

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 full gas cylinders, the length of available mobile therapy depends on 2 factors:

- Cylinder gas supply: From 14 minutes to 18.7 hours, based on the O₂/air gas ratio and flow rate settings on the Precision Flow.
- Battery life: Up to 1.5 hours from a full charge.
 - Tripp Lite recommends that the Power Supply be plugged into a wall outlet, charging the battery as often as possible. Charging the batteries for brief intervals **DOES** NOT adversely affect battery performance. However, leaving the batteries fully discharged for long periods of time DOES adversely affect battery performance.
 - o For long term storage, the battery should be fully charged at a minimum of once per month.

The VTU consists of the

- GCX Roll Stand
- Medical-Grade Mobile Power Kit
- Medical Air and Oxygen Manifold and E-Cylinder Holder
- Vapotherm Precision Flow (Optional)





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.

Only the Tripp-Lite Medical-Grade Mobile Power Retrofit Kit, model HCRK-36, has been validated for use with the Vapotherm Precision Flow. Using a power supply not validated by Vapotherm for use with the Precision Flow may result in inadequate device performance. Battery should be fully charged once a month at a minimum.

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 Operating Instruction Manual.
- Tripp Lite Medical-Grade Mobile Power Retrofit Kit: Important Safety Instructions, as published in the Owner's Manual.

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

- Vapotherm Precision Flow Operating Instruction Manual
- Tripp Lite Medical-Grade Mobile Power Retrofit Kit Owner's Manual

The VTU shall only be used in medical settings including the following medical environments: NICU, PICU, Adult ICU, Medical ICU, Cardiothoracic ICU, Surgical ICU, PACU, Long Term Acute Care Hospital, and Emergency Departments.

The VTU is not MRI compatible.

The VTU should never be used in pre-hospital settings.

Transfer Unit Components

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

Item Description				
Precision Flow Roll Stand – 5 Wheel Locking Base				
Mounted Medical-Grade Mobile Power Supply Kit:				
Battery Module	1			
Power Supply Module	1			
Remote User Interface	1			
 Communication Cables (1 Black – 1 Grey) 	1			
 Manifold and E-Cylinder Holder Kit: Air Manifold Block with CGA 950 Regulator, preset at 50 PSI, and Air Hosing 	1			
Oxygen Manifold Block with Hosing	1			
Dual E-Cylinder Holder	1			
AC Plug Cover	2			
NOTE: The VTU does not ship with an oxygen regulator.				
Tools Required:				
• 5/32" (4 mm) Hex Wrench	1			
 Phillips Screwdriver (for 10-32 x 9/16" PHMS) 	1			

Vapotherm Transfer Unit Assembly

For ease of assembly, Vapotherm recommends the following assembly sequence. The VTU arrives in the Vapotherm Transfer Unit Crate. <u>The VTU Crate is **reusable** and should be sent back to Vapotherm after VTU assembly.</u>

Vapotherm Shipping Address: 22 Industrial Drive, Exeter, New Hampshire, 03833

1. The VTU arrives in the crate shown below.



2. Remove the lid of the crate by unlatching the fasteners (5).







3. Unlatch the fasteners (4) on the front of the crate.



4. Open the front panel door to reveal the VTU components.





5. Confirm that the crate door is resting on the base edge.



6. Remove the board that is securing the VTU in the crate.







7. Unlock the VTU wheels and roll the VTU out of the crate.



8. Cut the cable tie and remove the top portion of the PF roll stand from the packaging.



9. Remove the 5/32" (4 mm) hex screws from the top of the PF roll stand.





10. Attach the top of the PF roll stand by aligning the screw holes and insert the 5/32" (4 mm) hex screws.



11. At this point the VTU should match the image below.



12. Locate the VTU accessory compartments in the VTU crate.



13. Remove the air and oxygen hoses from the VTU crate compartment.



14. Remove the hoses from the packaging. For both air and oxygen there are two 3-foot hoses and one 10-foot hose. Attach the 10-foot air hose labeled **WALL** to the corresponding connection port on the air manifold also labeled **WALL**. Coil the air hose around the Precision Flow roll stand basket.



15. Attach the 10-foot oxygen hose labeled **WALL** to the corresponding connection port on the oxygen manifold also labeled **WALL**. Coil the oxygen hose around the Precision Flow roll stand basket.





16. Attach the 3-foot air hose labeled **VT UNIT** to the corresponding connection port on the air manifold also labeled **VT UNIT**.



17. Attach the 3-foot oxygen hose labeled **VT UNIT** to the corresponding connection port on the oxygen manifold also labeled **VT UNIT**.



18. Attach the 3-foot air hose labeled **TANK** to the corresponding connection port on the air manifold also labeled **TANK**.



19. Attach the 3-foot oxygen hose labeled **TANK** to the corresponding connection port on the oxygen manifold also labeled **TANK**.



20. At this point the VTU should resemble the image below.



21. Remove the items below from the VTU accessories compartment to finish assembly of the mobile power supply (Grey Communication Cable, Black Communication Cable, Cable Tie Kit, and Battery Functional Test Report).





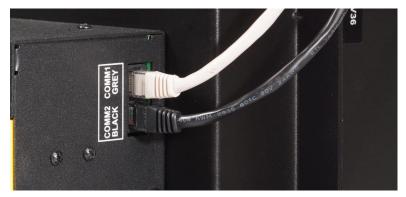
22. Remove the protective bubble packaging from the power cord with the yellow receptacle and insert it into the inverter.



23. Remove the black communication cable from the package and insert it into the inverter. The cable should be inserted into the receptacle labeled **COMM2 BLACK.**



24. Remove the grey communication cable from the package and insert it into the inverter. The cable should be inserted into the receptacle labeled **COMM1 GREY.**



25. Insert the other end of the black communication cable into the Remote User Interface **COMM2** receptacle. Insert the other end of the grey communication cable into the Remote User Interface **COMM1** receptacle.

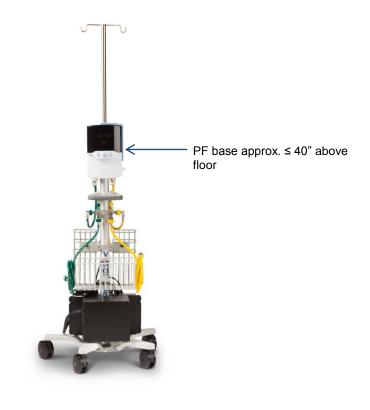


26. Use a cable tie to secure the black and gray cables.





27. Install the Precision Flow Unit on the PF roll stand.



28. Attach the hoses labeled **VT UNIT** for the air and oxygen to the Air and O_2 traps at the back of the Precision Flow device. Attach the air and oxygen hoses labeled **TANK** to their corresponding 50 psi regulated E-cylinder.



29. The VTU should resemble the image below.



- **30.** The VTU crate ships with the following documents: PF VTU Crate IFU, VTU Quick Reference Guide, and Mobile Power Supply Operators Manual. **The VTU crate is reusable and needs to be returned to Vapotherm.**
 - a. Place the return-shipping label on the top panel of the VTU crate and insert the RMA in the folder inside the VTU crate. (Customers will be charged for crates that are not returned)
 - b. Vapotherm Shipping address: 22 Industrial Drive, Exeter New Hampshire, 03833



Using the System

Preparation

- To run the Precision Flow with wall gas across its full operational range, attach the 10-foot oxygen and air hoses to a minimum of 40-psi gas supply.
- Before switching from wall to tank gas, make sure that the E-cylinders contain adequate gas supplies (2000 psi).
- <u>Allow the power supply to charge for 24 hours prior to initial use</u>. 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. This is indicated by 5 LEDs on the power supply Remote User Interface.

Transfer Setup

- 1. Connect the yellow **VT UNIT** 3-foot air hose to the air trap (AIR), and the green **VT UNIT** 3-foot oxygen hose to the oxygen (O₂) trap on the Precision Flow.
- 2. Plug the Precision Flow into the medical grade mobile power supply.
- 3. Insert the oxygen E cylinder into the dual cylinder holder. Repeat for the compressed air E Cylinder.

Note: Insert the oxygen E Cylinder on the same side as the oxygen trap on the Precision Flow.

- 4. Install the air and oxygen E Cylinders:
 - Connect the oxygen **TANK** 3-foot oxygen hose to the oxygen E cylinder.
 - Connect the air TANK 3-foot air hose to the air E cylinder.
- 5. Power on the medical grade mobile power supply.

Switching Gas and Power Sources

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

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

- 3. Disconnect the oxygen and air hoses from the wall gas supply.
- 4. Unplug the power cord from the medical grade mobile power supply and store securely on the unit.

Warning: Make sure the power cord does not drag on the floor and present a tripping hazard. Place the power cord into the VTU roll stand basket.

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 medical grade mobile power supply into a hospital-grade outlet.
 - Close the E cylinders once connected to a wall gas supply.

Note: When the VTU is stationary, lock the wheels of the PF 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. Refer to the Precision Flow Operating Instruction Manual 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 Operating Instruction Manual.

For maintenance and storage instructions for the medical grade mobile power supply, please see the Tripp Lite Medical-Grade Mobile Power Retrofit Kit Owner's Manual.

For cleaning and maintenance instructions for the PF Roll Stand, please see the PF Roll Stand Installation Guide.

Troubleshooting and Support

If you need assistance with the Vapotherm Precision Flow, please contact your local Clinical Product Specialist or email Vapotherm Technical Support at <u>TS@vtherm.com</u> (855-557-8276)

Referenced Documents

Vapotherm Precision Flow Operating Instructions Manual Document Number: 3001002

GCX Roll Stand Kit Installation Guide Document Number: DU-VAP-0001-61

Tripp Lite Owner's Manual for Medical-Grade Mobile Power Retrofit Kit Document Number: 200910241 93-2704-EN

Specifications

Precision Flow Operation and Performance

Flow:	1-40 L/min
Temperature:	33-43°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 8185:2007(E); Requirements for Medical Humidifiers
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

VTU Mobile Therapy Delivery Times

Low Flow Use Table (Duration of use blending from E-size oxygen and E-size air cylinders; times shown in minutes).

Total Flow	% Oxygen	l							
L/min	21%	30%	35%	50%	60%	70%	80%	90%	100%
1	560	632	681	681	1106	903	750	641	560
2	280	316	340	340	553	451	375	321	280
3	187	211	227	227	369	301	250	214	187
4	140	158	170	170	277	226	187	160	140
5	112	126	136	136	221	181	150	128	112
6	93	105	113	113	184	150	125	107	93
7	80	90	97	97	158	129	107	92	80
8	70	79	85	85	138	113	94	80	70

High Flow Use Table (Duration of use blending from E-size oxygen and E-size air cylinders; times shown in minutes)

Total Flow	% Oxygen	1							
L/min	21%	30%	35%	50%	60%	70%	80%	90%	100%
5	112	126	136	136	221	181	150	128	112
6	93	105	113	113	184	150	125	107	93
7	80	90	97	97	158	129	107	92	80
8	70	79	85	85	138	113	94	80	70
9	62	70	76	76	123	100	83	71	62
10	56	63	68	68	111	90	75	64	56
15	37	42	45	45	74	60	50	43	37
20	28	32	34	34	55	45	37	32	28
25	22	25	27	27	44	36	30	26	22
30	19	21	23	23	37	30	25	21	19
40	14	16	17	17	28	23	19	16	14

Warning: These mobile run time estimates are based on use of a 2000-psi E cylinder. Actual performance may vary depending on the amount of gas in the cylinders.

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- Cylinder gas supply: From 14 minutes to 18.7 hours, based on the O₂/air gas ratio and flow rate settings on the Precision Flow.
- Battery life: Up to 1.5 hours from a full charge.

Warranty

Vapotherm expressly warrants, for a period of ninety (90) days from the date of shipment by Vapotherm to the initial purchaser of the Vapotherm Transfer Unit ("Customer") that the Vapotherm Transfer Unit device shall meet the specifications set forth in the applicable official operating instructions for use provided with each Vapotherm Transfer Unit (the "Instructions"). The sole remedy for this warranty is that Vapotherm shall, at its sole option, either refund, repair or replace any part or all of any Vapotherm Transfer Unit that is defective at no cost to the Customer. Vapotherm shall pay any shipping charges required in repairing or replacing any part or all of a Vapotherm Transfer Unit during the warranty period. Customer shall be responsible for the cost of labor for repairs. This warranty does not apply to any other Vapotherm Product, including without limitation the Precision Flow device, the disposable patient circuits and hoses used with the Precision Flow device, or any disposable component used with the Precision Flow device.

The warranty set forth herein shall become null and void if: (1) the Vapotherm Transfer Unit is not used or serviced in accordance with the applicable Instructions or any related preventative maintenance instructions provided with the Vapotherm Transfer Unit; or (2) the Vapotherm Transfer Unit is tampered with, or if repairs or service are performed or attempted on the Vapotherm Transfer Unit by anyone other than Vapotherm or a Vapotherm-certified service center.

EXCEPT AS EXPRESSLY SET FORTH ABOVE, VAPOTHERM MAKES NO WARRANTY, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE PRODUCTS OR ANY OTHER ITEMS PROVIDED BY VAPOTHERM, AND HEREBY EXPRESSLY DISCLAIMS ANY OTHER FORM OF WARRANTY, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THIS STATED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES PROVIDED BY LAW.



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