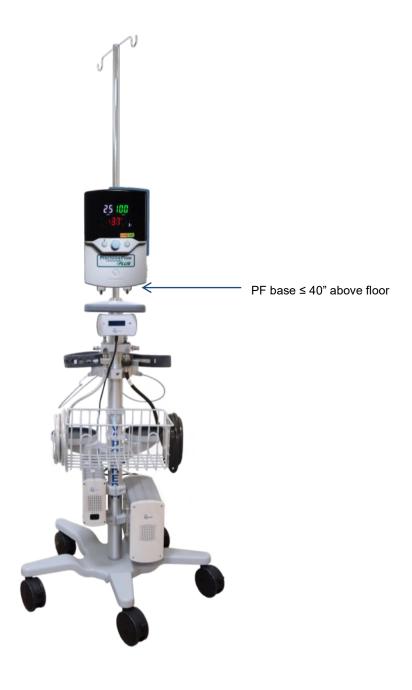






12. Mount the Precision Flow with its base no more than 40" (inches) above the floor.

Warning: To reduce the risk of tipping, the Precision Flow should be mounted on the pole no higher than 40" above the floor (Precision Flow base to floor).





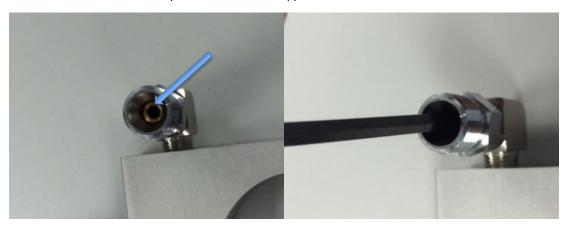
Using the System

Preparation

- To run the Precision Flow with wall gas, attach the 10-foot oxygen and air hoses to the wall gas supply.
- Before switching from wall to tank gas, make sure that the tanks contain adequate gas supplies.
- Allow the power supply to charge fully (reference remote user interface prior to initial use). The power supply should be fully charged before using the VTU for mobile therapy delivery.
- Before disconnecting the VTU from line power, make sure that the power supply is turned on.
- Before using the system, it is important to confirm there is no leaking from the manifold. Follow the instructions below to leak test the manifold system.

Valve Functionality Test:

- To check the functionality of the valves on the manifolds, actuate the brass piece found in the fittings on the air and oxygen manifolds using an Allen wrench or equivalent.
- Ensure that after being pressed down, the brass piece returns to its initial position.
- If the brass valve does not return to its initial position the manifold should be considered defective and a new one should be used. Call Vapotherm Technical Support



Manifold Leak Test:

- After assembly, ensure all hoses are securely connected to the manifold and the Precision Flow
- Turn on wall Air while leaving tanks turned off. Listen for any leaking from the manifold connection labeled "Wall" on the Air side
- Turn off wall Air and turn on wall Oxygen. Listen for any leaking from the manifold connection labeled "Wall" on the Oxygen side
- Turn off wall Oxygen and turn on Air tank. Listen for any leaking from the manifold connection labeled "Tank" on the Air side
- Turn off Air tank supply and turn on Oxygen tank supply. Listen for any leaking from the manifold connection labeled "Tank" on the Oxygen side



- Turn on all gas sources and confirm no leaks occur with the manifold fully pressurized
- Turn off all supply gasses when manifold is confirmed to have no leaks
- If in any step of the testing the manifold is suspected to be leaking, confirm the hoses are securely connected to the manifold. If leaking persists, contact Vapotherm Technical Support. The manifold may be defective and a new one should be shipped to replace the faulty manifold.

Transport Setup

1. Connect the **VT Unit** 18-inch air hose to the air (AIR) trap assembly, and the **VT Unit** 18-inch oxygen hose to the oxygen (O₂) trap assembly on the Precision Flow.



2. Insert the E tanks into the E-tank cylinder holder.

Note: If using oxygen, insert the oxygen E tank on the same side as the oxygen trap on the Precision Flow.

- 3. Install the air and O₂ E tank regulator:
 - Connect the **Tank** 18-inch oxygen hose to the oxygen E tank.
 - Connect the **Tank** 18-inch air hose to the air E tank.
 - Plug the Precision Flow into the Astrodyne-TDI MedipowerTM power supply. Power on the Astrodyne-TDI MedipowerTM power supply. Unplug the power cord from the Astrodyne-TDI MedipowerTM power supply to stop charging and store securely on the unit.

Switching Gas and Power Sources

- 1. Confirm the Precision Flow therapy settings.
- 2. Open the oxygen and/or air E tanks and confirm that the tanks contain adequate gas supply.

Warning: Do not attempt to transfer a patient with ≤ 400 psi in either tank.



- 3. Disconnect the oxygen and air hoses from the wall gas supply.
- Unplug the power cord from the Astrodyne-TDI Medipower[™] power supply to stop charging and store securely on the unit.

Warning: Make sure the power cord does not drag on the floor and present a tripping hazard.

- 5. Transfer patient to desired location within the hospital.
- 6. At destination
 - Connect the oxygen and air hoses to the wall gas supply,
 - Plug the Astrodyne-TDI Medipower[™] power supply into a hospital-grade outlet to charge.

Note: When the VTU is stationary, lock the wheels of the Precision Flow Roll Stand.

Warning: If the Precision Flow continuously sounds a gas alarm, confirm that all connections to the gas supply (wall or tank) are correct or that there is adequate gas supply in the tanks. If the Precision Flow continuously sounds a battery alarm, confirm that all power cords are plugged into an active and charged power source. Refer to the Precision Flow Instructions for Use for detailed information about the Precision Flow's alarm behavior.



Cleaning and Maintenance

For cleaning and maintenance instructions for the Precision Flow, please see the Precision Flow Instructions for Use.

For maintenance and storage instructions for the Astrodyne-TDI MedipowerTM Mobile Power Kit, please see the Astrodyne TDI Medipower Mobile Power System Installation and Operating Manual.

For cleaning and maintenance instructions for the Precision Flow Roll Stand, please see the GCX Roll Stand Installation Guide.

Troubleshooting and Support

If you need assistance with the Precision Flow or Vapotherm Transfer Unit, please contact Vapotherm Technical Support at <u>TS@vtherm.com</u> or +1 855-557-8276 (Domestic) or +1 603-658-5121 (International).

If you need assistance with the Precision Flow Roll Stand Kit, please contact GCX at 800-228-2555 or visit the GCX website at www.gcx.com/support.

If you need assistance with your Astrodyne-TDI Medipower[™] Mobile Power Kit, please contact Vapotherm Technical Support +1 855-557-8276. Before contacting Vapotherm we recommend visiting the Astrodyne-TDI website at /www.astrodynetdi.com/resources for initial trouble shooting.

Referenced Documents

Vapotherm Precision Flow and Precision Flow Plus Instructions for Use GCX Roll Stand Kit Installation Guide
Astrodyne TDI Medipower Mobile Power System Installation and Operating Manual

Specifications

Battery Operating Conditions

| Operating Temperature: | 0°C - +35°C |
|------------------------|----------------------|
| Relative Humidity: | 0-95% non-condensing |

Refer to Astrodyne-TDI MedipowerTM Mobile Power System User Manual

Precision Flow Operation and Performance

| Flow: | 1-40 L/min |
|------------------|---------------------------------|
| Temperature: | 33-43°C (Typically set to 37°C) |
| Oxygen Delivery: | 21-100% |

Environmental Criteria

| Ambient Temperature: | 18-30°C |
|----------------------|--|
| Relative Humidity: | 20-90% non-condensing |
| Ambient Pressure: | Standard atmospheric – not to be used in hyperbaric conditions |

Storage and Shipping

| Ambient Temperature: | 10-50°C |
|----------------------|---------|
| Relative Humidity: | 20-90% |

Standards

Designed to conform to the following standards:

| ISO 14971 Risk Management |
|---|
| IEC 60601-1 3 rd Edition |
| ISTA-2A, Ship Test |
| ASTM G93/CGA G-4.1 Off-the-Shelf components coming into contact with gas supply |



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