

FLUKE®

Biomedical

IDA-1S

Infusion Device Analyzer

Getting Started Manual

PN 4426198

February 2014, Rev. 2, 10/14

© 2014 Fluke Corporation. All rights reserved. Specifications are subject to change without notice.

All product names are trademarks of their respective companies.

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.

This warranty gives you specific legal rights and you may also have other rights that vary in different jurisdictions. Since some jurisdictions do not allow the exclusion or limitation of an implied warranty or of incidental or consequential damages, this limitation of liability may not apply to you. If any provision of this warranty is held invalid or unenforceable by a court or other decision-maker of competent jurisdiction, such holding will not affect the validity or enforceability of any other provision.

Notices

All Rights Reserved

© Copyright 2014, Fluke Biomedical. No part of this publication may be reproduced, transmitted, transcribed, stored in a retrieval system, or translated into any language without the written permission of Fluke Biomedical.

Copyright Release

Fluke Biomedical agrees to a limited copyright release that allows you to reproduce manuals and other printed materials for use in service training programs and other technical publications. If you would like other reproductions or distributions, submit a written request to Fluke Biomedical.

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

Table of Contents

Title	Page
Introduction	1
Intended Use	1
Unpack the Product	1
Safety Information	2
Symbols	4
Instrument Familiarization	5
Product Connections	7
Connect Infusion Devices	7
Connect Drains	8
Product Maintenance	8
Clean the Product (Outside)	9
Clean the Product (Inside)	9
Test Fluid	10
Storage	10
Shipping	10

General Specifications	11
Performance Specifications	12

Introduction

The IDA-1S Infusion Device Analyzer (the Product) is a portable, battery-operated 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:
 - o 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.

⚠⚠ Warning

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.**

⚠ Caution

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
	Risk of Danger. Important information. See Manual.
	Hazardous voltage. Risk of electric shock.
	Power input
	USB
	Conforms to European Union directives
	Conforms to relevant North American Safety Standards.

Table 1 Symbols (cont.)

Symbol	Description
	Conforms to relevant Australian EMC standards
	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.

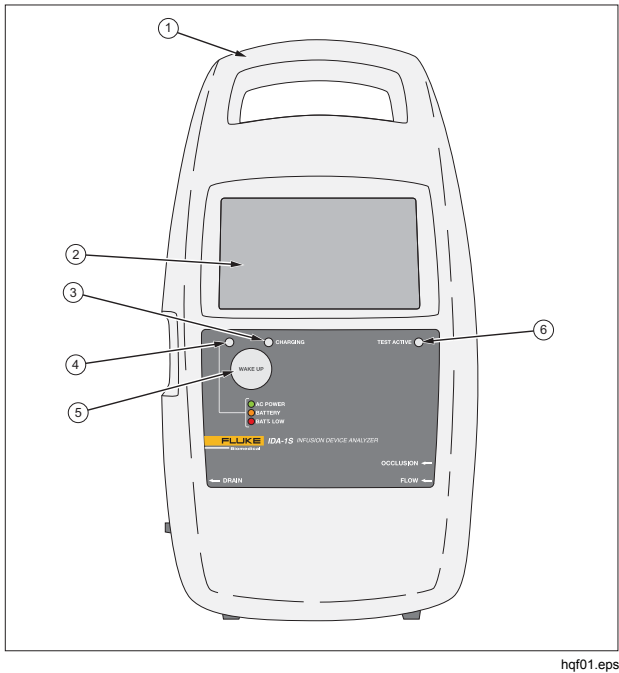


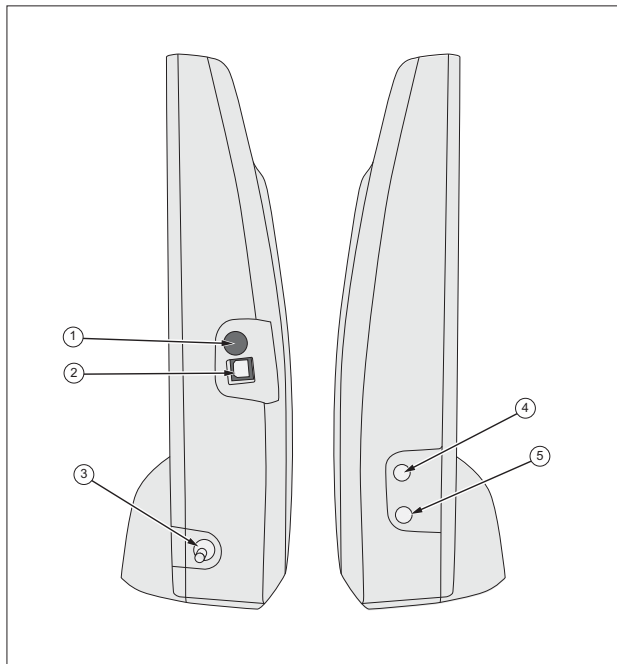
Figure 1. Front-Panel Controls and Indicators

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: <ul style="list-style-type: none">• Green – Operating on ac power using the charger• Orange – Operating on battery• Red – Battery low
⑤	WAKE UP Button – Turns on the Product. If the startup screen appears without errors, the product is ready to use.
⑥	Test Active Indicator – Flashes green when a test is active

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.

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



hqf02.eps

Figure 2. Side-Panel Connections

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

⚠⚠ Warning

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.

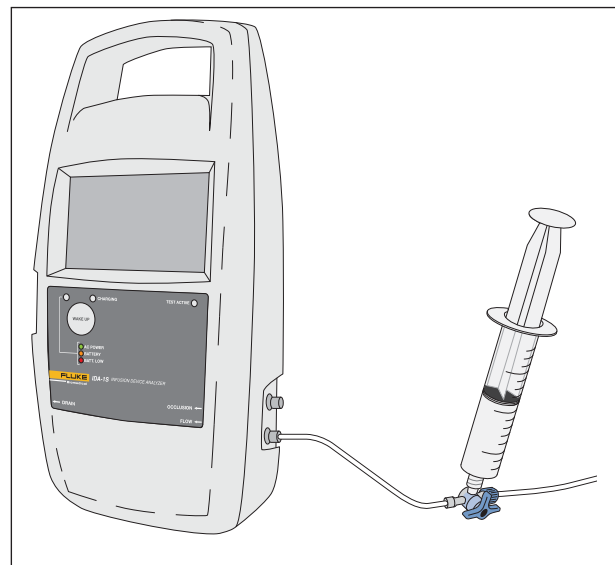
⚠ Caution

To avoid inaccurate readings, always repeat a test when “Bubble” or “Air Lock” is shown on the display while a test is running.

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.



hqf03.eps

Figure 3. Infusion Device Connections to the Product

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

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 Maintenance

⚠⚠ Warning

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.

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.

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 contaminants 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. For ordering information, see the IDA-1S Users Manual.

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	0.5 ml/h to 1000 ml/h
Accuracy	1 % of reading ± 1 LSD for flows of 16 ml/h 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....	10 hours on battery

Volume Measurement

Technique	Volume is measured directly by the measuring module in minimum sample sizes of 60 μ l
Range	0.06 ml to 999 ml
Accuracy	1 % of reading ± 1 LSD for flow rates of 16 ml/h 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....	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

For a complete list of specifications see the IDA-1S Users Manual.