FlowTrax® Infusion Device Analyzer

Operator's Manual



Compliant products conforming to the relevant standards and directives required for CE have a CE Mark label, as shown below, affixed to the unit. CE Marked products also comply with the WEEE directive for category 9 Monitoring and Control Instrumentation products. Do not dispose of this product as unsorted waste. To dispose, contact Pronk Technologies at support@pronktech.com. A Return Material Authorization will be issued to return the unit for disposal.



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This Operators Manual relates to FlowTrax software version 1.6. The user can verify the s/w version they have on their FlowTrax by press and hold of the setup key. Version number is located in upper left hand corner.

This product is intended for testing purpose only and is not used in diagnostics, treatment or any other capacity where they would come in contact with a patient.

The device shall only be used with the AC-DC adaptor provided or with AA Alkaline or Lithium batteries.

Operate this product using only accessories provided by Pronk Technologies.

If this equipment is used in a manner not specified by the Pronk Technologies, the protection provided by the equipment may be impaired.

Service and calibration must be performed by Pronk Technologies or a designated service organization approved by Pronk Technologies. Verify proper service and calibration by reviewing certification document returned with the device.

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Accessories

Standard Accessories	P/N	Description
6VDC/1.8 amp Power Supply	501-0701	6VDC/1.8 amp Power Supply for SimCube; OxSim - US Type A Plug
Carrying Case	501-0806	Carrying case for FlowTrax. Includes pockets for accessories.
Spare Filter Screen Assy.	501-9919	2 each Replacement filters, installs inside Input Luer.
High Pressure Fitting	501-9910	Input connector utilized for Pressure or vacuum testing.
Syringe Assembly	501-9912	60cc Syringe and 3-way stopcock. Utilized for priming FlowTrax in place of IV pump or to divert air-in-line into syringe by inserting at input at FlowTrax.
3 Way Stopcock	102-4023	3 way stopcock with luer fittings. Attaches to input of FlowTrax.
Output Hose	501-9908	Clear tubing. Connects to output Luer of FlowTrax.
USB Cable	501-9905	USB adapter cable for connecting FlowTrax to PC for software updates.
Temperature Probe Extension Cable	501-0404	Adapter connects to FlowTrax and YSI temperature probe. <i>Note: Temp. probe not sold by Pronk Technologies</i>
Bottle Brush	501-9913	Utilized to clean FlowTrax sample tube.
Cleaning Solution Assembly	501-9906	Used to clean sample tube. Contains Windex®.
Quick Reference Guide	501-0610	Quick reference guide for getting up and running quickly.
User Guide DVD	501-0611	Training videos on utilizing FlowTrax. Includes User Manual, DataSnap software

Optional Accessories	P/N	Description
IV Pole Mount	501-9909	IV pole mount bracket/clamp assembly. Provides a mechanism for clamping FlowTrax to IV pole or bench top. Pivots FlowTrax 90 degrees when needed. <i>NOTE: Available for S/N 1000 or above</i>
HydroBalance TM	501-9914	Automatically pivots IV bag in use to maintain fluid height relative to IV pump to meet IV Pump Manufacturer height requirements and improve accuracy of testing.
IV bags for HydroBalance	501-9915	Set of four Kangaroo 1000ml fluid bags for use with IV pump testing. Optimal size / volume for use with HydroBalance.
DataSnap	601-FT01	FlowTrax DataSnap serial port accessories for data collection and bi- directional communications. Includes (1) Stereo to USB cable, (1) FlowTrax DVD with DataSnap installation instructions.
FlowTrax Stereo To USB Cable	501-9918	FlowTrax serial plug to USB adapter cable.

Symbol Descriptions:

Connector panel symbol	Function
	Serial Port
1	YSI 400 Temperature Probe port
Ψ	USB port

FlowTrax FT-2 Operation

Instructions

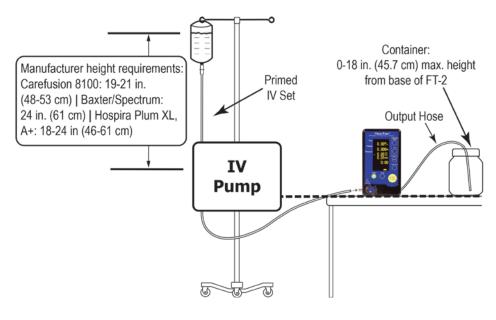
Introduction

The FlowTrax is quick to set up, easy to use and ready to go where you need to be. Your FlowTrax comes with a small 6VDC/1.8 amp power supply, a carrying case, two spare filter screen assemblies, a high pressure fitting, syringe, 3 way stopcock, output hose, USB cable, Temperature Probe extension cable, bottle brush, flush bottle, bottle of glass tube cleaner, Operators' manual, Quick Reference Guide and a training video.

Quick Start: (NOTE: FlowTrax will generate a tracking bubble itself, once flushed and priming has begun.)

- > Use Distilled, Deionized water only.
- ➤ Prime/purge the IV set before connecting to FlowTrax.
- > Zero Pressure transducer. With FlowTrax input luer vented to atmospheric pressure, press Pressure Zero button on FlowTrax.
- > Setup FlowTrax vertically on a level bench / surface, or attach to IV pole per figure 1.
- ➤ If FlowTrax has been unused for several hours or longer (overnight, for example), run 600ml/hr or more with 30ml of volume through FlowTrax to condition glass tube surface. If bubble is "sticking" or "dragging" on inside of glass, try using "CLEAN GLASS" Function, then run a volume of 20ml of distilled fluid through FlowTrax and re-Prime. If bubble sticking persists, clean glass with bottle brush and cleaner provided (see Routine Maintenance section).
- Flush FlowTrax (by selecting FUNCTION then FLUSH and running pump at 900+ml/hr for approximately 20ml Volume.
- ➤ Prime FlowTrax by exiting FLUSH Screen (at approximately 600ml/hr) FlowTrax will generate its own bubble (approx. 3/8") during priming process for tracking purposes.
- ➤ Place output bottle at the same height as FlowTrax. Output bottle should <u>not</u> be below FlowTrax, and should not be more than 18" above FlowTrax output fitting (right side).
- ➤ Clean Glass once a month with cleaning solution and bottle brush provided, once a week if running very low rate tests.

Figure 1 Setup Diagram



Detailed Operating Instructions:

1) Power up the FlowTrax:

Plug the FlowTrax into an AC socket via the small power supply provided. Press the green POWER button on the front of the FlowTrax to turn it on. Alternatively you can use 2 AA batteries to power FlowTrax. To install the batteries use the symbols inside the battery compartment for orientation. To remove batteries use your finger or flat object to pull the battery out of the compartment.

2) Test Solution:

Use only distilled, Deionized water with FlowTrax for proper operation, accuracy and longevity of the device.

3) Output bottle:

Place output bottle at the same height as FlowTrax or up to 18" above. The output bottle should <u>not</u> be below the level of FlowTrax.

4) Accelerometer (TILT) Check:

FlowTrax has a built in accelerometer utilized to detect when the FlowTrax is tilted. At power up it is important to verify you do NOT see the "TILT" message on the display. If a TILT message is displayed, verify FlowTrax is on a level surface in the upright or horizontal position. This message must be cleared to ensure the best accuracy of the readings.

NOTE: If the "TILT" message won't clear, and you are confident that the FlowTrax is on a very level surface, press SETUP, MORE, CHK TILT. Press ZERO in the upper right corner to calibrate the accelerometer to the level surface you are working with.

5) Priming FlowTrax:

Description: FlowTrax will tell you if it requires a prime. If FlowTrax posts "PRIME REQUIRED", in the flow/volume segments of the display, a new prime is required. Each time you press "RESET FLOW" it will scan the glass tubes to determine if the conditions of the visible fluid column are adequate for accurate flow/volume measurements. Always primed/purge your IV Set of any air bubbles before connecting to FlowTrax, as this scan can only evaluate the conditions inside the FlowTrax and cannot see air coming in from the IV set. These air bubbles can reach the optics during a reading and cause errors.

FlowTrax flow rate and volume testing generally requires a new prime under the following conditions: each time the glass has been cleaned, if FlowTrax has been stored (not in use) for more than a few hours or, in some cases, when a new IV set has is attached to FlowTrax (if the IV set has not been primed/purged of air). Once an initial prime has been completed on FlowTrax, it should not need to be repeated during a normal work day unless air is introduced into the FlowTrax.

There are two methods to prime FlowTrax depending on what type of pump you are testing and how you have configured your setup. Choose the appropriate method below that best matches the pump you're testing.

NOTE 1: When setting up FlowTrax at the beginning of each day, a ZERO pressure should be performed with FlowTrax void of fluid (Use "Clean Glass Function") and nothing connected to the input fitting *before* performing the "FLUSH" and "PRIME" steps to follow. See "Occlusion Testing" section for more information.

NOTE 2: ALWAYS prime/purge the IV set into a collection container **before** attaching it to the FlowTrax fitting to reduce priming time and to optimize performance.

a) Priming with Infusion Device (capable of rates 600ml/hr or more)

- With FlowTrax upright (vertical) and level, attach primed/purged IV set to the input (left side) fitting of FlowTrax.
- Flush FlowTrax by selecting FUNCTION then FLUSH and running pump at 900+ml/hr for approximately 20ml Volume.
- Leave FlowTrax on the FLUSH screen, reprogram IV Pump for 600ml/hr and 20ml Volume.
- Restart IV pump.

- Prime FlowTrax by exiting FLUSH Screen (with pump running approximately 600ml/hr) NOTE: FlowTrax will generate its own bubble (approx. 3/8") during priming process for tracking purposes.
- Continue this rate until "PRIME REQUIRED" message is replaced with actual flow rate numbers in the FLOW section of the screen. The Volume section of the screen will change from "PRIME REQUIRED" to "RESET FLOW TO START VOL" when priming has completed.
- Press RESET FLOW just prior to starting the infusion pump to zero Flow, Volume, Max pressure and timer.

b) Priming with syringe and 3-way stopcock (when testing units <u>not</u> capable of 600ml/hr or higher rates)

- Fill 60cc syringe with 50+ cc of distilled water.
- FlowTrax upright (vertical) and level
- Attach syringe to 3-way stopcock, then attach 3-way stopcock to input (left side) fitting of FlowTrax. Position the 3-way stopcock valve to allow flow from syringe into FlowTrax.
- Flush FlowTrax (by selecting FUNCTION then FLUSH) and using a high speed, hard push of the syringe for approximately 20ml Volume.
- Leave FlowTrax on the FLUSH screen, depress syringe plunger at a low speed for approximately 20ml Volume.
- Continue this rate until "PRIME REQUIRED" message goes away in the FLOW section of the screen and is replaced with rate average numbers. The Volume section of the screen will change from "PRIME REQUIRED" to "RESET FLOW TO START VOL" when priming has completed.

NOTE 3: If FlowTrax has been sitting unused for several days with water in the tubes, run for 5-10 minutes at a rate of 300ml/hr (syringe pump) or 600+ml/hr (IV Pump) before using for measurement. If FlowTrax has been sitting unused for a few days or more dry, it may be necessary to do a CLEAN GLASS process (See maintenance section) for best results.

6) Flow and Volume Measurements:

- a) Attach IV set to input of FlowTrax, or to remaining port on 3 way stopcock. ALWAYS prime/purge the IV set into a collection container *before* attaching it to the FlowTrax fitting to reduce priming time and to optimize performance.
- **b)** If a 3 way stopcock is still installed, position the 3 way stopcock valve to allow flow from the infusion device into FlowTrax and not into the syringe.
- c) Configure the infusion device for the desired flow/volume.
- **d)** Press the RESET FLOW button to reset both flow rate and volume numbers on the FlowTrax just prior to starting infusion device for testing.
- e) Start IV pump.
- f) The FlowTrax will automatically begin flow and volume measurement when it senses flow from the IV pump.

NOTE: It is not necessary to "stop" the FlowTrax at the end of a test. FlowTrax will capture an accurate total volume delivered and post an average Flow Rate at the end of a test without user interaction. If KVO (Keep Vein Open) feature on the IV pump is enabled on the infusion device being tested, Volume, and in some cases, the Flow Rate measurement may be affected.

Very Low Rate Testing:

NOTE: When performing flow and or volume tests involving Flow Rates below 20ml/hr, flushing and priming still must be performed with FlowTrax vertical (upright).

a) After FlowTrax is flushed and primed, lay FlowTrax on its back (horizontal) so that the buttons are facing the ceiling for the most accurate results at these lower rates. NOTE: You do not need to remove the IV bracket from the back cover. It is acceptable for FlowTrax to lean on one side when horizontal.



- b) If FlowTrax is mounted to an IV pole, turn it 90 degrees or remove from pole clamp and lay it on its back on flat/level surface.
- c) Run the pump being tested using its maximum rate it can be programmed for while observing the glass tubes. Make sure that there are no tiny bubbles in the front glass tube that are not travelling at the same speed as the primary tracking bubble. These tiny bubbles can interfere with the FlowTrax measurements, and it may be necessary to momentarily tilt the FlowTrax in order to cause the tiny bubble to attach to the primary / tracking bubble before starting a low rate test.
- d) Verify FlowTrax does NOT display a "TILT" message before starting a test.
- e) FlowTrax should be used in an upright (vertical) position rates above 20ml/hr and for priming.

7) Trending:

NOTE: The Trend screen can be used to determine Pass or Fail data from the last test performed. This is particularly helpful for unattended tests where the user was not able to see the final results before, for example, KVO started.

- Press the FUNCTION button, then TREND button.
- The FlowTrax captures and displays accumulated Volume and average Flow Rates at one minute intervals for up to 14 minutes.
- Pressing RESET FLOW button will clear all trend data from previous test.

8) Occlusion Testing:

NOTE: It is not normally necessary to ZERO pressure repeatedly throughout the day with FlowTrax. In fact, if an IV Set is attached and the output hose is above FlowTrax at the time zero is pressed, an error may be introduced to the zero offset and subsequent occlusion measurement. Performing a pressure ZERO is recommended at the beginning of each day unless **a**) there is a substantial shift in barometric pressure or **b**) FlowTrax is being moved from one location to another where there is a substantial change in altitude.

- a) If pressure ZERO is needed, remove input line from FlowTrax input fitting, press FUNCTION, then CLEAN GLASS. Press ZERO button on FlowTrax. It may take a few seconds for pressure to zero. Reinstall Input line, FLUSH and PRIME to start fluid measurements / occlusion tests.
- b) Connect (if not already) IV set to FlowTrax input (left side) fitting.
- c) Select desired units of measure by pressing UNITS button on FlowTrax.
- d) Press RESET FLOW to zero the MAX pressure value.
- e) Program infusion device for desired rate and start infusion device.
- f) Slowly turn occlusion knob on front of FlowTrax clockwise until the infusion device alarms or the occlusion knob is flush with front of FlowTrax (do not over tighten).

UNITS WITH ELECTRONIC OCCLUSION (E-OCCLUDE) FEATURE:

- i) Press FUNCTION key
- ii) Press 40PSI Occlude soft key at bottom of screen.
- iii) Program infusion device for desired rate and start infusion device.
- iv) Electronic Occlusion Screen will display the maximum pressure at the top of the screen and graph the results as the pressure in the IV pump rises, until the unit under test reaches the occlusion alarm threshold, as shown in the figure below. MAX AT equals the total elapsed time to achieve Occlusion. The pressure value below MAX AT is the real time pressure.



- g) Document "MAX" pressure indicated on FlowTrax.
- h) The last "MAX" pressure will remain on the display for 2 hours, or until "RESET FLOW" is pressed.

9) Air-In-Line Testing:

NOTE: To avoid air bubbles from flowing into the FlowTrax during an air-in-line test (which can force users to re-prime), use the 3 way stopcock and syringe to exhaust the air bubble prior to reaching the input of FlowTrax. This will allow you to run the air-in-line test without having to disconnect and reconnect the IV set to the FlowTrax.

- a) Attach syringe to 3 way stopcock, attach 3 way stopcock to input (left side) fitting of FlowTrax.
- Position the 3 way stopcock valve to allow flow from infusion device through to syringe and <u>not</u> into FlowTrax.
- c) Run the air-in-line test.
- d) Either run the infusion device at a high rate until the air bubble reaches the syringe, or remove the IV set from the infusion device mechanism and gravity flow the air bubble until it reaches the syringe.
- e) Re-position the 3 way stopcock valve to allow flow from infusion device to FlowTrax and not into the syringe.

Stopwatch Feature:

NOTE: The FlowTrax stopwatch feature can be used to perform any timed tests that you may need. The stopwatch will also start when FlowTrax is sensing flow, and stop when it senses flow has stopped.

- To start or stop the FlowTrax stopwatch, press the Stopwatch button once on FlowTrax.
- To zero the stopwatch, press and hold the Stopwatch button until zero is observed.

10) Pressure Meter Function (12.5 to +75 PSI):

NOTE: FlowTrax is not only an infusion device analyzer. It is also a full featured pressure meter. These steps are for DRY usage of the pressure meter, and *are not necessary for IV Pump occlusion testing*

- a) Place output hose in a collection container.
- b) Empty all fluid from FlowTrax by pressing the FUNCTION button, and then press the CLEAN GLASS button. The CLEAN GLASS function will automatically expel water from FlowTrax.
- c) Press ZERO button on FlowTrax for zeroing pressure.
- d) Select desired units of measure by pressing UNITS button on FlowTrax.
- e) Turn occlusion knob clockwise until knob is flush with front of FlowTrax panel (you do not need to over tighten the knob to obtain an occlusion).
- f) Press RESET FLOW to zero the MAX pressure.
- g) Using high pressure fitting provided, or similar, connect to the input (left side) fitting on FlowTrax.
- h) Begin pressure testing.

11) Temperature Measurements:

- 1. Connect temperature extension cable provided to temperature port on FlowTrax.
- 2. Connect YSI-400 probe to temperature extension cable.
- 3. This will automatically trigger the temp measurement to be displayed on the FlowTrax display.
- 4. Begin measuring temperature.

12) IMPORTANT Application Notes:

Accuracy: FlowTrax accuracy relies on optical sensors located on a moving carriage, which track a bubble in a fluid column (glass tube). FlowTrax software determines the rate and volume being delivered based on the carriage travel while tracking the bubble. This means care must be taken to ensure the FlowTrax is balanced and level relative to the bubble inside the FlowTrax fluid column for accurate results. Avoid any tilting or leaning of the FlowTrax. FlowTrax will post a "TILT" message in the lower left hand corner of the screen if it is not level. In addition, extraneous air / bubbles entering FlowTrax during priming or during an actual test may introduce errors in the results. Ensure IV set is cleared of any air before use. For flow rates of 20ml/hr or less, place FlowTrax on its back (horizontal). At all rates, output bottle must be level with FlowTrax or no more than 18" above FlowTrax.

Very Low Flow Rates: For flow rates of 20ml/hr or less, lay FlowTrax on its back so that the buttons are facing the ceiling. If FlowTrax is mounted to an IV pole, turn it 90 degrees or remove from pole clamp and lay it on its

back on flat/level surface. FlowTrax should be used in an upright position for all other flow rates and for priming. Verify a "TILT" message is NOT being displayed before using FlowTrax. FlowTrax should only be used in a level position vertically or horizontally.

Contamination of FlowTrax Fluid Path:

Use of any test fluid other than distilled water will cause damage to the FlowTrax components designed into the fluid path. Even tap water will shorten the life of these components because of corrosion caused by electrolysis. Since the solenoid valves used in the FlowTrax are magnetic, they cannot be made of Stainless Steel grade 316, which would be the optimal material to avoid corrosion. Therefore when non-distilled water is used, the valves may start corroding in a very short amount of time (see photos below- after only three days submerged in tap water) leading to an eventual failure.





WARNING: Warranty does not include contamination of fluid path components caused by use of test fluids other than distilled water. A repair of damage during the warranty period appearing to be the result of non-recommended test fluids being used will be performed at a nominal flat rate. See Services chart or contact Pronk Technologies for details.

13) Routine Maintenance:

Glassware: Use only distilled water with FlowTrax for proper operation, accuracy and longevity of the device. Cleaning the glass tube is easy to do and is recommended at least once a month. An extensive design effort went into making the FlowTrax glass tube assembly field removable to simplify glass cleaning/maintenance. A tube brush, cleaning solution (Windex® Original) and flush bottle have been provided for ease of maintenance. Use only Windex® Original for cleaning glass tubes- other cleaners may contain chemicals that could cause damage to FlowTrax.

IMPORTANT: Never remove Glass Tube Assembly before removing all water from FlowTrax.

Instructions for cleaning the removable Glass Tube Assembly:

- a) Remove IV set from input to FlowTrax.
- b) Power ON FlowTrax by pressing the green POWER button.
- c) Remove side door exposing glass tube assembly.
- d) Place FlowTrax Output hose into collection container.
- e) Press the FUNCTION button on FlowTrax. Press "CLEAN GLASS" button. The CLEAN GLASS function will automatically expel all visible water out of FlowTrax glass tube assembly. It will also position the optical carriage in the center of the tubes, thus avoiding any interference when removing.
- f) Remove Glass Tube Assembly by pulling outward from the top of the assembly, then pulling upward to completely remove.
- g) Using the tube brush provided, soak brush in the cleaning solution provided. Insert brush inside of the glass tube while twisting, pushing and pulling through the tube section. Continue for about five seconds in each tube section.
- h) Using distilled water and flush bottle provided thoroughly flush cleaning fluid out of Glass Tube Assembly. Dry off outside of glass tubes with a paper towel before re-installing into FlowTrax.
- i) Re-insert Glass Tube Assembly (bottom end first). Ensure positive fit into FlowTrax.
- j) Re-prime FlowTrax and it is ready to be used.

Filter: <u>Use only distilled water</u> with FlowTrax for proper operation, accuracy and longevity of the device. Cleaning the filter is easy to do and is recommended at least once every 90 days. An extensive design effort went into making the FlowTrax filter assembly field removable to simplify cleaning / maintenance.

Units configured with Removable Input Luer:

- 1. Turn input luer counterclockwise to remove it from the unit.
- 2. Inside the threaded side of the Input luer there is a white filter screen. Using a blunt tool, insert into the input luer to remove filter.
- 3. Hold up screen up to indoor lighting to inspect for debris. Using brush provided, clean filter then rinse with distilled water. If debris cannot be removed, replace with spare filter included with accessories.
- 4. Insert filter into threaded side of input luer using blunt tool. Verify filter completely covers opening of input luer, if not, remove and reinstall. **IMPORTANT:** Verify input luer is tightened so red dot on Luer is set to 12 o'clock position to ensure a secure fit and avoid leaks.

Units configured with Filter Drawer at bottom of Unit:

- a) Place FlowTrax output hose into collection container.
- b) Expel all water from FlowTrax by pressing the "FUNCTION" button on FlowTrax, then Press "CLEAN GLASS" button.
- c) Place FlowTrax horizontally on its back.
- d) Remove filter drawer assembly located at the bottom of the surface (See Figure 1) of FlowTrax with a small flathead screw driver.

(Figure 1)



(Figure 2)



- e) Inspect filter element for contamination and or corrosion.
- f) Contaminants can be blown out of the filter element by using compressed gas such as Dust-Off [®], or backflushed over sink using a faucet. (See Figure 2)
- g) Once contaminants and/or corrosion is removed, wet both sides of the filter drawer including the O-rings with distilled water to lubricate. Re-install filter drawer assembly. NOTE: Ensure correct orientation of filter drawer assembly, before re-installing. If installed backwards, FlowTrax will leak and cause errors in flow/volume measurements.

CORRECT Method to Install Filter

INCORRECT Method to Install Filter

Large Red O-Ring should face toward rear cover of FlowTrax





Warning: This will cause Leaks. Small O-Ring should NOT face toward rear cover

Clean the Product (Outside)

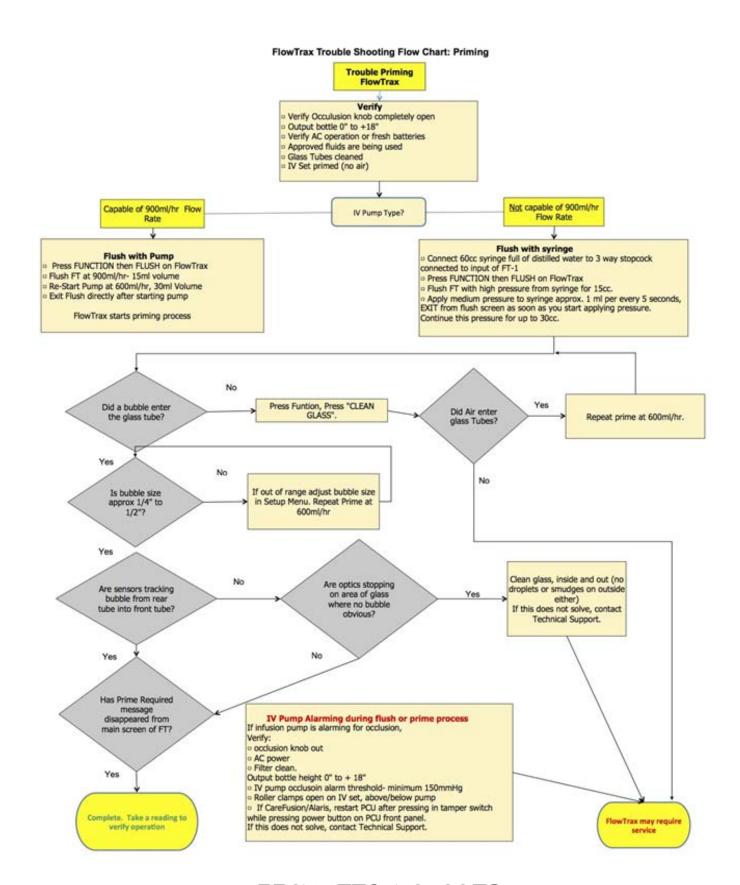
To clean the outside of the FlowTrax, disconnect from the power supply and use only a damp cloth with mild detergent.

Preventative and Routine Maintenance Chart:

Segment	Frequency	Description
Glassware	Monthly (weekly if testing very low rates)	Consists of Glass Tube Assembly found by removing side door of FlowTrax. Be sure to use "Clean Glass" function prior to removing Glass Tube Assembly. Remove glass and follow cleaning process described in Routine Maintenance section of this manual.
Filter Assembly	Quarterly	Remove filter assembly and follow cleaning process described in Routine Maintenance section of this manual.
Fluid Path	Annual	Consists of the manifold, occlusion chamber, O rings, transducer, check valve, interconnect hosing, filter assembly, valves and valve block. Glass Tube Assembly and Filter Assembly called out separately. Maintenance of the Fluid Path and associated components of the FlowTrax system is recommended on an annual basis, performed as part of the systemic calibration test.
Mechanical	Annual	Consists of stepper motor, optics carriage, belt and pulleys. Maintenance of the entire mechanical parts of the FlowTrax system is recommended on an annual basis, performed as part of the systemic calibration test.
System	Annual	Calibration and maintenance of the entire FlowTrax system is recommended on an annual basis. The Pronk FlowTrax calibration procedure must be followed by an authorized calibration company using NIST traceable fixtures defined in the procedure to guarantee the device meets all specifications.

14) FlowTrax Troubleshooting Tips:

SW version 1.6 or higher TROUBLESHOOTING TIPS		
SYMPTOM	SOLUTION	
"Prime Required" message intermittently appears	FlowTrax has determined the bubble in the glass tube assembly is not adequate for accurately measuring flow/volume. Press FUNCTION, then press FLUSH. Program IV pump for 900ml/hr, 10ml volume. Start IV pump. When complete, program IV pump for 600ml/hr, 20ml volume. While running this rate, press EXIT on FlowTrax. Continue until "Prime Required" message goes away.	
Can't remove or expel all bubbles from FlowTrax	FlowTrax will generate a "tracking" bubble once it determines that the glass tubes are full of water and no other unwanted bubbles are present. This bubble is necessary to measure Flow and Volume. Do not try to remove or expel this "tracking bubble.	
Volume number stopped during test, or came out much lower than expected	Glass cleaning may be necessary. Remove IV set from input. Press FUNCTION button, then press CLEAN GLASS button. Remove glass tube. Clean glass tubes with bottle brush and cleaning solution provided. Flush out cleaning solution from glass with flush bottle provided. Re-install glass tube. If running a low rate test (1-20ml/hr), place FlowTrax on its back (horizontal) for optimal performance.	
Volume measurement is higher or lower than expected	Make sure to press the RESET FLOW button just before starting the pump. This will ensure accurate results. Ensure Occlusion knob is completely open counterclockwise.	
Keep getting occlusion alarm on infusion device	Make sure occlusion knob on the FlowTrax is turned completely counter clockwise to allow fluid flow. If occlusion alarm persists, remove filter assembly and inspect for particles and or contamination. Clean filter assembly and reinstall.	
Occlusion pressure doesn't seem accurate	Make sure to ZERO the pressure on the FlowTrax to atmosphere and then press RESET FLOW before running an occlusion test.	
Can't zero STOPWATCH timer	Press and hold Stopwatch button for 2 seconds to return the timer to zero.	
Flow Rate does not seem accurate	Some pumps have very inconsistent flow patterns. Use the volume divided by time (V/T) for accurate flow rates with infusion devices with very long pauses. Press SETUP, MORE, READINGS, select VOL/TIME.	
TILT message won't clear or flashes on and off	If "TILT" message won't clear and the FlowTrax is on a very level surface, press SETUP, MORE, CHK TILT. Press ZERO in the upper right corner to calibrate the accelerometer to the level surface you are working with.	
Glass Tube Sensor Carriage does not move when priming or attempting to take a measurement	It's possible for a small bubble to stick against the glass tube which must be removed. Press FUNCTION, then CLEAN GLASS to remove water and small air bubble, and then re-prime. If problem persists, Press FUNCTION button, then press CLEAN GLASS button. Remove glass tube. Clean glass tubes with bottle brush and cleaning solution provided. Flush out cleaning solution from glass with flush bottle provided. Re-install glass tube.	
DataSnap: Displays COMM SEARCHING Won't capture data or control FlowTrax	 Verify COMM OK displayed at bottom of DataSnap 2,0 Home Screen. If not, check connection to FlowTrax. If still no COMM, then verify via Device Manager on PC that USB to Serial adapter cable is being recognized by PC. If not recognized by PC, then unplug USB to serial adapter from PC wait about 30 seconds and reconnect. Drivers may need to be reinstalled if PC does not recognize the USB to serial adapter cable. If USB Cable is recognized by PC and good connection to FlowTrax, cable should be replaced. 	
DataSnap: COMM OK but still not transferring data	Verify computer cursor is in location where data will be transferred, then select Hot Key to transfer data. NOTE: Data Streaming will turn off automatically if the operator moves to another program on PC.	
Unable to resolve	Contact Pronk Technologies Technical Support at: (800-541-9802)	



15) IV Pump Manufacturer height requirements chart:

Pump	Height Requirements	From	Tolerance
Manuf/Model			
CareFusion 8100	19 to 21 Inches	Top of Water to Top of Pump	+/- 1 Inch
B-Braun Outlook	10 to 14 Inches	Top of Water to inlet of pump	+/- 2 Inches
B-Braun Space	50 cm (19.68 Inches)	Top of Water to middle of pump	NA
Hospira Plum XL	18 to 24 Inches	IV bag to cassette chamber	+/- 3 Inches
Hospira Plum A+	46-61 cm (18-24 Inches)	IV bag to pump chamber	+/- 3 Inches
Baxter Spectrum	24 Inches	IV bag to pumping mechanism	NA

NOTE: These height requirements are for reference only, and are subject to change by each manufacturer.

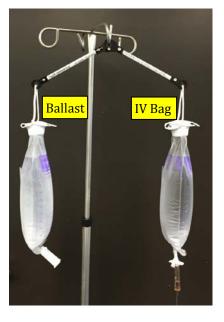
16) HydroBalanceTM Setup and Use

Description: HydroBalance ensures the IV source bag used for testing infusion pumps will be maintained at a constant head height even as that source bag begins to drain during use. It utilizes a patent pending swivel arm design that automatically adjusts the height of the IV source bag.

Setup:

NOTE: (2ea.) KendallTM (CovidianTM) 1000ml Gravity Feeding Bag, Kendall Part # 702505 is required. Remove fluid tubing right at the top of drip chamber. Utilize roller clamp to seal both bags. One bag will be used as ballast, the other as the primary IV bag.

- 1. Attach the HydroBalance (HB-1) center loop to the IV pole.
- 2. Attach Primary IV bag to one arm of HB-1. Attach the "ballast" bag to the opposite arm.
- 3. Ensure roller clamp on ballast bag is completely closed around end of tube to avoid leaks. Fill the ballast bag with 1200ml of distilled water.
- 4. Remove roller clamp from end of primary IV bag. Spike IV set into the tubing at the end of the bag. Ensure there is a tight seal. Clamp off IV set to avoid leaks.
- 5. Fill the primary IV bag to the same level as ballast bag.
- 6. Ensure the IV set is not interfering with the balance of the two bags. Adjust the water level in the ballast bag as needed so that both HB-1 arms are level. Start Testing.



17) DataSnap Electronic Data Transfer and Control

Description: DataSnap provides real time results capture from FlowTrax® to any file, form or record open on your PC. DataSnap also provides for control of your FlowTrax from your PC, including clearing prior test results for subsequent testing and "Flushing" FlowTrax for priming. Using your keyboard function keys, users can transfer FlowTrax test results or request FlowTrax send real time data for rate and volume at user programmable intervals for graphing Infusion pump performance over extended periods of time. In either case, the data will go directly into a file, form or record you have open on your pc where you have selected a cell or box that results are normally typed into (including notes fields in forms).

DataSnap Function Keys Use Function (FN) key on PC to select, F2, F3, F4, F6 features Use Ctrl+Shift+[desired letter/number] keys to select extended features	Description
F2 = Help	Legend of DataSnap Common Features Hot Keys
Ctrl + Shift + H = Extended Help Menu	Legend of DataSnap Extended Features Hot Keys
F3 or $(Ctrl + Shift + Z) = Reset Flow$	Clear prior Test Results on FlowTrax
F4 or (Ctrl + Shift + V) = Insert Volume	Request Real Time Volume Result
F6 or $(Ctrl + Shift + C) = Insert Max$. Pressure	Request Maximum Pressure (Occlusion Pressure)
Ctrl + Shift + D = 10 second Data Stream ON	Request Real time data for rate & volume at 10 second intervals
Ctrl + Shift + S = 10s Data Steam OFF	Turn off real time Data Stream
Ctrl + Shift + O = Electronic Occlusion ON	Activates Electronic Occlusion on FlowTrax
Ctrl + Shift + X = Electronic Occlusion OFF	Exit Electronic Occlusion and back to main screen on FlowTrax
Ctrl + Shift + R = Insert Rate	Request Real Time Rate value
Ctrl + Shift + P = Insert Real Time Pressure	Request Real Time Pressure Value
Ctrl + Shift + 1 = 1 second Data Stream ON	Request Real time data for rate and volume at 1 second intervals
Ctrl + Shift + 2 = 200 millisecond Data Stream ON	Request Real time data for rate and volume at 200 millisecond intervals
Ctrl + Shift + F = Flush Mode	Put FlowTrax into "Flush" mode for Priming.
Ctrl + Shift + T = Insert Real Time Temperature	Request Real Time Temperature Value (Requires temperature probe connected to FlowTrax)

FlowTrax Requirements: To connect FlowTrax to your PC for DataSnap capabilities, you will need the following items:

- (1) FlowTrax Stereo to USB cable, Part # 501-9918.
- Install software program DataSnap 2_0 available on FlowTrax User Guide DVD.
- FlowTrax software version 1.6 or higher. Units with software 1.2 or lower will require factory upgrade. **NOTE:** Only Model FT-2 units are compatible with Electronic Occlusion features.

PC Requirements for DataSnap Software

Operating Systems: Windows 7 and Windows 10.

DataSnap Overview: The DataSnap software translates serial data into keystrokes on your PC keyboard so that when a Function (FN) key or Ctrl + Shift + [letter/number] command is entered, it will initiate FlowTrax to execute the desired feature. FlowTrax software version 1.6 or higher is required and can be updated to this version remotely without sending the FlowTrax back to Pronk Technologies. Units with software 1.2 or lower will require a factory upgrade.

Setup Instructions

- 1. Load the DVD provided with your FlowTrax labeled FlowTrax User Guide into your PC DVD drive.
- 2. Select the DVD drive in Windows explorer or similar program, open folder labeled "DataSnap Setup" and use the Copy and Paste function to save DataSnap2_0.exe to desired file location on PC. Recommend saving to Desktop. Once complete, the following icon should appear:



3. Double Click DataSnap Icon on PC to launch program. Home screen should be displayed as shown below.



- 4. If Plug and Play feature is enabled on PC, connect Serial to USB cable provided with DataSnap accessories to PC. Driver will be downloaded automatically from a safe device driver website. If Plug and Play is not available, DO NOT connect Serial to USB cable. First load the Driver manually to PC by accessing the driver setup program called "CDM v2.12.06 WHQL Certified.exe" located on the FlowTrax User DVD under folder DataSnap Setup Information. Once driver is loaded, connect Serial to USB cable to PC.
- 5. With FlowTrax turned off, connect Stereo plug of the Adapter cable to top port on FlowTrax, then power up FlowTrax. DataSnap will automatically establish communication with FlowTrax and display COMM OK at bottom of DataSnap Home Screen.
- 6. To have DataSnap program always visible on PC, select View, then Always on Top. A virtual FlowTrax with real time data may also be viewed on DataSnap by selecting View, then On Screen. Display will extend as shown below.



IMPORTANT NOTE 1: When using the Stream Data feature of DataSnap, be aware that if minimizing the record where data is being captured will automatically turn streaming OFF. This is to prevent data from being streamed into other location. To resume streaming, return to program where data is being captured, place cursor in correct location and select Data Stream ON hot key.

IMPORTANT NOTE 2: Ensure stereo connection to FlowTrax is installed all the way into FlowTrax (door is not interfering) and that the FlowTrax is turned on and primed.

Running DataSnap: Collecting Data from FlowTrax:

- a) Press F3 (FN+F3 for laptops) this should Reset FlowTrax, clearing all data displayed. This confirms communications are functioning.
- b) Open any file, form record or program, click on a text box /cell where data will be transferred and use the select Hot Key to capture results from FlowTrax into that record.
 - **NOTE 1:** When DataSnap is streaming, moving to another program on PC will automatically disable streaming.
 - **NOTE 2:** Be sure to Reset (F3) to clear prior data before data capturing.

18) FlowTrax Serial Port Protocol

Overview: The FlowTrax with software version 1.5 or higher comes standard with a serial (RS-232) communication interface. This feature enables the FlowTrax to send results to a customer' supplied interface as well as commercially available programs like HyperTerminal. FlowTrax Serial Port can be easily adapted for computers with USB ports by using a Serial to USB converter. Test results that can be captured from FlowTrax via the Serial interface include Flow Rate, Volume, Pressure, Maximum Pressure, elapsed time and temperature. FlowTrax can also be controlled by the customer' supplied interface.

RS-232 Pin Assignments (chart/diagram at end of this section)

- **DB-9 Female:** Pin 2=Rx, Pin 3=Tx, Pin 5=Gnd.
- Stereo Jack: The Serial connector at 2.5mm Stereo Jack wired: Tip=Rx on DB-9, Base=Ground, Ring=Tx on DB-9.

Configuring communications: Baud rate is 57600, 1 start, 1 stop, no parity, no handshake.

Important Notes before starting RS-232 communications:

- 1. All polls or commands going to the FlowTrax must have at least 2ms spacing between them as the FlowTrax cannot receive back to back data at 57600 without losing data.
- 2. Use the Device ID report to verify the connection to the FlowTrax. ("I" upper case i)
- 3. Turn off Diagnostic mode when first establishing communications. ("g", then "l" lower case L)
- 4. Prime status can be checked using serial, by polling the volume ("v")
- 5. Run fluid into the FlowTrax until it primes. Then stop the flow and issue a Reset Reading command ("R"). Recheck prime status after the Reset Reading is complete.
- 6. Use the Zero Pressure command to zero the pressure transducer. This should always be done with the input Lure fitting disconnected. ("Z")
- 7. Pressure polling is available in PSI or mmHg. Pressure Curve data is always in PSI.
- 8. When connecting the stereo jack, Pressure units can sometimes change on the display.
- 9. Some FlowTrax keys may not function during serial communications.

Commands and Reports for all Modes		
Function	Command	Detailed Description
Reset Reading	'R'	Resets the bubble tracker and the flow meter (volume, rate and rate history cleared), Resets the trend data, stops and clears the stopwatch, stops and clears the trend timer. 1.0 and above.
Device ID Report	'I'	1.4 and below: returns "FlowTrax" future version: 'FlowTrax SN XXX'
Poll Software Version	'V'	Returns software version, e.g.: "SW: 1.4.0C2"

Enter Flush Mode	'F'	Enters flow thru mode. Use 'R' to exit.
Enter Clean Glass Mode	'A'	Fills glass with air. Use 'R' to exit.
Zero Pressure Command	'Z'	Zeros pressure transducer offset and Max Press
Zero Max Pressure	ʻz'	Zeros Maximum Pressure
Poll Tube Calibration	'С'	Returns tube cal, and settings: bubble size, front optical, rear
and settings	C	optical, e.g.: "C,1290,84,50,49"
Zero Stopwatch Time	'W'	
Poll Stopwatch Time	'w'	Returns the stopwatch time in seconds
Diagnostic Data On	'G'	1.4 and above. Default is on
Diagnostic Data off	ʻg'	1.4 and above

Polls and Replies for Data mode (SW 1.5 and higher)		
Function	Poll	Reply
Poll Pressure in PSI * 100	ʻp'	'p,'yyyy,xxxx <cr><lf> Y is current pressure, X is max pressure, positive or negative</lf></cr>
Poll Pressure in mmHg	'm'	'm,'yyyy,xxxx <cr><lf> Y is current pressure, X is max pressure, positive or negative</lf></cr>
Poll Volume in ul	'v'	'v,'xxxx <cr><lf> X is volume in ul. Returns 'NOT PRIMED' or 'NOT STARTED' when appropriate.</lf></cr>
Poll Rate in 0.1 ml/hr	ʻr'	'r,'xxxx <cr><lf> X is rate on the screen in 0.1 ml/hr. Returns 'NOT PRIMED' when appropriate.</lf></cr>
Poll YSI temp in 0.1C	'y'	'y,'xxxx <cr><lf> X is YSI temp in 0.1C</lf></cr>

Commands and reports for Trumpet mode (SW 1.5 and higher)

Function	Activated	Reports
	By	
Turn on trumpet curves at 10 sec resolution	'h'	reports "T,"XXX"V,YYY< <r><lf> where xxx is total reading time in ms and yyy is total reading volume in ul. Trumpet curve data does not start until the unit is primed, reset, and the flow begins.</lf></r>
trumpet at 5 sec	ʻi'	reports "T,"XXX"V,YYY <cr><lf> where xxx is total reading time in ms and yyy is total reading volume in ul. Trumpet curve data does not start until the unit is primed, reset, and the flow begins.</lf></cr>
trumpet at 1 sec	ʻj'	reports "T,"XXX"V,YYY <cr><lf> where xxx is total reading time in ms and yyy is total reading volume in ul. Trumpet curve data does not start until the unit is primed, reset, and the flow begins.</lf></cr>
trumpet at 200 ms	'k'	reports "T,"XXX"V,YYY <cr><lf> where xxx is total reading time in ms and yyy is total reading volume in ul. Trumpet curve data does not start until the unit is primed, reset, and the flow begins.</lf></cr>
pressure curve at 200ms	ʻn'	Reports "T," XXX "P," YYY "X",ZZZ <cr><lf> where xxx is time since curve start in ms and yyy is current pressure, and zzz is the maximum pressure. Pressure and Max pressure are always in 0.01PSI. Pressure curves begin immediately, regardless of prime status and continues to run until "q" is sent or a different trumpet selection is made.</lf></cr>
All curves off	ʻq'	Turns pressure and trumpet curves off

FlowTrax Serial Communications: Pin outs and wiring chart						
Signal		DB-9 Pin	Storeo Ingly	Diagram ref.		
Name	Abbreviation		Stereo Jack	Diagram rei.		
Transmitted Data	Tx	3	Ring	Shown as 2		
Received Data	Rx	2	TIP	Shown as 3		
Common Ground	G	5	Base	Shown as 1		
5 1 ••••• 9 6						
D-sub 9 Female				3		

19) Updating Software:

NOTE: Loading a new software version into your FlowTrax can be done in the field with a PC laptop, the USB cable provided and a file with the new version of software code. Update FlowTrax software only in conjunction with a file provided by Pronk specifically for your FlowTrax. Use of any other file may cause damage to the operation of your FlowTrax.

- a) Connect the AC power adapter (provided) to your FlowTrax. Wait for full boot up to complete.
- b) Press SETUP button, then USB button.
- c) Next, press GO USB button. The FlowTrax screen will go dark.
- d) Plug in USB cable provided to PC and to FlowTrax USB connector. (Right side)
- e) Your PC will probably recognize that a new 'drive' has been connected and show you that the drive is available. If not, navigate on the PC to look for the drive labeled "FlowTrax."
- f) On your PC, open the FlowTrax drive. You should see various file names on the drive, including the current version of software. DO NOT REMOVE ANY FILES LOCATED IN THIS DRIVE.
- g) On your PC, navigate to the file where the new version of FlowTrax software is located. Drag and drop the new file into the FlowTrax drive file / folder. Wait until the file has completely uploaded. This may take up to a minute.
- h) Once the file has uploaded, you may get a message from your PC stating "USB drive not recognized" or similar. Ignore this message.
- i) Verify that the FlowTrax drive file / folder now includes the correct version name/number for the software you just uploaded.
- j) Disconnect USB cable at your FlowTrax.
- k) Remove the AC power adapter from the FlowTrax. Wait 10 seconds, then re-connect AC power adapter. Wait for full boot up to complete.
- l) Verify successful software upload by pressing SETUP button and confirming the correct version number at the top of the Setup page.
- m) Your new software has been completely uploaded.

Flow Rate and Volume Accuracy- Time vs. Volume

3 Minute Testing Quick Reference Chart					
Desired RATE (ml/hr)	Required VOLUME	Desired RATE (ml/hr)	Required VOLUME		
0.5 – 10	0.5	110	5.5		
15	0.75	115	5.75		
20	1	120	6		
25	1.25	125	6.25		
30	1.5	130	6.5		
35	1.75	135	6.75		
40	2	140	7		
45	2.25	145	7.25		
50	2.5	150	7.5		
55	2.75	155	7.75		
60	3	160	8		
65	3.25	165	8.25		
70	3.5	170	8.5		
75	3.75	175	8.75		
80	4	180	9		
85	4.25	185	9.25		
90	4.5	190	9.5		
95	4.75	195	9.75		
100	5	200 - 999	10		
105	5.25				

FlowTrax Limited Warranty

The FlowTrax Infusion Device Analyzer is warranted against defects in materials and workmanship for a period of four (4) years from the date of shipment to the original purchaser. Warranty is valid only to the original buyer. Defective equipment should be returned freight prepaid to Pronk Technologies. Equipment returned with defective parts and assemblies shall be either repaired or replaced at the manufacturer's sole discretion. This warranty is not applicable if the unit has been opened, if repair has been attempted, if the unit has been damaged due to operation outside the environmental and power specifications for the product, if a test fluid is used other than distilled water or due to improper handling or use, or if it has been calibrated by an unauthorized calibration lab.

Warranty is for a period of one (1) year from date of shipment to the original purchaser, when original purchaser is located outside North and South America. This warranty is extended to (2) years, if the product is calibrated by Pronk or a Pronk authorized service center within 14 months of original shipment. All other standards warranty terms apply.

If any fault develops, notify Pronk Technologies (*see Returns and Repairs*) giving full details of the difficulty, and include the model and serial number of the device. Upon receipt of shipping instructions, forward the device prepaid and repairs will be made at the factory.

If Pronk Technologies determines a fault has occurred as a result of test fluid being used that is not recommended, that repair will be billable. A repair during the warranty period resulting from non-recommended test fluids being used will be performed at a nominal flat rate. The warranty will be reinstated following that repair (i.e. if the repair occurs 3 years into the warranty, the warranty period will continue for one more year).

The foregoing warranty is in lieu of all other warranties expressed or implied, including but not limited to any implied warranty or merchantability, fitness or adequacy for any particular purpose or use. Pronk Technologies shall be liable only for repair or replacement of the FlowTrax Infusion Device Analyzer and optional features. Pronk Technologies shall not be liable for any incidental or consequential damages.

Order Cancellation and Refund Policy

You may return your item within 14 days of delivery for a full refund. We are unable to exchange items however, if you received a defective or incorrect item, we will be happy to make an exchange). Item(s) returned for refund must be in its original condition, undamaged and with no missing parts, packed in its original packaging, and include both the original receipt and an RMA number.

We will notify you via e-mail or fax of your refund once we have received and processed the returned item. You can expect a refund within 7 to 14 business days of our receiving your return in the same form of payment originally used for purchase.

Returns and Repairs

Please call Pronk Technologies' Service Department at 800-541-9802 to obtain a Return Merchandise Authorization (RMA) number and the shipping address. Returns should be <u>packaged securely in the original packaging materials</u>. The RMA number should be clearly marked on the packaging. If the return is for a new item and is a result of our error, we will make arrangements for payment of return shipping. Otherwise, items should be returned freight prepaid to Pronk Technologies.

DataSnap Warranty and Support:

TWedge software- from Tec-IT: Disclaimer

The actual version of this product (document) is available as is. TEC-IT declines all warranties which go beyond applicable rights. The licensee (or reader) bears all risks that might take place during the use of the system (the documentation). TEC-IT and its contractual partners cannot be penalized for direct and indirect damages or losses (this includes non-restrictive, damages through loss of revenues, constriction in the exercise of business, loss of business information or any kind of commercial loss), which is caused by use or inability to use the product

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Script File: It was developed by Pronk Technologies as "shareware" and there is no implied or specific warranty or support. It can be modified by users where more customization is needed.

Services:

SERVICE ITEM NUMBER	DESCRIPTION	PRICE
	, s	Call For Pricing
Maintenance Service	certificate.	
Rejuvenation Service	May be required if FlowTrax is used with	Call For Pricing
	other than Distilled or Deionized water.	
	Inspect, clean and replace as needed: (2) Fluid	
	valves, (1) filter assembly, (1) transducer and	
	(1) check valve.	