FLUKE ®

Biomedical

# IDA-6

Infusion Device Analyzer

User Manual

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# Notices

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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, please contact technical support at: www.flukebiomedical.com/support/technical-support.

## 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

For customers based in the U.S.A., contact Fluke Biomedical at globalcal@flukebiomedical.com, or call 1-833-296-9420.

All other customers, please go to www.flukebiomedical.com/service to find the nearest service center.

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 met Fluke Biomedical's manufacturing specifications when shipped from the factory. Calibration measurements are traceable to the International System of Units (SI) through National Metrology Institutes such as NIST (USA), NMI (Sweden), NIM (China), etc. Devices for which there are no SI-traceable 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.

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# About IDA-6

IDA-6, the product, is intended for measurements and tests on medical infusion devices, carried out by trained staff.

Administration sets and other components that have been connected to the product shall never be used for patient infusion.
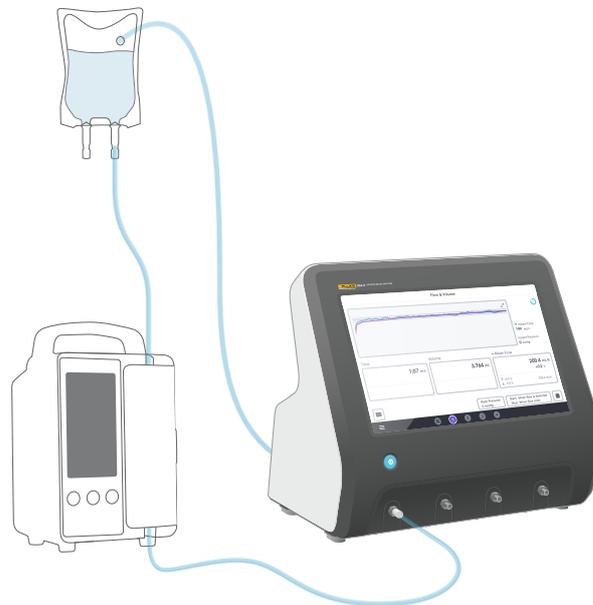
**Figure 1:** Intended use of the product.

# Safety information

Read the safety information and all instructions before you use the product.

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

*Use the product only within its specifications.*

*Do not use the product on any device that is attached to a patient.*

*Do not use administration sets, test tubing or syringes with the product, if they have been or will be in contact with patients.*

*Use this product indoors only.*

*Only qualified service personnel should service the product.*

### Caution

*Only use distilled or deionized water with the product.*

*Remove internal water from the product before shipping or storing. Do not use compressed air to clean out the product. For instructions, see "Drain a channel" on page 31.*

# Symbols

Table 1 details symbols applicable to the IDA-6 product and user manual.

For a full list of applicable product symbols, please visit: www.flukebiomedical.com/resource/certification-sheets.

**Table 1:** Symbols

| Symbol | Description |
|--------|-------------|
| 🛈 | Consult user documentation. |
| ⏻ | Power button |
| ⊖-C-⊕ | Power input polarity |
| CE | Conforms to European Union directives. |
| UK CA | Conforms to United Kingdom regulations. |
| ETL Intertek | Certified by ETL Intertek to North American safety standards. |
| | Conforms to relevant Australian Safety and EMC standards. |
| | Conforms to relevant South Korean EMC standards. |

| Symbol | Description |
|--------|-------------|
| | This product complies with the WEEE Directive 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. |

# Product overview

The product can be used for measuring flow and volume, as well as verifying occlusion and bolus functionality on infusion devices. The product automatically saves all measured data. The data can be synchronized to OneQA or exported to a USB drive. Read more about OneQA in "Using OneQA" on page 22.

Firmware version and calibration date for the channels can be found in the about section of the settings.

The following figures and tables indicate the different parts of the product. The product can contain 1–4 channels.



**Figure 2:** Front side of the product.

**Table 2:** Front side of the product

| Item | Description |
|------|-------------|
| 1 | Touch screen display |
| 2 | On/Off power button |
| 3 | Inlet ports, one per measurement channel |
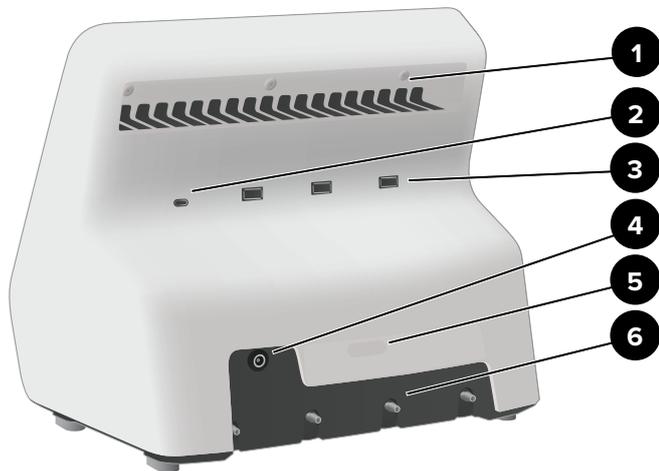
**Figure 3:** Rear side of the product.

**Table 3:** Rear side of the product

| Item | Description |
|------|-------------|
| 1 | Carrying handle |
| 2 | USB device port, computer connection |
| 3 | USB host ports, for peripherals |
| 4 | DC power input |
| 5 | Product label |
| 6 | Outlet ports, one per measurement channel |
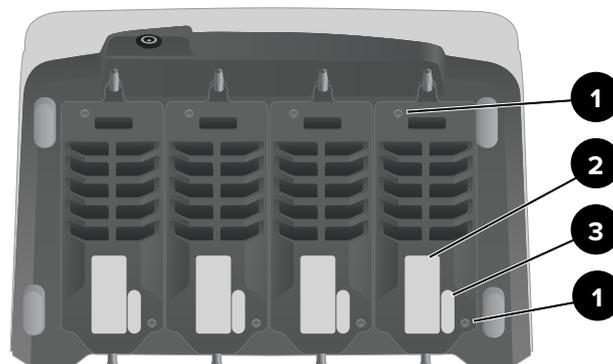


**Figure 4:** Bottom side of a product with four channels installed.

**Table 4:** Bottom side of the product

| Item | Description |
|------|-------------|
| 1 | Mounting screws |
| 2 | Channel calibration label |
| 3 | Channel serial number label |
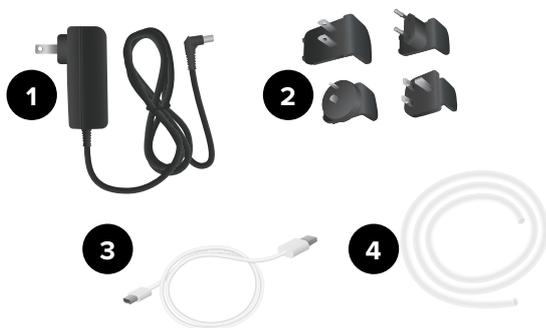
**Figure 5:** Standard accessories

**Table 5:** Standard accessories

| Item | Description |
|------|-------------|
| **1** | Power adapter |
| **2** | AC plugs (for various regions) |
| **3** | USB cable |
| **4** | Drain tube |

## Optional accessories

Examples of other accessories, using USB, that can be used with the product:

- **Barcode scanner**, for scanning asset IDs.
- **WiFi adapter**, enables synchronization of procedures, results, assets and users with OneQA.
- **Printer**, for printing results.

Information about optional accessories can be found at www.flukebiomedical.com.

# Getting started



**Figure 6:** Measurement setup.

1. Connect the included power adapter and turn on the product.
2. Connect a drain tube to the outlet port of a channel. Lead the other end of the drain tube to a sink or leave it in a container on the table to collect the fluid.
3. Connect an infusion device to the inlet port on the front side of the product. Use distilled or deionized water.
4. Let the infusion device fill the administration set and the channel with fluid. The internal volume of the channel is about 1 mL.

The setup is now ready for making measurements.

At the home screen, you have two options:

- For running procedures, see "Register the product in OneQA" on page 22.
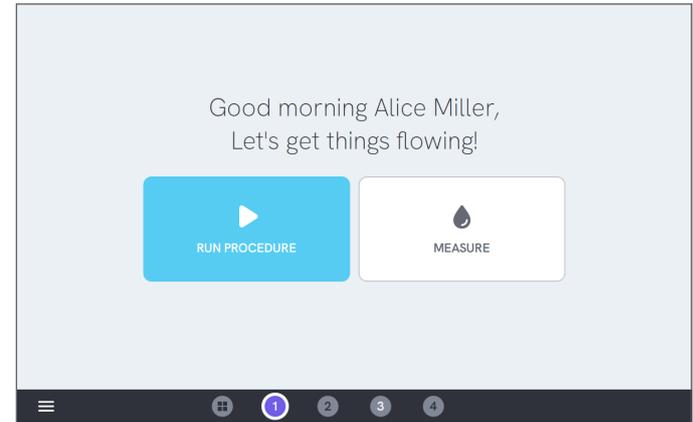- For measurement sessions, see "How to measure" on page 13.



**Figure 7:** The home screen.

**Note**

*The pressure is measured at the inlet of the channel. It is recommended to position the infusion device at the same level as the inlet of the channel to ensure an accurate reading. If you position the infusion device above or below the inlet position, be aware that you will get a pressure difference of approximately 7 mmHg (1 kPa, 0.14 psi or 0.01 bar) per 10 cm (4 in) of height difference.*



**Figure 8:** Reference height for pressure.

**Note**

*Since each channel has a volumetric pump that isolates the inlet from the outlet, it normally does not matter if the drain tube ends above or below the outlet. See "Back pressure" on page 37. This feature enables setups with a closed loop.*
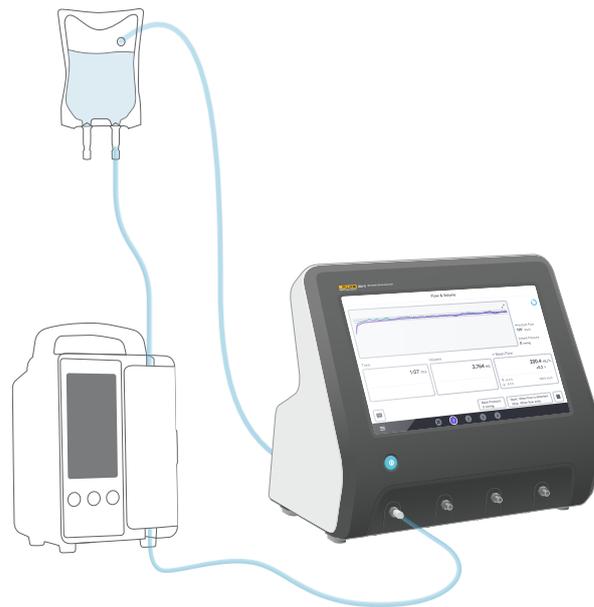


**Figure 9:** Closed loop setup.

# How to measure

## Measurement types

From the home screen, you have the option to run a procedure (requires OneQA registration, see "Register the product in OneQA" on page 22) or perform individual measurements. A procedure can include measurements. For measurements included in procedures, the start and stop conditions, as well as set values and limits, are defined by the procedure and cannot be edited on the product screen.

The product has three measurement types, accessible both in procedures and as individual measurements:

- **Flow & volume** (see "Flow & volume" on page 16)
- **Occlusion** (see "Occlusion" on page 18)
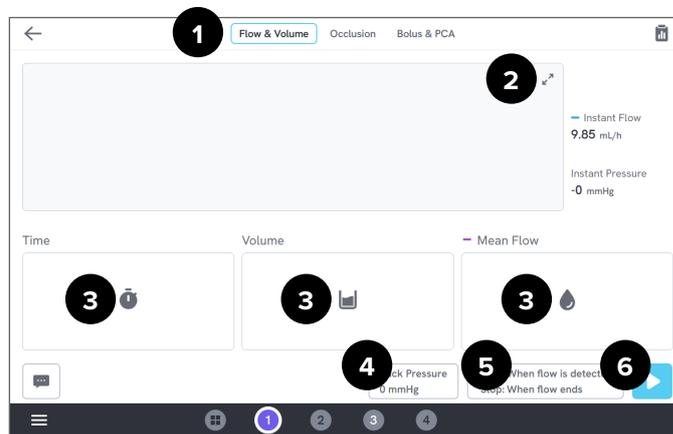- **Bolus & PCA** (see "Bolus & PCA" on page 20)



**Figure 10:** Measurement screen, before measurement.
1: Select measurement type.
2: Expand graph.
3: Access set value and limits.
4: Edit back pressure.
5: Edit start and stop conditions.
6: Run measurement.

To start a measurement, tap the run button ▶ on the measurement screen. Even if you are using automatic measurement start, you have to tap the run button to get the product prepared for measurement.

To manually stop the measurement, tap stop ■ . The measurement is automatically stored in the product, unless you select to discard it.

## General settings and parameters

When a measurement screen is visible, the instant flow and the instant pressure are continuously updated on the screen, both during and in between measurements. The definitions of these two parameters are the same for all three measurement types:

- **Instant flow** is the flow through the channel, updated once per second, with a moving average filter.
- **Instant pressure** is measured on the channel inlet, updated once per second.

Use **back pressure** to set a pressure that you want the product to regulate against. Default back pressure is 0 (zero).

## Start and stop conditions

For each measurement type, there is a different set of start and stop conditions to select from.

### Note

*When measuring on an infusion pump with a non-continuous flow, e.g. peristaltic pump, you might need to increase the stop delay (the time to continue waiting for flow before ending the measurement) to prevent the measurement to end in the pause between contractions in the infusion pump.*

## Limits and set values

For the main measurement quantities, you have the possibility to add set values to show deviations, and test limits to get pass or fail when the measurement ends. Tap on the quantity icon to access set values and limits.

With no limits set, the result will get a neutral status.

## Graphs

For every measurement, a graph is displayed and populated during the measurement. To expand the graph, tap the arrows in the upper right corner.

In the expanded graph view, you can tap on the plotted line to see values for specific samples in the graph.

## Measurement sessions

When a measurement has ended, it is automatically saved. To add measurements, tap the **+** button in the lower right corner.

In the upper right corner, you can see the number of measurements in the current session. Tap the number to go the summary screen for the measurement session. From the summary screen, you can complete the session to store it as a result.
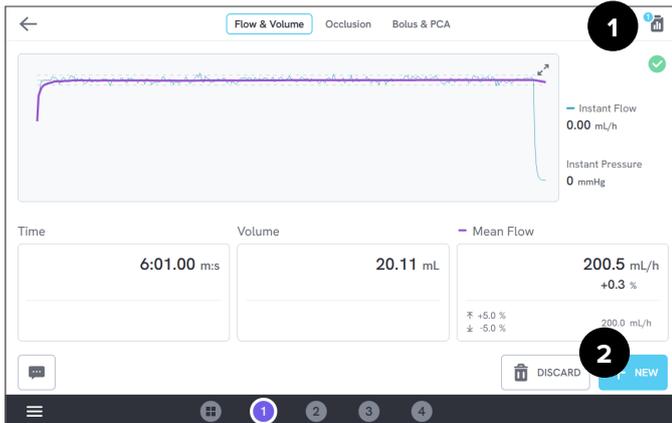


**Figure 11:** Measurement screen.
1:  Access the summary screen.
2: Add more measurements to the session.

# Flow & volume

A flow & volume measurement can be used to verify fluid delivery characteristics of an infusion, such as volume and mean flow.
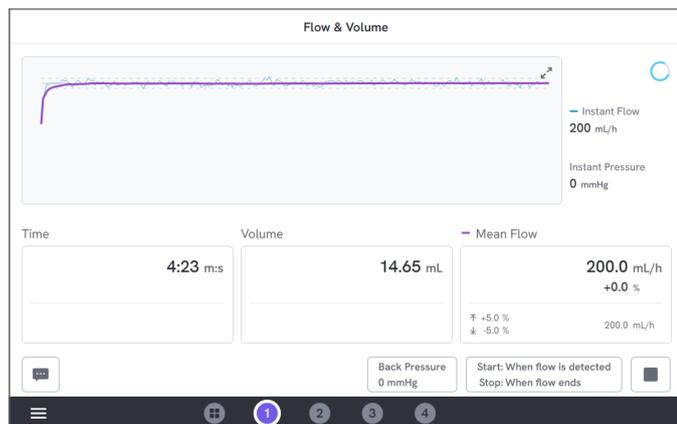


**Figure 12:** A flow & volume measurement.

## Start and stop conditions

The measurement can either be auto triggered by flow, or manually started. The measurement can be ended manually, automatically when the flow ends (with a stop delay setting), or automatically after a set time or volume.

## Parameters during measurement

The flow & volume measurement displays the following parameters during a measurement:

- **Time** depends on the start condition:
  - *Manual:* Time since tapping the run button.
  - *When flow is detected:* Time since flow was detected.
- **Volume** is measured since tapping the run button.
- **Mean flow** is calculated as volume/time.

## Parameters in result

When the measurement has ended, the following parameters are stored in the result:

- **Time** starts as described above, and ends depending on the stop condition:
  - *When flow ends:* Time ends the last occasion the flow falls below 0.5 × mean flow.
  - *Set time:* Time stops when the set time is reached.
  - *Set volume:* Time stops when the set volume is reached.
  - *Manual:* Time stops when tapping stop.
- **Volume** is the total volume recorded from tapping the run button until the measurement has ended.
- **Mean flow** is volume/time.

## Trumpet curve

The product can create a trumpet curve, according to standard IEC 60601-2-24:2012.

From the flow & volume screen, tap the arrows in the top right corner of the graph and then change graph type in the upper left corner.



**Figure 13:** Default settings for generating a trumpet curve.

The default values was selected according to a common example in the defining standard.

- **Sample interval** (Δt) is how often the volume is measured.

- **Observation window durations** is a set of durations used for calculating minimum and maximum flow errors.

- **Start time** and **stop time** define the end points of the interval used for calculating the trumpet curve.

**Note**

*You must input a set value for mean flow to get a trumpet curve.*

The curve is updated once per Δt, but not more often than every 15th second.
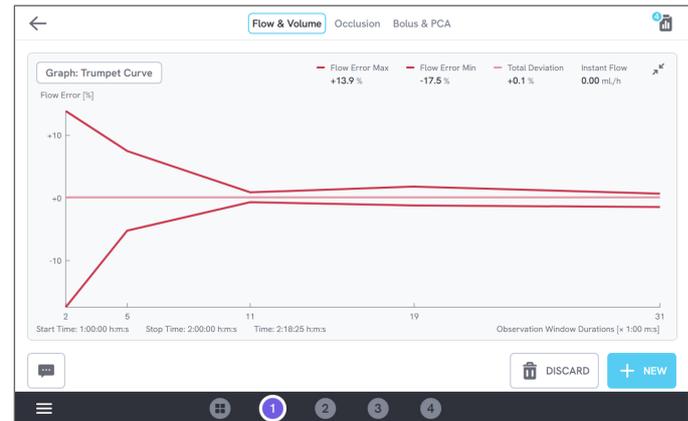


**Figure 14:** A trumpet curve.

# Occlusion

An occlusion measurement can be used to verify the occlusion behavior of an infusion pump, such as peak pressure and alarm functionality.

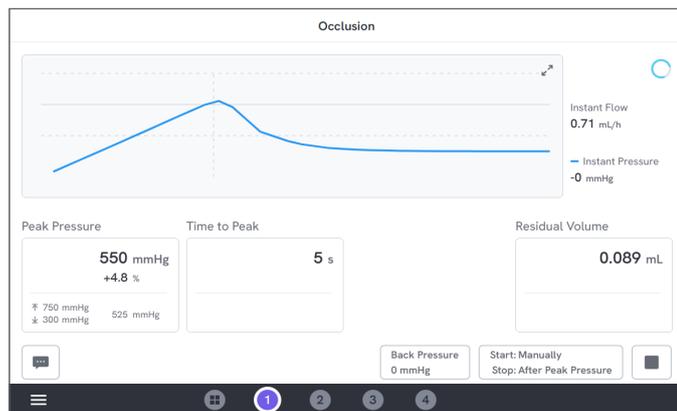For correct pressure readings, ensure that the infusion device is level with the inlet port of the channel.



**Figure 15:** An occlusion measurement.

## Start and stop conditions
Start the infusion device before you manually start the measurement. The product will block the inlet and start the occlusion. The occlusion can be released either manually, or automatically with a selectable delay after the last peak pressure. When residual volume is selected, the measurement will continue after release and end automatically when the residual flow stops. Otherwise, the measurement ends immediately after release.

## Parameters during measurement
The occlusion measurement displays the following parameters during a measurement:

- **Peak pressure** is the highest pressure recorded, using a 50 ms moving average window.
- **Time to peak** is the time passed from tapping the run button until the most recently recorded peak pressure.
- **Time to alarm** (optional) is the time passed from tapping the run button until the last tap on the alarm button.
- **Residual volume** (optional) is the volume caused by remaining overpressure in the administration set, measured from when the occlusion was released.

## Parameters in result

When the measurement has ended, the following parameters are stored in the result:

- **Peak pressure** is the highest pressure recorded during the whole measurement, using a 50 ms moving average window.

- **Time to peak** is the time passed from tapping the run button until peak pressure.

- **Time to alarm** (optional) is the time passed from tapping the run button until the most recent tap on the alarm button.

- **Residual volume** (optional) is the total residual volume measured.

# Bolus & PCA

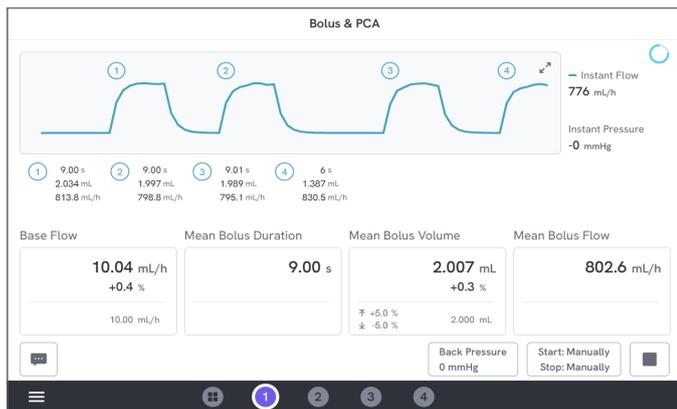A bolus & PCA measurement can be used to verify the bolus functionality of an infusion pump.



**Figure 16:** A bolus & PCA measurement.

## Start and stop conditions

You have to manually start and stop the measurement.

There is a bolus stop delay setting, defining how long to wait when deciding if a bolus has ended. If you experience that one bolus is counted as more than one, try increasing the bolus stop delay.

Before starting a measurement, you have to set an expected base flow value.

## Parameters during measurement

The bolus & PCA measurement screen shows the following parameters during a measurement:

- **Base flow** is the mean flow rate since tapping the run button, excluding periods with boluses.
- **Mean bolus duration** is the mean duration of all completed boluses (sum of durations / number of boluses).
- **Mean bolus volume** is the mean volume of all completed boluses (sum of volumes / number of boluses).
- **Mean bolus flow** is the mean flow of all completed boluses (sum of individual bolus flows / number of boluses).

Each individual bolus is characterized using the following definitions:

- Boluses are **numbered** in order of detection.
- **Bolus duration** is recorded from start trig until the last time the flow falls to half of the bolus mean flow rate. To trigger, the bolus needs a flow rate of at least 10 times the base flow rate.
- **Bolus volume** is the total volume of the bolus, with or without the base flow included, according to user setting.
- **Bolus flow** is calculated as volume / duration. For this calculation, the volume always includes the base flow.

## Parameters in result

When the measurement has ended, the following parameters are stored in the result:

- **Base flow** is the mean flow from tapping the run button until tapping the stop button, excluding periods with boluses detected.
- **Mean bolus duration** is the mean duration of all completed boluses (sum of durations / number of boluses).
- **Mean bolus volume** is the mean volume of all completed boluses (sum of volumes / number of boluses).
- **Mean bolus flow** is the mean flow of all completed boluses (sum of individual bolus flows / number of boluses).

# Using OneQA

OneQA is a cloud connected software to help you streamline your workflow and make reporting easier. Once the product is registered to OneQA, procedures created in OneQA are synchronized to the product. The procedures can be run from OneQA on a computer, or directly on the product. The results are synchronized to OneQA for easy access and export. Assets are synchronized both ways.

The measurement types described in "How to measure" on page 13 onwards can also be used as components within the OneQA procedures.

## Register the product in OneQA

Before using the product with OneQA, you must register the product to a OneQA tenant. Connect the product via USB cable to a computer running OneQA and follow the instructions on the computer screen.
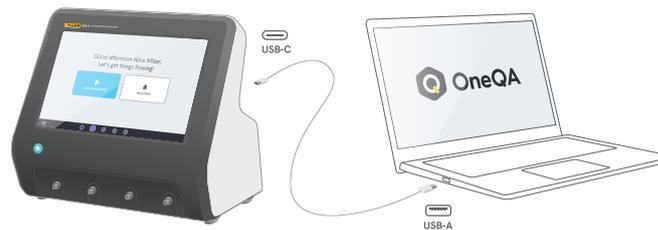


**Figure 17:** Connect the product to a computer running OneQA.

When the registration is done, the synchronization of procedures, assets and results will start automatically.

The data continues to synchronize periodically, provided the product either is connected to the Internet (via a WiFi adapter with USB), or connected via USB cable to computer running OneQA. To manually initiate a synchronization, check the OneQA section of the settings on the product.

# Users

The product provides the ability to document the individual that performs a procedure or a measurement session. A list of users can be found via the navigation menu.

When a user is selected as the active user from the navigation menu, that user will automatically be selected as a tester when running a procedure or measurement session.

There are two types of users:

- **Local users**, created and edited in the product, never synchronized to OneQA.
- **OneQA users**, created and edited in OneQA.

To add OneQA users to the product, the product must be registered and synchronized with OneQA. Every OneQA user must be manually added to the product, using the username from OneQA.

### Note

*Depending on settings in OneQA, the OneQA users may need to enter their password to be added to the product. OneQA can also prohibit local users on a registered product.*

# Assets

An asset is a device to be tested, in this case an infusion device. The product can store a collection of assets. A list of assets can be found via the navigation menu.

If the product is connected to the Internet (via a WiFi adapter with USB), or connected via USB cable to computer running OneQA, assets are synchronized with OneQA.

## Add and remove assets

To create new assets, tap the plus symbol in the top right corner of the asset list.

To remove assets, tap the check box in the top right corner of the asset list and select which assets to remove. Tap the remove button at the bottom of the screen.

**Note**

*Assets synchronized with OneQA must be removed from OneQA running on a computer.*

## Export assets

Assets can be exported from the product to a USB drive.

1. Insert a USB drive in one of the USB host ports on the back side of the product.
2. Open the list of assets via the navigation menu.
3. Tap the check box in the top right corner.
4. Select one or multiple items in the list.

5. Tap the export button at the bottom of the screen.
6. An excel file listing all the assets and their result status is created on the USB drive.
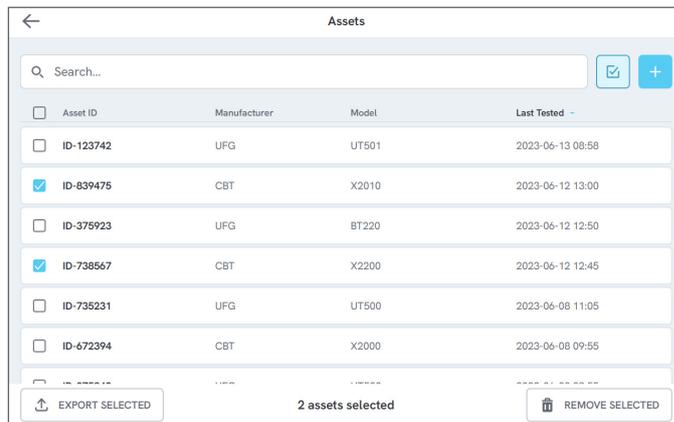


**Figure 18:** List of assets.

# Procedures

A procedure is a set of measurements and tasks that are defined in advance.

Procedures may be built and customized using OneQA on a computer. Once created, procedures will automatically be synchronized to the product if it is connected to the Internet (via a WiFi adapter with USB), or connected via USB cable to computer running OneQA. A list of procedures can be found via the navigation menu.

You may start a procedure two ways:

1. Tap the procedure button on the home screen and follow the setup instructions on the screen.

2. Connect the product via USB cable to a computer running OneQA and start a procedure remotely. The product will show a remote mode interface with limited functionality on the screen when measuring.

## Start a procedure

To start a procedure from the home screen, tap the procedure button from the home screen and follow the setup instructions on screen.

You can also start a procedure from the procedure list, found via the navigation menu.
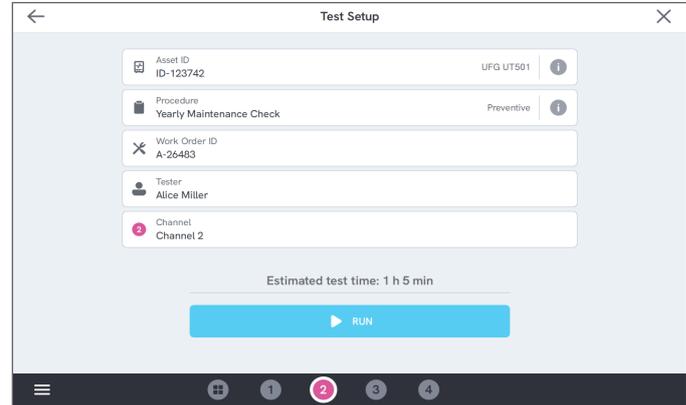


**Figure 19:** Setup screen for running a procedure.

## Run a procedure

When running a procedure, the screen shows one task at a time. Procedure status and navigation functionality can be found at the bottom of the screen.
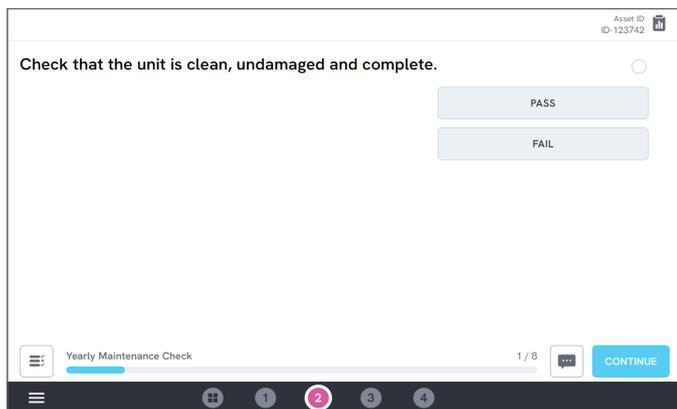


**Figure 20:** Running a procedure.

Mandatory steps are indicated with a red star.

To get an overview of the procedure, or return to a previous step, tap the button to the right of the progress bar.

## Complete a procedure

When the procedure is finished, you have the option to view and edit procedure information before completing the procedure. When completed, the procedure will be stored as a result.
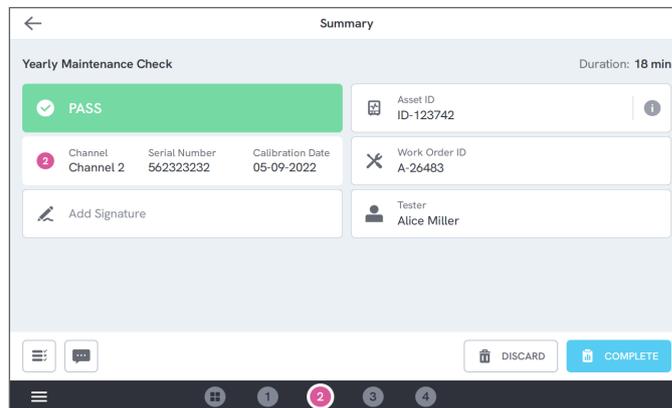


**Figure 21:** Procedure summary screen.

If a USB printer is connected, you will get the option to print the result.

# Results

A result is a completed procedure or measurement session.

A list of results can be found via the navigation menu.

If the product is connected to OneQA, results will automatically be synchronized to OneQA.

## Export results

Results can be exported from the product to a USB drive.

1. Insert a USB drive in one of the USB host ports on the back side of the product.
2. Open the list of results via the navigation menu.
3. Tap the check box in the top right corner.
4. Select one or multiple items in the list.
5. Tap the export button at the bottom of the screen.
6. Select export format and export.



**Figure 22:** List of results.

## Print results

Results can be printed using a USB printer.

1. Connect a USB printer to one of the USB host ports on the back side of the product.
2. View a result to access a printer button at the bottom.
3. Select printer type and print format. You can also access the printer settings to add custom fields to the printout before printing.

# Multiple channels

The product can be equipped with 1 to 4 independently calibrated channels.

You can view one channel at time, or an overview of all channels simultaneously. Tap the icons on the bottom navigation bar to switch between the views.
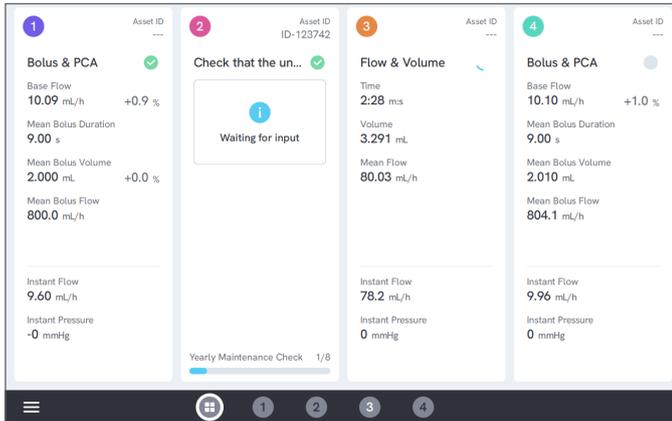


**Figure 23:** Split view with four channels.

# Settings

Settings can be reached from the navigation menu.

Changed settings will take effect immediately.

## Units

Select the unit of measurement of your choice. See "Measurement units" on page 37 for specification.

Procedures and results are not affected when changing unit of measurement.

## Zero adjust pressure

If the instant pressure does not stabilize on zero (0), or if the channel pump speeds up by itself when there are no connections to the channel inlet, you may need to perform a zero adjustment of the inlet pressure sensor.

Make sure there are no connections to the inlet of the channel. Tap the button for the selected channel to get the zero pressure level adjusted.

## Screen & sound

The screen brightness and volume are adjustable.

Adjust the sound options as desired. For example, the product can make an audible sound when a measurement has ended.

## Language

The interface and the user manual are available in several languages. You can also select what keyboard language to use.

## Date & time

Select time zone and date format. If the product is connected to OneQA via USB cable, or has an The Internet connection, date and time will automatically be adjusted.

## Printer

If the product has a USB printer connected, results can be printed. Add custom text here to be included in the printout.

## Network

The product may be connected to a wireless network using a WiFi adapter. Connect the adapter to one of the USB host ports on the back side of the product and edit the network settings to connect.

If the product is registered to a OneQA tenant and connected to the Internet, data will be synchronized regularly.

## OneQA

Status and functions related to the OneQA connection. For registration, see "Register the product in OneQA" on page 22.

## About

Information about the system, such as serial numbers, system version and calibration dates.

Factory reset and system update can be initiated from this screen.

### System update

Before updating the system, complete all procedures and measurements. System update files are published on www.flukebiomedical.com.

1. Save the system update file on a USB drive.
2. Insert the USB drive to one of the USB host ports on the back side of the product.
3. Tap the system update button and follow the instructions on the screen.

# Maintenance

## Cleaning

Turn off the product and disconnect the power adapter before cleaning with a cloth dampened with a mild detergent solution.

## Storage and transportation

Before storing or transporting the product, drain the channels as described in "Drain a channel" on page 31. For packaging recommendations, see "Notices" on page 3.

#### Note

*Draining is particularly important if the product is at risk of being exposed to freezing temperatures.*

## Drain a channel

To remove liquid from a channel, use a syringe with air:

1. Make sure that the product is turned on.
2. Disconnect the drain tube from the outlet port.
3. Connect a syringe filled with air to the inlet port.
4. Gently push air through the channel. The amount and rate should be approximately 20–30 mL of air during 30 seconds.



**Figure 24:** Draining a channel.

## Remove and install channels

You can send individual channels for calibration and service.

### Remove a channel

1. Drain the channel from water by following the instructions under "Drain a channel" on page 31.

2. Turn the product off by pressing the power button.

3. Disconnect the power adapter.

4. Place the product on a dry, clean and non-abrasive surface with the display down, to get access to the bottom side.

5. Unscrew the two screws holding the channel you want to remove.

6. Gently pull out the channel and disconnect the channel power cable from the channel.
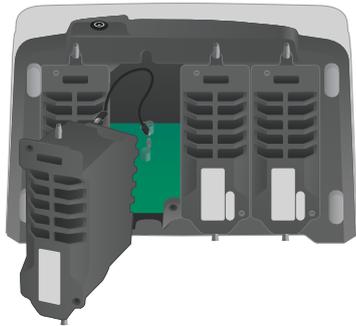


**Figure 25:** One channel unmounted.

### Install a channel

1. Turn the product off by pressing the power button.

2. Disconnect the power adapter.

3. Place the product on a dry, clean and non-abrasive surface with the display down, to get access to the bottom side.

4. If the channel slot is occupied by an empty channel, unscrew the two screws and remove the empty channel.

5. Connect the channel power cable to the port on the PCB inside the product. Note that the internal power sockets define the order of the channels showed on screen.

6. Connect the channel power cable to the channel and position the channel in the slot. Pay attention to the guiding grooves located above the inlet.

7. Secure the channel with two screws.

The installation is now completed and the channel will show up the next time you power on the product.

# Troubleshooting

## Channel not detected

*Possible cause:* Internal power issue.

*Solution:* Restart the product. If the problem persists, power off the product and reconnect the channel power cable, or try a different channel power socket if possible. See "Remove and install channels" on page 32 for instructions.

## Pressure not stable on zero when nothing is connected

*Possible cause:* The zero level of the pressure sensor has drifted, and needs an adjustment.

*Solution:* Remove everything connected to the inlet port and perform a pressure zero adjustment, see "Zero adjust pressure" on page 29.

## Boluses are not detected, or measurement ends early

*Possible cause:* Low and non-continuous flow. Peristaltic pause causes end of measurement.

*Solution:* Prolong the applicable stop delay.

## Product not responding

*Possible cause:* Unknown

*Solution:* Disconnect the power adapter. Wait 30 seconds before reconnecting the power adapter and turning the power on again. If the problem persists, contact support. See "Notices" on page 3 for contact information.

## My WiFi adapter or USB printer does not work

*Possible cause:* The accessory is not compatible with the product.

*Solution:* Visit www.flukebiomedical.com to find out which accessories to use with the product.

## Some procedures are not synchronized to the product

*Possible cause:* All steps in the procedure are not compatible with the product.

*Solution:* Run the procedure from OneQA on a computer, with the product connected with USB cable.

# Specifications

## General

Safety standard..............................................Complies with IEC 61010-1:2010, pollution degree 2

Infusion device standard...........................For testing according to IEC 60601-2-24:1998

EMC standard...............................................Complies with IEC 61326-1:2012

Dimensions (w × d × h)...............................295 mm × 210 mm × 260 mm (11.6 in × 8.3 in × 10.1 in)

Weight............................................................3.8 kg (8.4 pounds)

Operating temperature..............................+15 – +30 °C (+59 – +86 °F)

Storage temperature...................................-20 – +70 °C (-4 – +158 °F), when drained

Atmospheric pressure................................70 – 107 kPa, altitude up to 3000 m (10 000 ft)

Humidity........................................................< 90 % relative humidity, non condensing

Power .............................................................19 V DC, 3 A

Power supply................................................Input: 100 – 240 V, 50 – 60 Hz, 1.5 A. Output: 19 V, 3.15 A, 60 W.

Connectivity.................................................1 × USB-C for PC communication, 3 × USB-A for peripherals, max 3 m cable

Display...........................................................10-inch multi-touch, 800 × 600 pixels

Data storage .................................................> 10 000 measurements

Channels........................................................1 to 4, depending on configuration

## Electromagnetic Compatibility (EMC)

International ...................................................IEC 61326-1: Portable Electromagnetic Environment

CISPR 11: Group 1, Class A

*Group 1: Equipment has intentionally generated and/or uses conductively-coupled radio frequency energy that is necessary for the internal function of the equipment itself.*

*Class A: Equipment is suitable for use in all establishments other than domestic and those directly connected to a /ow-voltage power supply network that supplies buildings used for domestic purposes. There may be potential difficulties in ensuring electromagnetic compatibility in other environments due to conducted and radiated disturbances.*

*Caution: This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments. Emissions that exceed the levels required by CISPR 11 can occur when the equipment is connected to a test object.*

Korea (KCC)..................................................... Class A Equipment (Industrial Broadcasting & Communication Equipment)

*Class A: Equipment meets requirements for industrial electromagnetic wave equipment and the seller or user should take notice of it. This equipment is intended for use in business environments and not to be used in homes.*

USA (FCC) ...................................................47 CFR 15 subpart B. This product is considered an exempt device per clause 15.103.

## Flow & volume

Mean flow range...........................................0 – 3000 mL/h (steady flow), 0 – 1500 mL/h (peristaltic flow)

Mean flow resolution...................................0.001 mL/h

Mean flow accuracy
(after > 0.1 mL and > 10 s)...........................± (1 % + 0.005 mL/h) at < 500 mL/h, otherwise ± 2 %

Volume range................................................0 – 100 000 mL

Volume resolution........................................0.001 mL

Volume accuracy
(after > 0.1 mL and > 10 s)...........................± (1 % + 0.003 mL) at < 500 mL/h, otherwise ± 2 %

Time range.....................................................0 s – 1000 h

Time accuracy...............................................± (0.2 % + 0.2 s)

Time trig volume...........................................≤ 3 µL

Graphs...........................................................Instant flow and mean flow with up to 1 s resolution
(gradually reduced after 1 hour), IEC 60601-2-24 trumpet curve

## Occlusion

Peak pressure range....................................-200 – +2600 mmHg (-3.8 – +50 psi)

Peak pressure resolution............................1 mmHg (0.01 psi)

Peak pressure accuracy..............................± (1 % + 5 mmHg (0.1 psi)), 50 ms moving average

Time to peak range .....................................0 s – 1000 h

Time to peak accuracy.................................± (0.2 % + 0.05 s)

Time to alarm................................................0 s – 1000 h

Time to alarm accuracy ..............................Operator dependent, manual stop button

Residual volume accuracy..........................± (2 % + 0.01 mL)

Graphs...........................................................Pressure with up to 50 ms resolution (gradually reduced after 3 minutes)

## Bolus & PCA

Bolus volume range......................................0.01 – 100 000 mL

Bolus volume accuracy
(after > 1 s)......................................................± (2 % + 0.01 mL)

Bolus flow range..........................................10 × base flow – 3000 mL/h (steady flow),
10 × base flow – 1500 mL/h (peristaltic flow)

Bolus flow accuracy
(after > 0.1 mL and > 10 s)...........................± (1 % + 0.005 mL/h) at < 500 mL/h, otherwise ± 2 %

Base flow range...........................................1 – 100 mL/h

Base flow accuracy
(after > 0.1 mL)................................................± (1 % + 0.005 mL/h)

Bolus duration range...................................0 s – 1000 h

Bolus duration accuracy.............................± (0.2 % + 0.2 s)

Graphs...........................................................Instant flow with up to 1 s resolution (gradually reduced after 1 hour),
numbered boluses

## Back pressure

Range ............................................................-200 – +600 mmHg (-3.8 – +11.6 psi)

Additional flow uncertainty........................± $\Delta P$ × 0.001 mL/h

Additional volume uncertainty ....................± (test duration in hours) × $\Delta P$ × 0.001 mL

*Where $\Delta P$ is the average pressure difference between inlet and outlet, in mmHg.*

## Measurement units

Pressure........................................................mmHg, kPa, psi, bar

Volume ..........................................................mL, g (1 mL = 0.998 g)

# 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.

7/07