

IDA-1S Infusion Device Analyzer

Users Manual

Warranty and Product Support

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Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Technical Support

For application support or answers to technical questions, either email <u>techservices@flukebiomedical.com</u> or call 1-800-850-4608 or 1-440-248-9300. In Europe, email <u>techsupport.emea@flukebiomedical.com</u> or call +31-40-2965314.

Claims

Our routine 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 are any other problems not caused by shipping damage, please contact Fluke Biomedical or your local sales representative.

Returns and Repairs

Return Procedure

All items being returned (including all warranty-claim shipments) must be sent freight-prepaid to our factory location. When you return an instrument to Fluke Biomedical, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Fluke Biomedical will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all
 projecting parts.
- Use at least four inches of tightly packed, industry-approved, shock-absorbent material around the instrument.

Returns for partial refund/credit:

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from our Order Entry Group at 1-440-498-2560.

Repair and calibration:

To find the nearest service center, go to www.flukebiomedical.com/service or

In the U.S.A.:

Cleveland Calibration Lab Tel: 1-800-850-4608 x2564

Email: globalcal@flukebiomedical.com

Everett Calibration Lab

Tel: 1-888-99 FLUKE (1-888-993-5853) Email: service.status@fluke.com In Europe, Middle East, and Africa: Eindhoven Calibration Lab Tel: +31-40-2675300

Email: ServiceDesk@fluke.com

In Asia:

Everett Calibration Lab Tel: +425-446-6945

Email: service.international@fluke.com

To ensure the accuracy of the Product is maintained at a high level, Fluke Biomedical recommends the product be calibrated at least once every 12 months. Calibration must be done by qualified personnel. Contact your local Fluke Biomedical representative for calibration.

Certification

This instrument was thoroughly tested and inspected. It was found to meet Fluke Biomedical's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibration standards are measured against inhouse performance standards using accepted test procedures.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Fluke Biomedical will not be responsible for any injuries sustained due to unauthorized equipment modifications.

Restrictions and Liabilities

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Manufacturing Location

The IDA-1S Infusion Device Analyzer is manufactured at Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

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IDA-1S

Users Manual

Introduction

The IDA-1S Infusion Device Analyzer (the Product) is a portable, batteryoperated instrument that verifies the performance of medical infusion devices. The Product measures the flow rate and volume delivered and the pressure generated in occlusions or blockages of the fluid line.

Intended Use

The Product is to be used by infusion device manufacturers, hospital biomedical engineering departments, and third-party service organizations. Use the Product to verify accurate performance of infusion devices through measurement of flow, volume, and pressure. The performance of a wide range of infusion devices can be analyzed including syringe, drop counting, peristaltic, and volumetric types. Non-steady flow rate pumps can also be analyzed. The Product uses distilled or deionized water with an optional wetting agent only.

Unpack the Product

Carefully unpack all items from the box and check that these items are included:

- The Product
- Battery charger / power supply
- Accessory Set:
 - plastic syringe (20 ml)
 - o 3-way Luer plastic stop-cock
 - o extension tube, short (20 cm)
 - o drain tube (1 m)
 - o Micro-90[®] (100 ml)
- CD (contains Users Manual and HydroGraph software)
- USB Cable

Safety Information

A **Warning** identifies conditions and procedures that are dangerous to the user. A **Caution** identifies conditions and procedures that can cause damage to the Product or the equipment under test.

∧ Marning

To prevent possible electrical shock, fire, or personal injury:

- Read all safety information before you use the Product.
- Use the Product only as specified, or the protection supplied by the Product can be compromised.
- Remove the batteries if the Product is not used for an extended period of time, or if stored in temperatures above 50 °C. If the batteries are not removed, battery leakage can damage the Product.
- The battery door must be closed and locked before you operate the Product.
- Replace the batteries when the low battery indicator shows to prevent incorrect measurements.
- Carefully read all instructions.
- Do not touch voltages >30 V ac rms, 42 V ac peak, or 60 V dc.
- Do not use the Product around explosive gas, vapor, or in damp or wet environments.
- Examine the case before you use the Product. Look for cracks or missing plastic. Carefully look at the insulation around the terminals.
- Use this Product indoors only.
- Use only the mains power cord and connector approved for the voltage and plug configuration in your country and rated for the Product.
- Replace the mains power cord if the insulation is damaged or if the insulation shows signs of wear.
- Use only the external mains power supply included with the Product.
- Remove all probes, test leads, and accessories before the battery door is opened.
- Disable the Product if it is damaged. Remove the batteries to disable the Product.
- Do not use the Product if it is damaged.
- Do not use the Product on infusion devices that are attached to patients.

- Do not reuse test tubing or syringes for patient infusion.
- Avoid possible contamination of reusable components due to backflow conditions. Some older style infusion devices may have reusable components that could come in direct contact with the fluids being pumped. When testing these types of devices take care to avoid possible contamination of reusable components.

To prevent possible damage to the product or to equipment under test:

- Only use degassed de-ionized water with the Product.
 Wetting agent may be added.
- Remove internal water before shipping or storing. Do not use compressed air to clean out the Product.
- Do not expose the Product to temperature extremes. For proper operation, ambient temperatures should be from 15 °C to 30 °C (59 °F to 86 °F). Performance may be adversely affected if temperatures fluctuate above or below this range. For Storage Temperature limits, see the Specifications section.
- Do not use the Product in close proximity to sources of strong electromagnetic radiation (for example, unshielded intentional RF sources). These sources may interfere with proper operation.

Symbols

Table 1 is a list of symbols used on the Product and in this document.

Table 1. Symbols

Symbol	Description	Symbol	Description
Δ	Risk of Danger. Important information. See Manual.	Δ	Hazardous voltage. Risk of electric shock.
$\ominus \bullet \oplus$	Power input	•	USB
NiMH	Recycling information	C€	Conforms to European Union directives
c ⊕ ®	Conforms to relevant North American Safety Standards.		Conforms to relevant Australian EMC standards
<u>X</u>	This product complies with the WEEE Directive (2002/96/EC) marking requirements. The affixed label indicates that you must not discard this electrical/electronic product in domestic household waste. Product Category: With reference to the equipment types in the WEEE Directive Annex I, this product is classed as category 9 "Monitoring and Control Instrumentation" product. Do not dispose of this product as unsorted municipal waste. Go to Fluke's website for recycling information.		

Instrument Familiarization

Figure 1 and Table 2 show the controls and indicators on the front panel of the Product.

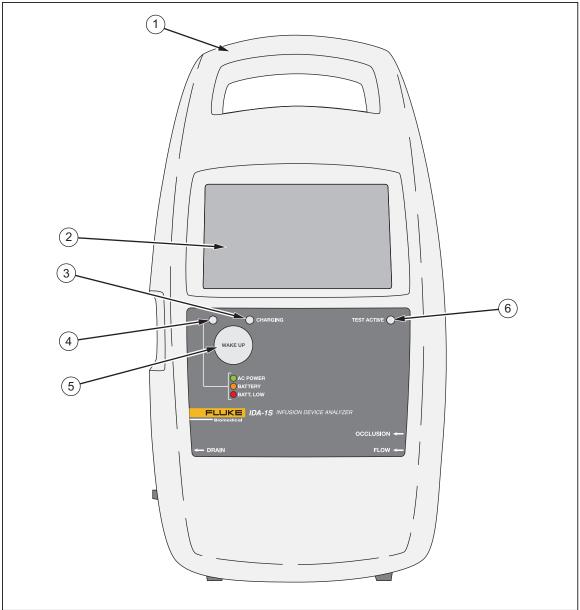


Figure 1. Front-Panel Controls and Indicators

hqf01.eps

Table 2. Front-Panel Controls and Indicators

Item	Description	
1)	Integrated Carrying Handle	
2	Touch Display (LCD)	
3	Charging Indicator – Illuminates when the battery is charging	
4	Power On Indicator:	
	Green – Operating on ac power using the charger	
	Orange – Operating on battery	
	Red – Battery low	
(5)	WAKE UP Button – Turns on the Product	
6	Test Active Indicator – Flashes green when a test is active	

(3)

Figure 2 and Table 3 show the connections on the side-panel of the Product.

Figure 2. Side-Panel Connections

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Table 3. Side-Panel Connections

Item	Description
1)	Power Input for Battery Charger / Power Supply 9 V dc
2	USB Port – Computer connection
3	Fluid Outlet (drain)
4	Pressure Inlet – For occlusion tests
5	Fluid Inlet – For flow tests

Product Connections

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To prevent possible electrical shock, fire, or personal injury:

- Only assemble and operate high-pressure systems if you know the correct safety procedures. High-pressure liquids and gases are hazardous and the energy from them can be released without warning.
- Do not put metal objects into connectors.

The Product connects to an infusion device through the inlet ports on the side panel. The side panel also has the connections for drain hoses and accessories.

Connect Infusion Devices

Figure 3 shows the Product connected for a flow test with a 20 ml syringe attached to one 3-way stopcock inlet. Use a syringe to prime the line before a test. Fluke Biomedical recommends that you make all infusion device connections to the Product through 3-way stopcocks.

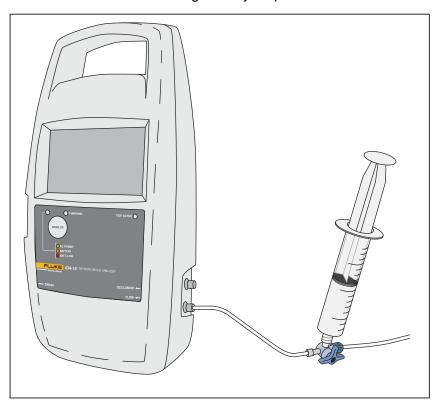


Figure 3. Infusion Device Connections to the Product

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Follow these recommendations when you connect to the inlet tubing circuits:

- Use adequate prime volumes (for example, 10 ml) to push through any bubbles.
- Use the stopcocks at the inlet to prevent fluid backflow out of the inlet between tests.

 When you connect to the inlet circuits (for example, when you attach the priming syringes to the stopcocks) make sure no new bubbles are introduced.

⚠ Caution

To prevent possible damage to the product or to equipment under test, do not use delivery set or components that have been used for prior testing for patient infusion.

Note

Before you use the delivery set (the tubing, the syringe, and stopcocks), make sure it is within the specified use period of the manufacturer. Many sets are made to be used only once.

Connect Drains

Figure 4 shows a drain tube connected to the Product.

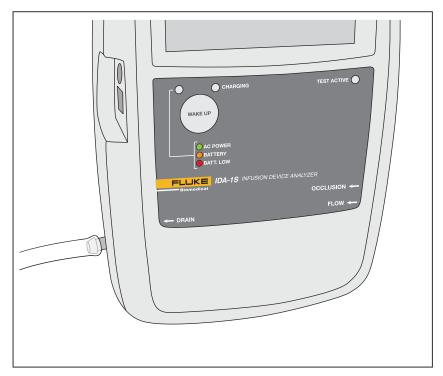


Figure 4. Drain Connections to the Product

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Follow these recommendations when you connect the drain tubes to the Product outlets:

- Do not allow the drain tubes to rise more than 10 cm (4 in) at any point above the height of the inlet ports of the Product.
- The discharge end of the drain tubes must not be more than 10 cm (4 in) below the bottom of the Product.

Product Operation

The Product has rechargeable batteries that can supply a minimum of eight hours of operation. The Product can operate while it charges. Control the Product with the LCD touch screen.

Before you turn on the Product, make sure the Product calibration is up-to-date, check for signs of wear, and ensure the battery door is closed.

To turn on the product and display the Start menu:

- 1. Push the **WAKE UP** button. If the startup screen appears without errors, the Product is ready to use.
- 2. Touch PRESS TO PROCEED.

The Start menu has these options:

- Flow
- Occlusion
- Utilities
- Shut Down

Preferences

Before you use the Product for the first time, set your preferences for display functions, date and time, and the name of your location. The instructions for how to set preferences are in the *Utilities* section in this manual.

How to Set Up for a Test

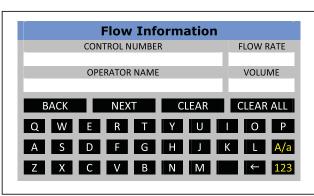
Each test starts with an information screen that contains data for the test. You can change the data on the information screen for each test.

To change the data on the information screen:

- 1. Touch a field and use the on-screen keyboard to enter the data.
- 2. Use the buttons on the information screen to move between screens, to save data, and delete data.

Table 4 explains the fields and buttons on the information screen. Subsequent tests keep the data until you select **Shut Down** from the Start menu.

Table 4. Information Screen



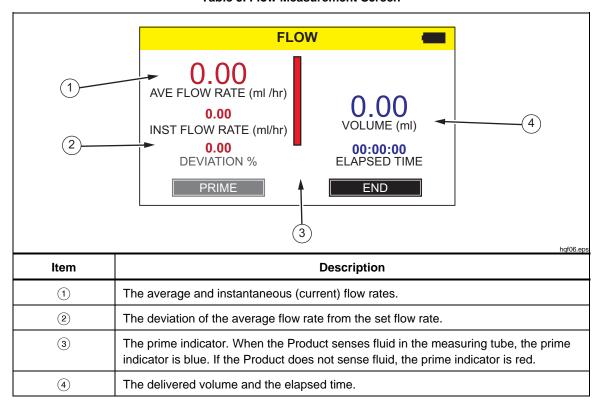
Field/Button Description **CONTROL NUMBER** An alphanumeric code that identifies the instrument for the test. A maximum of 20 characters. The set flow rate of the infusion device in ml/hr. A FLOW RATE maximum of four characters. **OPERATOR NAME** The name, initials, or identification code of the person who is doing the test. This is a required field. A maximum of 20 characters. VOLUME The amount of fluid intended to be supplied during the test, in ml. A maximum of 20 characters. **BACK** Return to the previous screen. **NEXT** Advance to the next screen. **CLEAR** Clear all the data from the selected field. **CLEAR ALL** Clears the data from all the fields and selects the Control Number field. SAVE Saves the test in non-volatile memory. If memory is full, the Product deletes the oldest test. This button displays at the end of the test only. Delete Removes the tests results. The Product removes the test results once the action is confirmed. This button displays at the end of the test only. A/a Toggles between the upper case keyboard and the lower case keyboard. 123 Shows the numeric keyboard. abc Shows the alphabetic keyboard.

Flow Tests

To do a flow test:

- 1. Select Flow from the Start menu.
- 2. Complete the fields on the Flow Information screen. See the *How to Set Up for a Test* section in this manual.
- 3. Touch **Next**. The Flow Measurement screen appears. See Table 5.

Table 5. Flow Measurement Screen

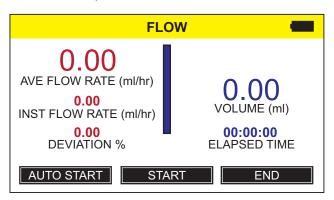


4. Prime the Product by continuously pushing water into the Flow inlet until the prime indicator (the vertical bar) is all blue. Continue to push 5 ml into the Flow inlet to make sure that no bubbles follow.

∧ Caution

To avoid inaccurate readings, always repeat a test when "Bubble" or "Air Lock" is shown on the display while a test is running. See the *Troubleshooting* section of this manual.

5. Touch **Auto Start** to start the measurement when the Product senses the flow. As an alternative, touch **Start** to start the test immediately.



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6. When the test is complete, touch **End**. The Product prompts you to save the results.

Occlusion Tests

(2)

End

To do an occlusion test:

- 1. Select Occlusion from the Start menu.
- 2. Complete the fields on the Occlusion Information screen. See the *How to Set Up for a Test* section in this manual.
- 3. Touch **Next** and follow the on-screen instructions. See Table 6 for an example of the Occlusion Measurement screen.
- 4. When the test is complete, touch **End**. The Product prompts you to save the results.

Note

You must remove the tube from the occlusion inlet, before you touch ZERO to make sure that the Product senses the pressure correctly.

The initial display shows the pressure field is 0 (zero). The units of pressure display as selected on the User Preferences screen. See the *Utilities* section in this manual.

OCCLUSION

7.05
INST PRESSURE (mmHg)
00:06:52
ELAPSED TIME

Description

1 The current pressure detected by the Product.

The peak pressure and the time the pressure was detected.

Stops the test. The Product prompts you to save the test.

Table 6. Occlusion Measurement Screen

Utilities

To open the Utilities menu screen, select **Utilities** from the Start menu. The Utilities menu has these options:

- Recall Tests
- User Preferences
- View Settings
- Set Clock
- Report Heading
- Instructions
- Calibration History
- Touch Calibration
- Start Menu

Recall Tests

Use Recall Tests to view and delete test results for saved tests. Table 7 shows the menu controls on the Recall Tests screen. Flow tests display in blue and Occlusion tests display in red.

To select an individual test, touch anywhere on the line of the test. The Product displays the final test result in the same layout as the end screen for that test.

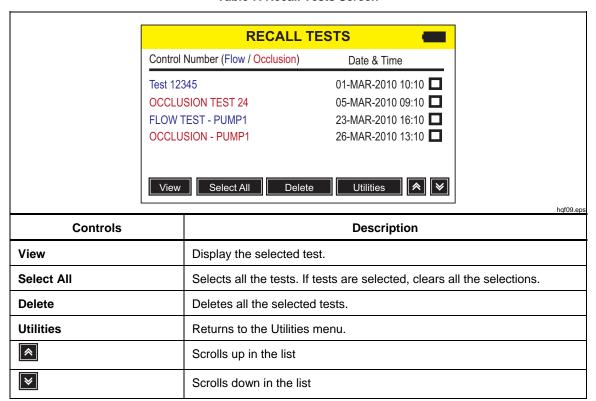
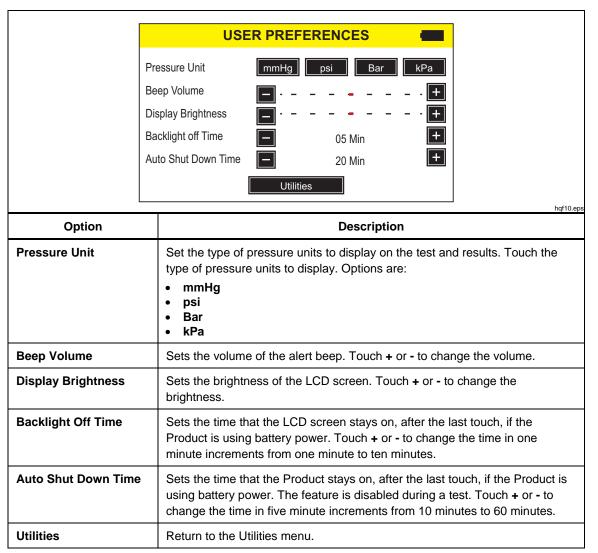


Table 7. Recall Tests Screen

User Preferences

Use the User Preferences screen to set the Pressure units and other display features. Table 8 explains the User Preferences screen.

Table 8. User Preferences Screen



View Settings

Use View Settings to monitor the operation of the optical detectors on the measuring burette. The **Sensor** column lists the sensor numbers from the top to the bottom of the burette. The **ADC** column lists the output of each sensor. The values change to reflect the water position in the burette. Use this information to help diagnose fluid detection issues. Touch **Utilities** to return to the Utilities menu.

Set Clock

Use Set Clock to set the date and time for your location. Touch the field and then touch + or - to change the value.

Report Heading

Use Report Heading to enter a maximum of three lines of text. This text shows when saved records are transferred to a PC. Fluke Biomedical recommends using the first line for the name of the establishment. Touch a line and use the on-screen keyboard to enter up to 20 characters per line. Touch **Utilities** to return to the Utilities menu.

Instructions

The Instructions selection displays brief operating instructions for the Product. Touch the **Next** and **Prev** (Previous) buttons to step through the instructions.

Calibration History

Calibration History retrieves the calibration change history records from the measuring module and displays the details. Use the arrow buttons to scroll through the list. Touch **Utilities** to return to the Utilities menu.

Touch Calibration

Use Touch Calibration to do a touch calibration process. Use a stylus to touch the reference points on the screen. Touch **Utilities** to cancel and return to the Utilities menu. The screen layout and calibration points follow the recommendations of the touch panel manufacturers.

Troubleshooting

Tables 9 and 10 list Bubble and Air Lock errors and their solutions.

Table 9. Bubble Errors

Possible causes	Solution
Air caught in the delivery tubing.	Make sure to remove all air when you connect the infusion device to the analyzer. Use care with the connections.
Incorrect priming.	Use the method given in this manual to prime the product.
Degassing of the test fluid.	For longer flow tests, let the test fluid become stable to room temperature before use.

Table 10. Air Lock Errors

Possible causes	Solution
Incorrect arrangement of drain tubing.	Use the method given in this manual. Use a syringe of air to gently push all excess water out of the measuring channel.
Blockage of the drains (such as trapped or kinked tubing).	Examine and unblock drains as necessary.
Contamination of the fluid measuring circuit.	Use the cleaning instructions found in the <i>Product Maintenance</i> section of this manual.

Product Maintenance

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To prevent possible electrical shock, fire, or personal injury:

- Batteries contain hazardous chemicals that can cause burns or explode. If exposure to chemicals occurs, clean with water and get medical aid.
- Do not disassemble the battery.
- Do not disassemble or crush battery cells and battery packs.
- Do not put battery cells and battery packs near heat or fire.
 Do not put in sunlight.
- Do not short the battery terminals together.
- Do not keep cells or batteries in a container where the terminals can be shorted.
- Remove the input signals before you clean the Product.
- Use only specified replacement parts.
- Have an approved technician repair the Product.

For safe operation and maintenance of the product:

- Repair the Product before use if the battery leaks.
- Be sure that the battery polarity is correct to prevent battery leakage.
- Use only Fluke approved power adapters to charge the battery.

After troubleshooting or maintenance, restart the Product and ensure it starts without errors. (See *Product Operation*.)

Clean the Product (Outside)

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

Clean the Product (Inside)

It is possible that microbial growth can become present in the measuring module of the Product. It is recommended that you clean the fluid paths at 3 month intervals. To clean the inside of the Product, inject 20 ml of a warm water and detergent solution into the Fluid Inlet Port. After 5 minutes, flush with clean water. Always pass water from the fluid inlets to the outlets.

Replaceable Parts

Table 11 lists the replaceable parts for the Product.

Table 11. Replaceable Parts

Item	Fluke Biomedical Part Number
IDA-1S Infusion Device Analyzer	4468525
Hydrograph software and IDA-1S Users Manual on CD	4418071
Plastic syringe (20 ml)	4497350
3-way Luer plastic stop-cock	4480194
Drain tube (1 m)	4478942
Micro-90® (225 ml)	4541948
USB Cable	1740487
Power supply, 4-plug mains adapter kit for US, UK, EURO, AUS	2461300
IDA-1S power supply cord without mains adapters, universal wall mount	4329971
NiMH Battery	4481150
IDA-1S Getting Started Manual	4426198

Test Fluid

The Product operates with distilled or de-ionized water with added detergent. Fluids intended for use on patients, high viscosity fluids, oily, or corrosive substances will cause damage to the measurement system. Tap water can contain contaminates that can cause damage to the fluid paths.

You can make test fluid with de-ionized water and a wetting agent such as MICRO-90. Fluke recommends that you prepare a 0.1 % solution of MICRO-90 in de-ionized water (preferably degassed) in volume for daily use. Keep the solution in a sealed container. If the solution makes too much foam, then you can use a 0.05 % dilution.

MICRO-90 is available from:

International Product Corp. 201 Connecticut Dr. P.O. Box 70 Burlington, NJ 08016-0070 USA Tel 609 386 8770

also

International Product Corp.
1 Church Row
Chistlehurst, Kent BR7 5PG United Kingdom
Tel. 0208 467 8944

Storage

Remove all water from the Product before storage, especially if temperatures can fall below 5 °C (41 °F). Do not pressurize the inlet ports. It is safest to use a medical suction pump to drain the measuring channels.

Shipping

Remove all liquid from the Product before shipping. To prevent liquid from entering the ports, put the Product in a large plastic bag. Put the bagged Product into its shipping carton. If this is not available, make sure there is shock protection with a minimum of 5 cm compressible cushioning inside the carton (for example, 40 cm x 30 cm x 20 cm).

General Specifications

Battery Power	. 4 x Panasonic HHR210AB NiMh 2000 mAh batteries
Charger	
Operating Voltage Range	. 100 V ac to 240 V ac
Supply Frequency	. 50 Hz / 60 Hz
Supply Power	. <20 VA
Size (HxWxD)	. 30 cm x 17 cm x 10 cm (12 in x 8 in x 4 in)
Weight	. ~1.2 kg (2.7 lb)
Temperature	
Operating	. 15 °C to 30 °C (59 °F to 86 °F)
Storage	20 °C to +40 °C (-4 °F to +104 °F) when drained of all liquid.
Humidity	. 10 % to 90 % non-condensing
Altitude	. 0 meters to 2000 meters (6500 feet)
Safety	. IEC 61010-1: Overvoltage category II, Pollution Degree 2
Electromagnetic Environment	. IEC 61326-1: Basic
Emissions Classification	.IEC CISPR 11: Group 1, Class A. (Group 1 have intentionally generated and/or use conductively coupled radio-frequency energy which is necessary for the internal functioning of the equipment itself. Class A equipment is suitable for use in non-domestic locations and/or directly connected to a low-voltage power supply network.)
FCC	. CFR47: Class A Part 15 subpart B
Storage of Results	. Test results stored for later viewing, printing or transfer to PC. Typical practical capacity: 100 tests
Power Down	. The results of tests in progress will be saved in the case of accidental power down
Computer Control	. The Product can be fully controlled from a PC using HydroGraph software

Performance Specifications

Average Flow Rate Measurement

Technique	Flow is calculated by measuring volume over time
•	· · · · · · · · · · · · · · · · · · ·
Range	
Accuracy	
Max test duration	10 hours on battery
Volume Measurement	
Technique	
Range	0.06 ml to 999 ml
Accuracy	
Max test duration	10 hours on battery
Pressure Measurement	
Technique (Occlusion test)	Direct measurement of pressure at the inlet port
Range	0 psi to 45 psi and equivalent in mmHg, Bar and kPa
Accuracy	1 % of Full Scale ±1 LSD under laboratory conditions
Max test duration	30 minutes

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