FLUKE®
Biomedical

IDA-5

Infusion Device Analyzer

Getting Started

PN 3975990
April 2013, Rev. 1

Warranty and Product Support

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one year from the date of original purchase OR two years if at the end of your first year you send the instrument to a Fluke Biomedical service center for calibration. You will be charged our customary fee for such calibration. During the warranty period, we will repair or at our option replace, at no charge, a product that proves to be defective, provided you return the product, shipping prepaid, to Fluke Biomedical. This warranty covers the original purchaser only and is not transferable. The warranty does not apply if the product has been damaged by accident or misuse or has been serviced or modified by anyone other than an authorized Fluke Biomedical service facility. NO OTHER WARRANTIES, SUCH AS FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSED OR IMPLIED. FLUKE SHALL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOSSES, INCLUDING LOSS OF DATA, ARISING FROM ANY CAUSE OR THEORY.

This warranty covers only serialized products and their accessory items that bear a distinct serial number tag. Recalibration of instruments is not covered under the warranty.

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7/07

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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 techservices@flukebiomedical.com or call 1-800- 850-4608 or 1-440-248-9300. In Europe, email techsupport.emea@flukebiomedical.com 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 in-house 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

Information in this document is subject to change and does not represent a commitment by Fluke Biomedical. Changes made to the information in this document will be incorporated in new editions of the publication. No responsibility is assumed by Fluke Biomedical for the use or reliability of software or equipment that is not supplied by Fluke Biomedical, or by its affiliated dealers.

Manufacturing Location

The IDA-5 Infusion Device Analyzer is manufactured at Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

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Introduction

The Fluke Biomedical IDA-5 Infusion Device Analyzer (the Product) is a precision instrument that examines the performance of medical infusion devices. The Product measures the flow rate and volume supplied, and the pressure generated in occlusion or blockages of the fluid line. A maximum of 4 infusion devices can be independently examined with the four-channel version of the Product.

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.

Safety Information

A **Warning** identifies hazardous conditions and actions that could cause bodily harm or death. A **Caution** identifies conditions and actions that could harm the Product, the equipment under test, or cause permanent loss of data.

⚠⚠ Warning

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

- **Read all safety Information before you use the Product.**
- **Carefully read all instructions.**
- **Use the product only as specified, or the protection supplied by the product can be compromised.**
- **Do not use the Product if it operates incorrectly.**

- **Do not use and disable the Product if it is damaged.**
- **Use this Product indoors only.**
- **Connect an approved three-conductor mains power cord to a grounded power outlet.**
- **Never use a two-prong plug adapter to connect primary power to the Product.**
- **Use only the mains power cord and connector approved for the voltage and plug configuration in your country and rated for the Product.**
- **Make sure the ground conductor in the mains power cord is connected to a protective earth ground. Disruption of the protective earth could put voltage on the chassis that could cause death.**
- **Replace the mains power cord if the insulation is damaged or if the insulation shows signs of wear.**
- **Turn the Product off and remove the mains power cord before cleaning the outer surface of the Product.**
- **Do not open the Product unless you are qualified.**
- **Do not use the Product around explosive gas, vapor, or in damp or wet environments.**
- **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.**
- **Do not use delivery set or components that have been used for testing for patient infusion.**
- **Do not connect the Product to a patient or equipment connected to a patient. The Product is intended for equipment evaluation only and should never be used in diagnostics, treatment or in any other capacity where the Product would come in contact with a patient.**

- **The Product must be properly earthed. Only use a supply socket that has a protective earth contact. If there is any doubt as to the effectiveness of the supply socket earth, do not connect the Product. Do not use a two-conductor adapter or extension cord. This will break the protective ground connection.**
- **Many components on the printed circuit board are static sensitive. ESD precautions should be observed when handling the printed circuit board assembly.**
- **To avoid shock hazard and for proper Product operation, connect the factory supplied three-conductor line power cord to a properly grounded power outlet. Do not use a two-conductor adapter or extension cord; this will break the protective ground connection.**
- **The Product is intended for use by trained service technicians to perform periodic inspections on a wide range of medical equipment. The testing procedures are menu-driven, and simple to operate.**
- **The Product is intended for use with single-phase, grounded power. It is not intended for dual, split-phase or three-phase power configurations. But it can be used with any power system that supplies the correct voltages for single-phase and is grounded.**
- **This Product is intended to be used in the laboratory environment, outside of the patient care area, and is not intended for use on patients, or to test devices while connected to patients. This Product is not intended to be used to calibrate medical equipment and not intended for over the counter use.**

⚠ Caution

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

- **Only qualified service personnel should service the Product.**
- **Only qualified technical personnel should perform troubleshooting and service procedures on internal components.**
- **Only use degassed de-ionized water with the Product. Wetting agent may be added.**
- **Do not use high-viscosity fluids. Oils (solvents, or strong chemicals) may also damage or contaminate the Product.**
- **Do not use "Bleach" sterilizing agents or alcohols.**
- **Do not rapidly switch the Product On or Off, nor remove the line cord while energized.**
- **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 (e.g., unshielded intentional RF sources). These sources may interfere with proper operation.**

Symbols

Symbols used on the Product or in this manual are shown in Table 1.

Table 1. Symbols

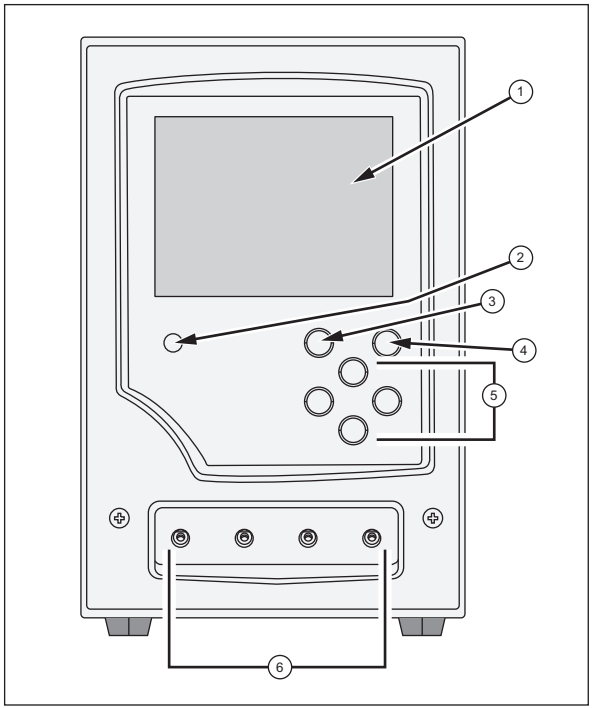
Symbol	Description	Symbol	Description
	Risk of Danger. Important information. See Manual.		Hazardous voltage. Risk of electric shock.
CE	Conforms to European Union directives.	CAT II	Measurement category II is applicable to test and measuring circuits connected directly to utilization points of low voltage mains installation.
	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

Tables 2 and 3 and Figures 1 and 2 tell you about the controls and connections on the front and rear panels of the Product.

Table 2. Front-Panel Controls and Connections

Item	Description
①	Display (LCD)
②	Power on indicator
③	ESC (escape) button – Moves back one step or does the operation given on the display.
④	ENTER button – Operates the highlighted function or moves to the subsequent data-entry field.
⑤	Arrow buttons – Moves the highlight on menus in the direction of the arrow or operates the function shown on the display.
⑥	Flow inlet ports – One port for each measurement channel.



gir01.eps

Figure 1. Front-Panel Controls and Connections

Table 3. Rear-Panel Controls and Connections

Item	Description
①	Handle
②	Power switch
③	Power inlet
④	Equipotential post
⑤	USB “B” connector – Computer connection.
⑥	USB “A” connectors – Connect a maximum of four accessories such as: Keyboard Printer Bar-Code reader
⑦	Fluid outlets – One per measurement channel. Channel 1 at right and channel 4 at left.

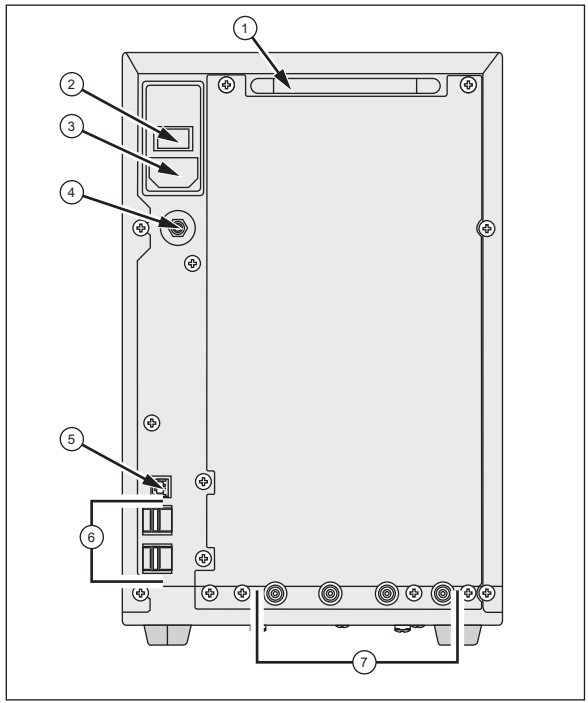


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Figure 2. Rear-Panel Controls and Conn

Product Connections

The Product connects to infusion devices through the front-panel inlet ports. Fluid drain hoses and accessories connections are made through the rear-panel connections.

Connect Infusion Devices

As shown in Figure 3, it is recommended that all infusion device connections be made to the Product front-panel inlet connectors through 3-way stopcocks.

The channel 4 inlet shown in Figure 3, shows a 20 ml syringe attached to one 3-way stopcock inlet. The syringe can be used to help priming. It can be used as shown or can be connected further away from the inlet to help for flow tests. The syringe can be shared among the channels and removed after the channel is primed.

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 inlets 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.

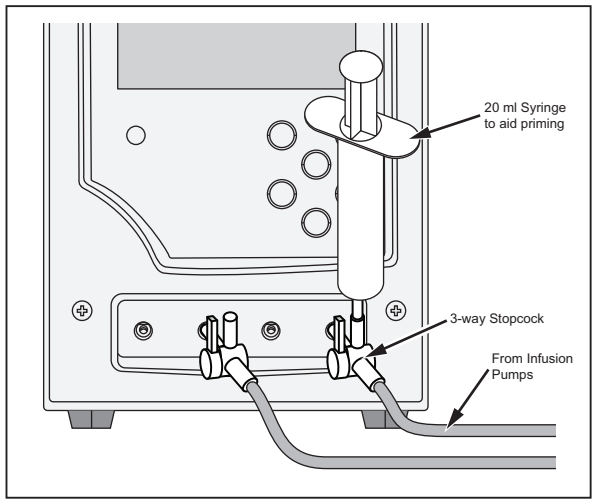

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Figure 3. Infusion Device Connections to the Product

⚠ Caution

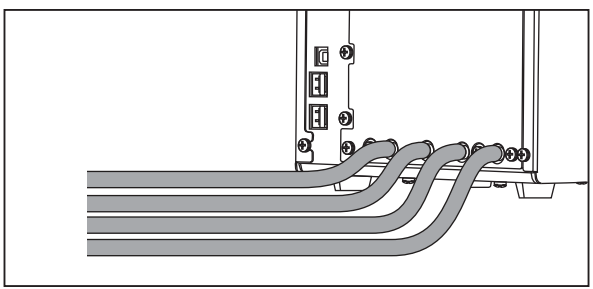
Do not use delivery set or components that have been used for prior testing for patient infusion.

Note

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

Connect Drains to the Product

Figure 4 shows tubing connected to the rear-panel outlets of the Product.



gir04.eps

Figure 4. Drain Connections to the Product

When you connect drain tubing to the Product outlets:

- Connect different drain tubes to each channel.
- Do not connect the drain tubes together.
- The drain tubes should not be allowed 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.

Connect Accessories

Accessories connect to any of the four USB “A” ports on the rear-panel of the Product. Use a USB cable that is less than 3 meters long.

Note

When an accessory is connected to a Product that is ON, some seconds are necessary before the accessory is recognized.

Keyboard

It is recommended that a small footprint USB keyboard be used with the Product. The keyboard is necessary to record data about the infusion device under test.

Note

The keyboard must not have an internal USB hub (for example, no extra USB ports).

Bar Code Reader

A bar code reader can also be used to scan infusion device data into the Product.

Printer

A printer that supports PCL-5 (or higher) printer-command language can be used with the Product to print test results and reports.

Product Maintenance

The subsequent sections tell you how to maintain the Product.

Clean the Product

⚠⚠ Warning

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

- **Turn the Product off and remove the mains power cord. Stop for two minutes to let the power assemblies discharge before you open the fuse door.**
- **Do not operate the Product with covers removed or the case open. Hazardous voltage exposure is possible.**
- **Disconnect the mains power cord before you remove the Product covers.**
- **Remove the input signals before you clean the Product.**
- **Use only specified replacement parts.**
- **Use only specified replacement fuses.**
- **Have an approved technician repair the Product.**

- **Do not pour fluid onto the Product surface. Fluid seepage into the electrical circuitry may cause the Product to fail.**
- **Do not use spray cleaners on the Product. Such action may force cleaning fluid into the Product and damage electronic components.**

⚠ Caution

To prevent possible damage to the Product or to equipment under test, remove the input signals before you 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.

Inside

It is possible that microbial growth can become present in the transducers of the Product. It is recommended that you clean the transducers 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.

Test Fluid

The Product is intended to operate with de-ionized water with added detergent. Fluids intended for use on patients, such as high viscosity, oily, or corrosive substances will damage the measurement system. Tap water can contain contaminates which can also damage the transducer.

Test fluid can be made with de-ionized water and a wetting agent such as MICRO-90. It is recommended that a 0.1 % solution of MICRO-90 in de-ionized water (preferably degassed) be prepared in volume for daily use and kept in a sealed vessel. If the water makes too much foam, then a 0.05 % dilution is recommended.

MICRO-90 is available from:

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

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, particularly 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 and use the Cycle Valves from the Calibration menu (follow on-screen instructions).

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 (e.g. 60 cms x 60 cms x 60 cms).

Specifications

General Specifications

Operating Voltage

Range	100 to 240 V ac
Supply Frequency	50/60 Hz
Supply Power	<50 VA
Fuses	20 mm T1.6 A H 250 V x 2
Size	30 H x 20 W x 20 D (cm) 12 x 8 x 8 (in.)
Weight	5 kg (approx) (11 lbs.)
Altitude	0 to 3000 m (10000 ft)

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

Performance Specifications

Flow Rate Measurement

Method	Flow is calculated by measuring volume over time
Range	0.1 to 1500 ml/h (2500 ml/h is shown)
Accuracy	1 % of reading ±1 LSD for flows of 16 to 200 ml/h for volumes over 20 ml, otherwise 2 % of reading ±1 LSD for volumes over 10 ml under laboratory conditions. Degassed water at 15 to 30 °C (59 to °86 F) is recommended for long tests. Accuracy for >1500 ml/hr not specified.
Max Test Duration	100 hours

Volume Measurement

Method	Volume is measured directly by the measuring module in minimum sample sizes of 60 µl
Range	0.06 ml to 9999 ml
Accuracy	1 % of reading ±1 LSD for flow rates of 16 to 200 ml/h for volumes over 20 ml. otherwise 2 % of reading ±1 LSD for volumes over 10 ml under laboratory conditions.
Max Test Duration	100 hours

PCA Bolus/Dual Flow Measurement

Method	See Volume measurement above
Min Bolus Volume	0.5 ml
Resolution	60 µl increments
Max Test Duration	100 hours

Pressure Measurement

Method (back Pressure and Flow test)..... Direct measurement of pressure at the inlet port.

Range..... 0 to 45 psi or equivalent in mmHg and kPa

Accuracy..... 1 % of Full Scale ±1 LSD under laboratory conditions

Max Test Duration..... 1 hour

Other Specification

Templates ..... Predetermined Test Sequences. Typical capacity 200

Storage of Results.... Test results stored for later viewing, printing or transfer to PC. Typical capacity 250 tests.

Power down ..... The results of tests in progress will be saved in accidental power down

Computer Control..... The Product can be fully controlled using PC Hydrograph and Ansur software for the Product

Applicable Standards

Safety ..... IEC 61010 -1

EM Environment..... IEC 61326-1: Portable

FCC CFR47 Part 15.107 and 15.109 Class A