



User Manual



Infusion Pump Analyzer

1.1 Copyright

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1.2 Quality Assurance

Netech Corporation is ISO 9001-2000 Registered. This instrument was thoroughly tested and inspected according to Netech's ISO 9001-2000 quality standards (ISO/IEC 17025) and test procedures, and was found to meet those specifications when it was shipped from the factory.

1.3 Warranty

Netech warranties the IPA 2000 Infusion Pump Analyzer against defects in materials and workmanship for one year from the date of original purchase. The standard warranty is extended for second year if the instrument is returned to Netech for its recommended yearly recalibration.

During the warranty period we will repair or, replace at no charge a product that proves to be defective, provided the product is returned to Netech Corporation with prepaid shipping. This warranty does not apply if the product has been damaged by accident, misuse, if its serial number is defaced or removed, or if the product is serviced or modified by someone other than Netech Corporation.

Netech reserves the right to discontinue the IPA 2000 at any time, or change its specifications, price, or design without notice and without incurring any obligation. Netech will make a concerted effort to supply service parts for 5 years after discontinuation.

The warranty is void if you elect to have the unit serviced and / or calibrated by someone other than Netech.

The purchaser assumes all liability for any damages or bodily injury that may result from the use or misuse of the unit by the purchaser, his employees, agents or customers.

In no event shall Netech Corporation be liable for consequential damages.

1.4 Warranty Disclaimer

Should you elect to have your instrument serviced and/or calibrated by someone other than Netech, please be advised that the original warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization. We strongly recommend, therefore, that you send your instrument to Netech for factory service and calibration, especially during the original warranty period.

1.5 Patent / Trademarks

IPA 2000 utilizes a patent pending measurement technology. Netech and IPA 2000 are trademarks of Netech Corporation. Any other trademark names used in this manual are only for editorial purposes and the benefit of the respective trademark owner, with no intention of improperly using that trademark.

1.6 Claims

Our standard method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim.

If the instrument is delivered in good physical condition but does not operate within specifications, or if there is any other problem not caused by shipping damage, please contact Netech or its representative.

1.7 Obtaining Assistance

If you have trouble in setting up or operating the IPA 2000, contact Netech Tech support at support@netech.org.

1.8 Returning the Instrument to Netech

Products returned to Netech require a RMA (Return Authorization Number) for speedy processing of the service required. To obtain a RMA number follow the link <u>http://www.netech.org/rma.asp</u> and fill in the required information, Email <u>service@netech.org</u> or call 800-547-6557 (US & Canada), International 631-531-0100.

1.9 Warnings

IPA 2000 has been designed for testing infusion devices. It must not be used while it is connected to a patient. Tubing sets used to connect IPA 2000 to the infusion device under test must never be used to administer fluids to patients. Follow manufacturers recommendations to avoid contamination due to back flow conditions.

Do not use any other fluids other than distilled water, bottled dinking water or domestic filtered tap water.

Care should be taken to prevent any dirt or other contaminants entering the fluid inlet.

Use of saline solution or other high viscosity fluids will void the warranty.

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3 About this User Manual

This Manual is provided to explain the operation of the IPA 2000 – Infusion Pump Analyzer. IPA 2000 is designed to quickly test the performance of any given infusion device and to determine the performance qualities of the device.

The operator must be familiar with the unit before starting the test procedures.

This document is divided into the following chapters:

- Chapter 1, Introduction
- Chapter 2, Table of contents
- Chapter 3, About this Manual
- Chapter 4, General overview
- Chapter 5, Setup and Operating Instructions
- Chapter 6, Setup Menu
- Chapter 7, Maintenance, Service / Calibration

3.1 Features

- Fast and accurate test utilizing Netech's patented technology
- Flow measurement
- Volume measurement
- Occlusion pressure measurement
- Back flow measurement
- Test data storage over 10000 test results.
- RS 232 PC interface to down load test results.
- Compact and light weight.

3.2 Package Contents

IPA 2000 is shipped with the following:

- Main Unit IPA 2000
- AC Adapter
- Luer lock
- Tubing
- User Manual
- Calibration Certificate
- Warranty Registration Card

3.3 Specifications

The IPA 2000 specifications are listed as follows.

3.3.1 Flow Rate Measurement:

Flow measurement is calculated utilizing Netech's patent pending flow measurement technology. The rate of rise of fluid in a calibrated tube is precisely measured by a series of optical sensors.

Range: 0.5 - 1000 mL/hr Accuracy: Flow rate up to 250 mL/hr, 1% of reading +/- 1 LSD, Flow rate over 250 mL/hr, 2% of reading +/- 1 LSD

3.3.2 Volume Measurement:

The volume is measured by a minimum sample of 100 micro liters.

Range: 0.1 – 999 mL/hr

Accuracy: 1%, +/- 1 LSD for flow rate up to 250mL/hr for Volume up 20 mL.

2%, +/- 1 LSD for flow rate over 250mL/hr for Volume under 20 mL.

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3.3.3 Occlusion Pressure Measurement:

Occlusion pressure is measured by closing the fluid line prior to the measurement column.

Range: 0 –30 PSI or equivalent units mmHg, kPa, cmH2O, bar, PSI **Accuracy:** 0.5 % of full scale +/- 1 LSD.

3.3.4 Electrical Specifications:

A power adapter whose specifications are as follows powers IPA 2000.

AC Adapter input voltage: 110-220 VAC

Output Voltage: 9 Volt DC, 0.500 Amps

3.3.5 Mechanical:

Dimensions: 11" x 9" x 5" (L x W X H)

3.3.6 Enviornmental:

Operational: $15 - 30^{\circ}$ C, Relative Humidity 50%

4 General Overview

IPA 2000 – Infusion Pump Analyzer is designed for measuring the Flow Rate, Volume Delivered and Occlusion Pressure of Infusion Pump Devices.

It is used to verify the performance of infusion pump devices. The test results are displayed on the instrument's LCD as well as saved into the internal flash memory for subsequent printing or downloading to a PC.

4.1 Theory of Operation

Fluid from the infusion pump enters the inlet and is directed to a pressure sensor and a set of valves that directs the fluid to a measurement chamber consisting of a column of calibrated tubing along with an array of optocouplers (sensors) mounted vertically along the tubing. As the fluid passes through the chamber, precise time is obtained as fluid passes each sensor and the flow rate is calculated.

There are two modes of operation, single or continuous. In the single mode as the fluid reaches the top of the column, the measurement is completed, and the mean value is displayed. In the continuous mode, the fluid in the measurement chamber is evacuated and ready for the next sample and the measurement is repeated until the user stops the measurement.

The volume is computed from the time obtained from the individual sensors as the fluid passes through the measurement column. The measurement results are automatically stored in the internal memory from which the results can either be printed or downloaded to a PC (an Excel spreadsheet or other data capture software).

4.2 Measurements

The unit can be used in testing the following parameters of any Infusion Pump Devices

- Flow rate measurement in single and continuous mode.
- Volume measurement in single and continuous mode.
- Occlusion pressure measurement
- Back Flow measurement.

4.3 Controls and Displays



Front Panel

- 1. Liquid Crystal Display 128 x 64 graphics with multiple view ports.
- 2. Key pad
- 3. Function keys, F1, F2, F3, F4 (for menu selection)
- 4. Arrow keys, <, > (for scrolling the menu selection)
- 5. Enter Key
- 6. Esc key
- 7. Alpha numeric keypad for data entry.
- 8. Power ON / OFF key
- 9. Side Panel Right
 - 9.1. Fluid Inlet Luer lock (Female)
 - 9.2. Fluid Outlet Luer lock (Male)
- 10. Side Panel Left
 - 10.1. Power Input
 - 10.2. RS 232 port DSUB 9 Male
- 11. Carrying Handle

5 Setup and Operating Instructions

IPA 2000 has several menu selections. The menu selections are user friendly. Each menu selection has a set of function keys "soft-keys" along the bottom corresponding to the function keys F1 through F4 on the keypad. Any menu that contains more than four functions will display two small arrows at the left (<) and right (>) edges, which correspond to the left and right arrow keys on the keypad. This allows you to scroll through more than one set of function keys.

During menu selection, "ESC" key brings you back to the previous menu and "MAIN" key brings you back to the main menu. The following screen shots can be used to get familiar with the menus and display parameters.

5.1 Initial Setup

Always make sure that IPA 2000 is not connected to a patient. IPA 2000 is operated through the power adapter supplied along with the unit. Connect the adapter jack to the power inlet, which is at the bottom of the left hand side panel of IPA 2000 (Refer Fig 1).

5.2 Power up

The power ON/OFF switch is located on the bottom right hand corner of the instrument. When the instrument is turned on, the Netech Logo, Model, Software version, Serial Number (S/N:), and the Calibration Date is displayed for about 5 seconds, after which the main menu comes up.



Power UP Screen



Main Menu Screen

5.3 Connecting to the Infusion Pump under Test

Refer to the Infusion pump manufacturer's service manual for specific device inspection requirements.

Observe all safety precautions. Use only distilled water to test the instrument. Follow the pump manufacturer's instruction to connect the pump to IPA 2000.

Connect the infusion pump to the inlet of IPA 2000, which is located on the upper side of the right hand side panel (Ref Fig 1.). Connect the tubing provided with IPA 2000 to the outlet valve, which is located on the bottom side of the right hand side panel (Ref Fig 1.).

Ensure that the pump is secured to the IPA input connecter. Turn on the unit and start the pump. Ensure that no fluid drips through the input connector.

5.4 Measuring Flow

The rate key allows you to enter the Flow measurement mode. Selecting Rate by pressing F1 will display the Rate screen. The flow progress bar is divided into nine segments and displays the progress of the fluid as it travels through the column of optocouplers.



- Flow is the instantaneous flow rate obtained
- Average is the average flow rate of the entire instantaneous rate obtained.
- Volume is the accumulated volume.

The Available soft keys are as follows:

- 1. Sngl': Starts measurement in single mode. Press F1 key to select this mode.
- Cont': Starts measurement in continuous mode. Press F2 key to select this mode.
- 3. Vol'm: Goes to the volume measurement mode. Press F3 key to select this mode.
- 4. Stop: Stops a measurement in progress. Press F4 key to select it.
- R'set: Press left/ right arrow key to display this function key and then press F1 to select it. This function resets all measurement to zero. If a measurement is in progress it is first stopped.
- Save: Press left/ right arrow key to display this function key and then press F2 key to select it. At the end of a single measurement, Save will record the current results to the next internal records.
- Exit: Press left/ right arrow key to display this function key and then press F4 key to select it. Stops any measurement in progress and exits to the Main Menu.

5.5 Measuring Volume

Selecting Volume from Main or Rate screens will display the volume screen. This screen displays accumulated volume, average Flow rate, and elapsed time from the start of the current measurement. This screen contains all the same soft-keys as the rate screen except for Pres.



1. **Pres:** Press F3 to select this function. This function displays the pressure screen.

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5.6 Measuring Flow with Back Pressure

Selecting Pres from the Volume Measurement screen will display the pressure results screen. This screen displays maximum pressure, current pressure and average flow rate. The available soft keys are as follows:



- 1. **Sngl':** Starts measurement in single mode. Press F1 key to select this mode.
- Cont': Starts measurement in continuous mode. Press F2 key to select this mode.
- 3. Rate: Returns to the Rate result Screen. Press F3 key to select this mode.
- 4. Stop: Stops a measurement in progress. Press F4 key to select it.

5.7 Measuring Occlusion Pressure

Selecting Occl'n from the Main menu by pressing F3 key, displays the occlusion results screen. This screen displays maximum pressure, current pressure, and elapsed time from the start of the measurement. The available soft keys are as follows :





- 1. **Start:** Sets the valves for occlusion mode, resets the maximum reading, and begins a measurement. Press F1 key to select it.
- Stop: Stops a measurement and resets the valves to standby (or pass through) mode. Note-If a high pressure is present at the inlet, stopping an occlusion measurement will direct that pressure to the drain outlet. Any water in the drain tube may squirt suddenly. Press F2 key to select it.
- 3. **Unit:** This function allows you to toggle between the available pressure units for display. Available units are psi, bar, mmHg, cmH2O, and kPa. Press F3 key to select it.
- 4. **Exit:** Stops any measurement in progress and exits to the Main Menu. Press F4 key to select it.
- R'set: Press left/ right arrow key to display this function key and then press F1 to select it. Stops any measurement in progress, resets the elapsed time, and sets the maximum pressure reading to the current pressure.
- Zero: Press left/right arrow key to display this function key and then press F2 key to select it. Allows the pressure sensor to be zeroed before a measurement. This key will not function when a measurement is in progress.
- Save: Press left/ right arrow key to display this function key and then press F3 key to select it. At the end of a single measurement, save will record the current results to the next internal record along with any flow rate measurements not yet saved.

6 Setup Menu

The Setup Menu has various sub menus like Initial Condition, Prime, Flush, Purge, Settings, Records, Calibration and Info. This Sub Menu's can be selected by pressing the select option using the F1 key. You can toggle between the sub menus using the Prev and Next Keys or the arrow keys. Press Exit to exit to the main menu.

6.1 Setup

The various options provided in the Setup Menu are as follows:

• **Initial Condition:** Enters a submenu, which displays the applied flow rate and initial volume.

Setup					
Initial	Cond.	Settings			
Prime		Records			
Flush		Calibration			
Purge		Info			
Sel'ct	Prev	Next	Exit		
Initial Conditions					
Flow Applied: 0.000					
Initial Volume: 0.000					
Edit	Prev	Next	Exit		

- 1. **Flow Applied:** Allows the user to enter the flow rate of the Infusion pump that is to be tested.
- Initial Volume: Enables the user to enter the volume that is already dispensed by the Infusion pump before the actual flow measurement. This value is used only for the first measurement cycle after which it is cleared. Prime operation also automatically clears this value.

• **Prime:** Displays the Prime Analyzer screen. This screen allows you to prime the fluid up to the first detector when setting the unit up for the first time. Priming should also be done every time a manual flush is performed.



Step 1: If there is fluid in the column the IPA will flush the measuring column.

Step 2: IPA is ready for priming.

Step 3: Start the connected Infusion Pump, which is to be tested.

Step 4: The fluid enters the measurement column and is detected by the system.

Step 5: System will stop and is ready for the measurement.

Step 6: Stop the connected Infusion pump. Using Exit option return to the main Menu to start the measurement.

• Flush: Provides a screen for manually flushing the measurement tubes. If "Bubbles Detected" message appear in the rate screen or if you suspect flushing is not complete, a manual flush can be performed by pressing and holding the Start soft key for as long as needed. Pressing Exit will return to the setup screen. A Prime operation should then be performed prior to starting any new flow measurements.



• **Purge:** Purging flushes any residual fluid or air bubbles left behind in the measurement columns.





Step 1: Connect a 20-PSI air source to the input port.

Step 2: Press the start key to begin purging.

Step 3: System enters the purging mode.

Step 4: System beeps indicating the end of purging cycle.

Step 5: Disconnect the air supply, Press Exit to return to main menu.

• Settings: Enters a submenu with additional selections for machine settings.



The following options are available in the settings submenu

 Backlight: Enters a submenu with additional selections. Used to set the backlight timings. Available options are Always On, Always Off, 30 sec, 1 min, 2 min, 5 min, 10 min, and 20 min.



2. **Shutdown:** Enters a submenu with additional selections. Used to automatically shut down the unit after a specified time interval. The available time intervals are 5 min, 15 min, 30 min, 45 min, and 60 min. selecting the disabled option in the shutdown menu can disable this automatic shutdown.



Shutdown: Disabled					
Disabled	45	min			
5 min	60	min			
15 min					
30 min					
Sel'ct Prev	Next	Exit			

3. Baud Rate: Enters the sub menu for different baud rate options.



4. **Beeper:** Enters the sub menu to enable/ disable the beeper.



5. Time: Enters the sub menu for the user to setup the system clock



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6. **Date:** Enters the sub menu for the user to set up the system date.





• **Records:** Enters a sub Menu for the user to Print, Export and clear the saved records.





Print: Enables the user to print the saved records in a text format via the serial port. Connecting a serial printer to the IPA can also print the records.
Export: Enables the user to export the saved records in a CSV (Comma Separated Value) format via the serial port.
Clear: Enables the user to delete all saved records.

• **Calibration:** This sub menu is not available for the end user.



• Info: Enters a sub menu, which provides information about the unit.

7 Maintenance, Service / Calibration

The following chapter explains the maintenance/ service procedures that should be followed to ensure that the unit functions within manufacturer's specifications.

7.1 Routine Maintenance

Maintenance of IPA 2000 is straightforward, requiring little more than keeping it clean. It is important to keep dust and dirt from getting inside the unit or into the inlet water column. Periodic purging of the unit using compressed air of 20 PSI is recommended.

Do not use any liquids other than distilled water to operate the unit. The use of a light detergent and non-abrasive cleaning pad is acceptable on the exterior of the unit.

7.2 Service

The mechanical assembly of IPA 2000 contains no parts that can be serviced by the user. The unit should be returned to Netech Corporation for repair or calibration. The alignment and adjustment parameters are critical to the performance of the IPA 2000 and can be performed only at the factory.

For service, pack the IPA 2000 according to the *Repacking and shipping* instructions in this chapter. **Failure to do so may void the warranty**.

Call Netech Customer service at 1-800-547-6557(U.S.) or 1-631-531-0100 (International) for shipping instructions.