RIGEL MEDICAL

Innovating Together.

MULTI-FLO

Infusion Device Analyser

Last Update: 5th July 2012

Instruction Manual
385A550 Revision 1.0

Rigel Medical 24 Month Warranty Statement

Rigel Medical provides a standard 12-month manufacturer's warranty against breakdown during normal use. This warranty can be upgraded to a 24-month warranty (terms and conditions apply*). Problems caused through misuse, damage, fair wear & tear, consumables and accessories are excluded from standard warranty. Such components found to be being used in excess of their manufacturer's operating recommendations are also excluded. Shipping to an authorised service center is the responsibility of the sender.

*Terms and Conditions of 24 Month Warranty

The Rigel product must be registered with Rigel Medical within 30 days of purchase to be eligible for the extended 24-month warranty. Instruments must be returned to an authorised service center complete with proof of purchase within 13 months of purchase for calibration at the current rate. Any items returned for calibration outside of the 13 month period stated above may not be eligible for the second 12 month section of warranty. The second 12 month section of the warranty begins at the expiry of the initial 12 month period, not when the unit is calibrated.

Details correct at time of going to print. The manufacturer retains the right to make amendments to the above terms and conditions without prior notice.

Calibration Statement

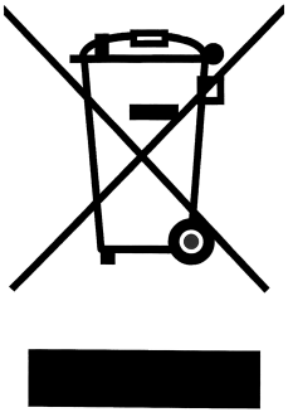
The Rigel Multi-Flo Infusion Device Analyser is fully calibrated and found to be within the specified performance and accuracy at the time of production. The Seaward Group provides its products through a variety of channels; therefore it may be possible that the calibration date on the provided certificate may not represent the actual date of first use.

Experience has indicated that the calibration of this instrument in not effected by storage prior to receipt by the user. We therefore recommend that the recalibration period be based on a 12 month interval from the first date the unit is placed in to service.

Date received into service; ___/___/_____.

Due to a policy of continuous development the SEAWARD GROUP reserves the right to alter the equipment specification and description outlined in this publication without prior notice and no part of this publication shall be deemed to be part of any contract for the equipment unless specifically referred to as an inclusion within such contract.

Disposal of old product



The Rigel Multi-Flo has been designed and manufactured with high quality materials and components, which can be recycled and reused.

When this symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC.

Please familiarise yourself with the appropriate local separate collection system for electrical and electronic products or contact your local supplier for further information.

Please dispose of this product according to local regulations. Do not dispose of this product along with normal waste material. By offering your old products for recycling, you will help prevent potential negative consequences for the environment and human health.

Certificate of Conformity

Manufactured by:

Seaward Electronic Ltd, Bracken Hill, South West Industrial Estate

Peterlee, County Durham, SR8 2SW, England

As the manufacturer of the apparatus listed, declare under our sole responsibility that the product:

Rigel Multi-Flo Infusion Device Analyser

To which the declaration relates are in conformity with the relevant clauses of the following standard:

BS EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.

BS EN 61326:2006 Electrical equipment for measurement, control, and laboratory use - EMC requirements.

Performance: The instrument operates within specification when used under the conditions in the above standards EMC and Safety Standards.

The product identified above conforms to the requirements of Council Directive 2004/108/EC and 2006/95/EC.

This Conformity is indicated by the symbol CE, i.e. “Conformité Européenne”

Seaward Electronic Ltd. is registered under BS EN ISO9001:2000 Certificate No.: Q05356.

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Introduction

Design Philosophy

The Rigel Multi-Flo Infusion Device Analyser provides accurate and fast analysis of the performance of all common infusion devices. The Multi-Flo's instant flow measurement allows for high resolution flow and pressure analyses and provides a highly accurate calibration method for proving the correct function of all infusion devices.

Infusion devices can be tested under positive and negative pressure settings whilst bolus and PCA tests are conducted with the highest possible resolution.

Measuring flow rates, volume and pressure, the Multi-Flo is available in 1, 2 and 4 channel configuration which can be upgraded in the future to include additional channels up to a maximum of 4 channels. The Multi-Flo will ensure it meets your current and future requirements.

Note; This version of the manual (V1.0) describes the manual function of the Multi-Flo only. Software upgrades available by the end of 2012 will activate the automatic testing sequences, remote PC control, data storage and download. Register your product asap to receive notification of the free firmware upgrade. To register your product, please visit:

www.rigelmedical.com/register-product

Unpacking the Multi-Flo

Carefully unpack all items from the box and ensure the following items are included:

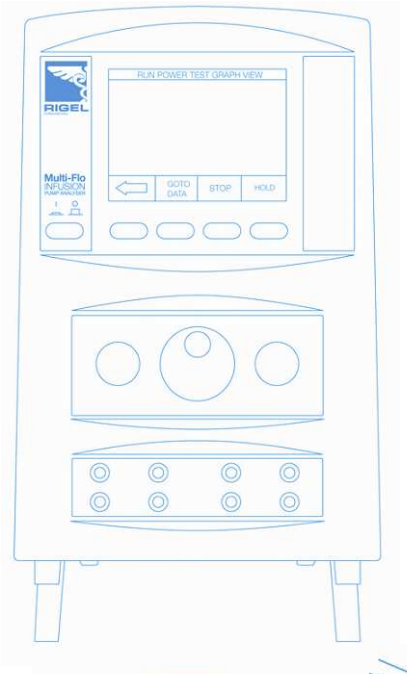
Rigel Multi-Flo Infusion Device Analyser

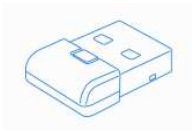
Mains Power Lead

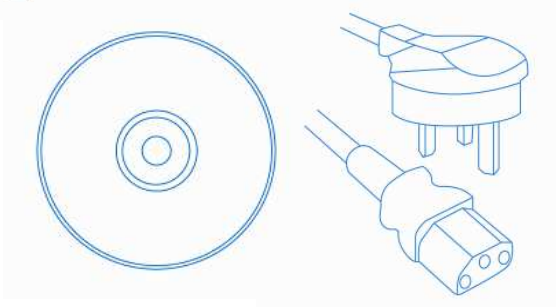
Multi-Flo Quick Start Guide

Utilities Disc

USB Bluetooth Adaptor







Warnings and Cautions

User Notes

Ensure that the Multi-Flo is operated with the **distilled or de-ionised water** only.

The following symbols are used throughout this Instruction Manual;

Warning of electrical danger! Indicates instructions must be followed to avoid danger to persons.

Important, follow the documentation! This symbol indicates that the operating instructions must be adhered to in order to avoid danger.

Safety Notes

Users - The Rigel Multi-Flo Infusion Device Analyser is designed for use by adequately trained technical personnel only.

Operation - The Rigel Multi-Flo Infusion Device Analyser is designed for use within the published specifications. Any application outside of these specifications or any unauthorised user modifications may result in hazardous conditions or improper operation.

Operation - Refer to the Device Under Test (DUT) manufacturer operating instructions to ensure safe operation whilst analysing the DUT.

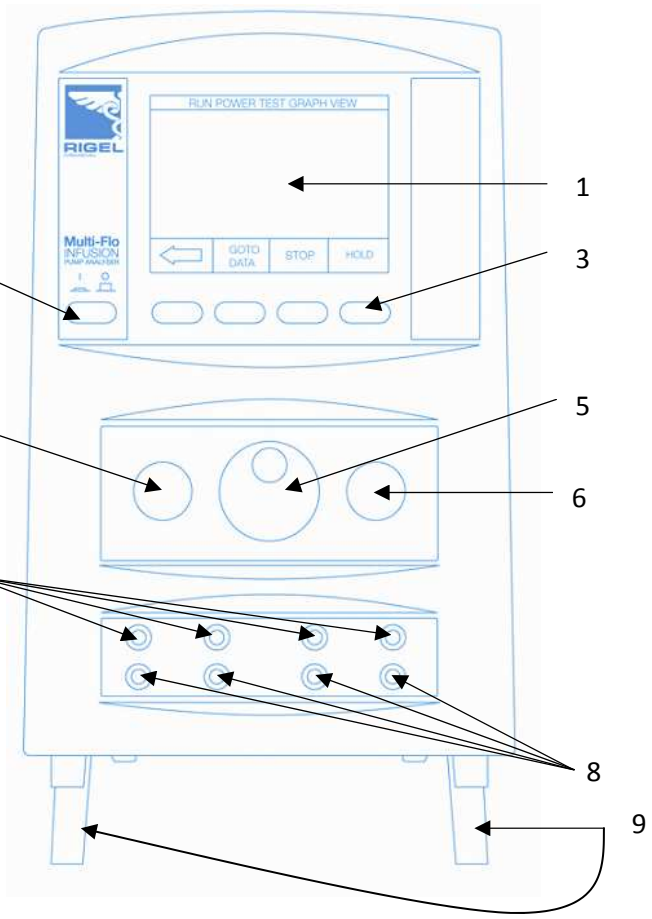
Safety - Ensure that only accessories supplied by the manufacturer or accessories that meet the manufacturer's specification are used.

Safety - Where safe operation of the Multi-Flo is no longer possible it should be immediately shut down and secured to prevent accidental operation.

It must be assumed that safe operation is no longer possible:

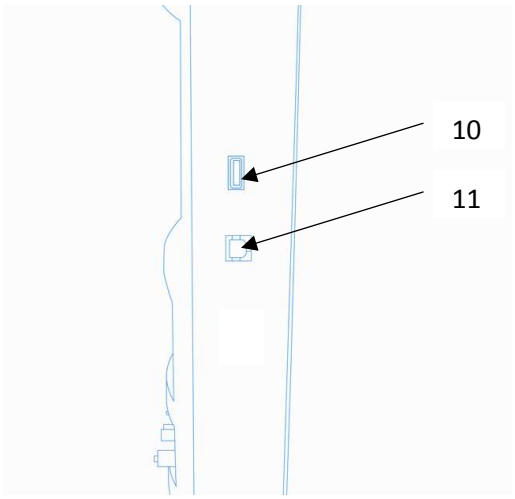
- if the instrument or leads show any sign of damage or
- the instrument does not function or
- after long periods of storage under adverse environmental conditions.

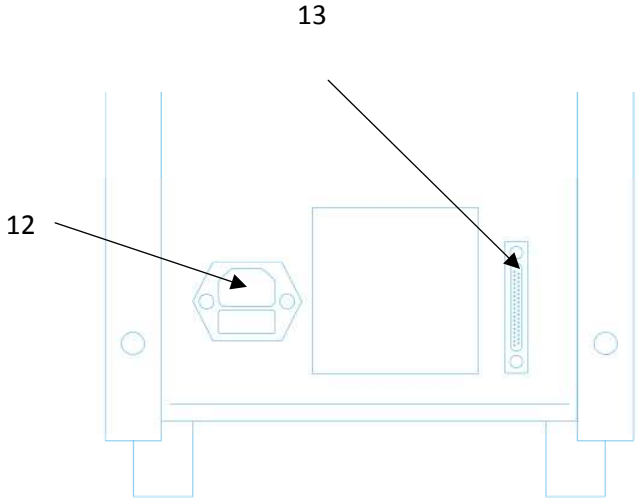
Multi-Flo Overview



KEY

1	Large colour graphic display.
2	ON/OFF button
3	Function keys F1 - F4
4	Start button
5	Rotary encoder
6	Stop/End button.
7	Channel inlet connectors.
8	Channel drain connectors.
9	Folding legs
10	Type A USB connection
11	Type B USB connection
12	IEC mains power lead connection
13	Auxiliary output connection





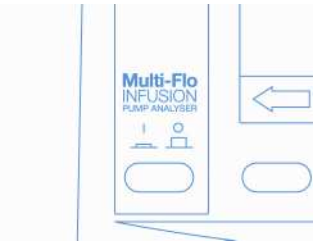
1 Getting Started

1.1 Before you Switch On!

Ensure that the Multi-Flo is operated with the **distilled or de-ionised water** only.

The Rigel Multi-Flo has two legs on the front base of the unit. These are designed to raise the front of the unit to improve the viewing angle of the colour graphic display.

1.2 Turning the Multi-Flo On and Off

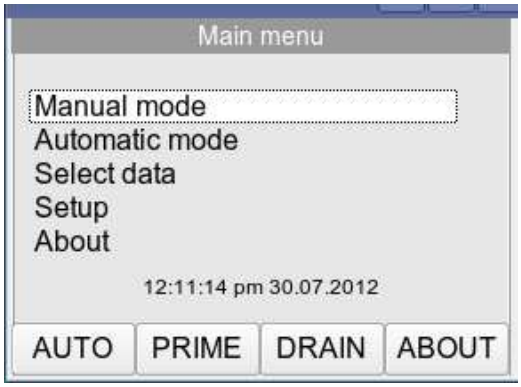


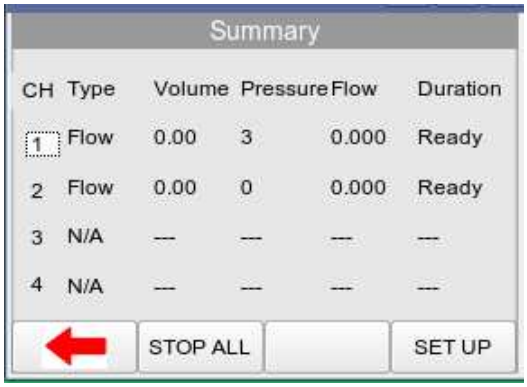
To turn the Multi-Flo ON, press the orange I/O key so it is in the in position.

To turn the Multi-Flo OFF, press the orange I/O key so it is in the out position.

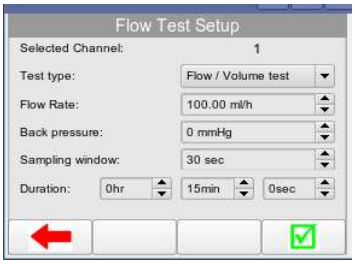
1.3 Accessing the Multi-Flo Tests

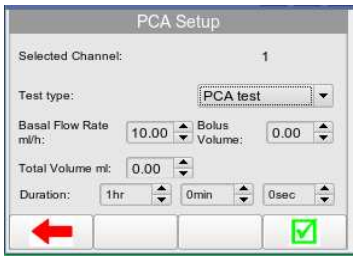
From the main menu, use the rotary encoder to highlight Manual mode. Press the rotary encoder to enter manual mode.

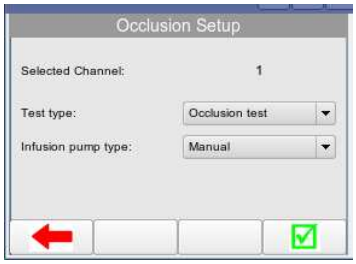




Here you can access the test menu for each individual channel.





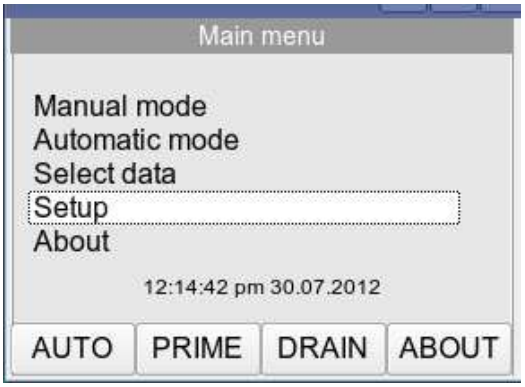


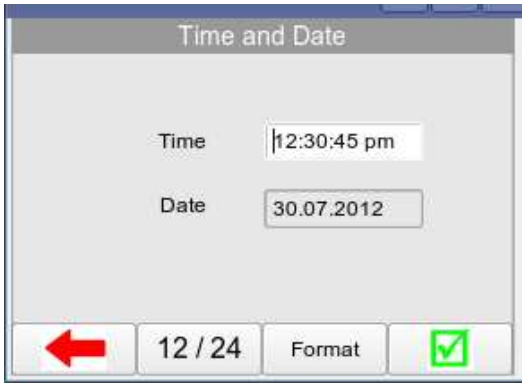
Highlight the required channel and press **SET UP** or push the rotary encoder. Highlight the Test type menu and push the rotary encoder. This will allow you to toggle between PCA test, Occlusion test and Flow Rate.

Press ☑ to save or ← to exit without saving.

1.4 Setting the Time/Date

From the main menu, use the rotary encoder to highlight Setup. Press the rotary encoder to enter the setup menu.





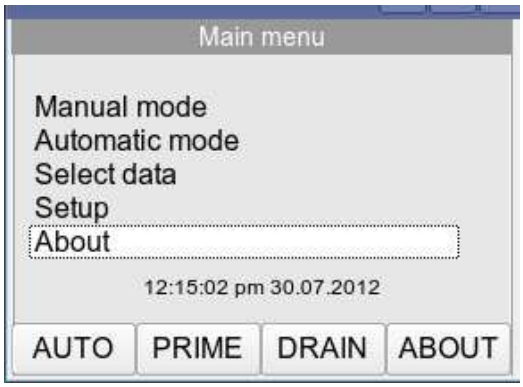
Highlight the part of the time/date you wish to change using the rotary encoder and push to enter. Use the rotary encoder to increase or decrease the value then push again to confirm. Alternatively, use a USB keyboard to enter data.

Press **12/24** to toggle between 12 and 24 hour clock mode.

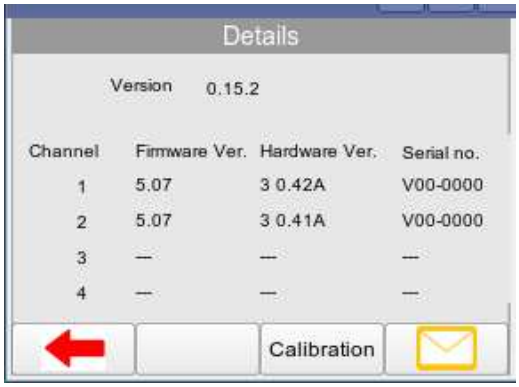
Press **Format** to toggle between DDMMYYYY and MMDDYYYY date format.

Press ☑ to save the changes, then ← to exit.

1.5 Displaying the Multi-Flo Information



From the main menu, press the **About** function key. The main About screen displays telephone, email and website information for the equipment manufacturer.



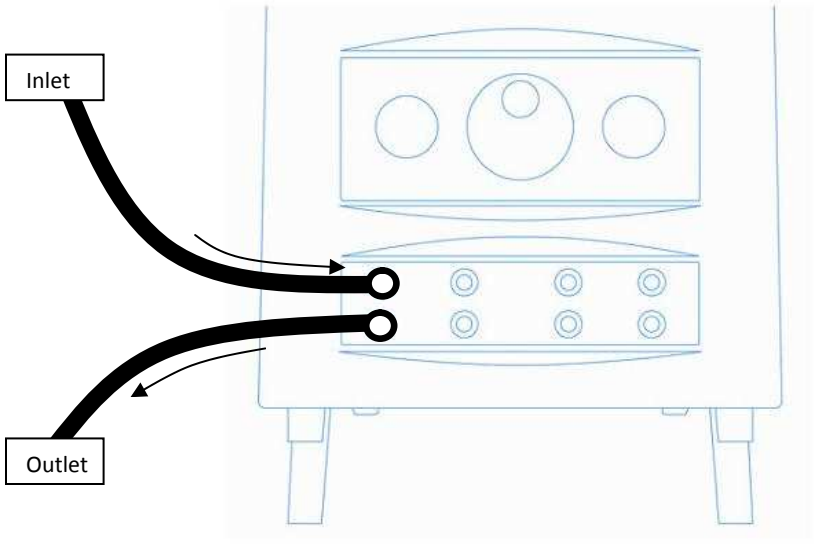
Press **Details** to view the firmware version, hardware version and serial no. for the Multi-Flo unit and each individual installed channel.

Press **Calibration** to view the calibration data of the installed channels.

Press ✉ to view the Service and Calibration contact information.

2 Analysing an Infusion Device

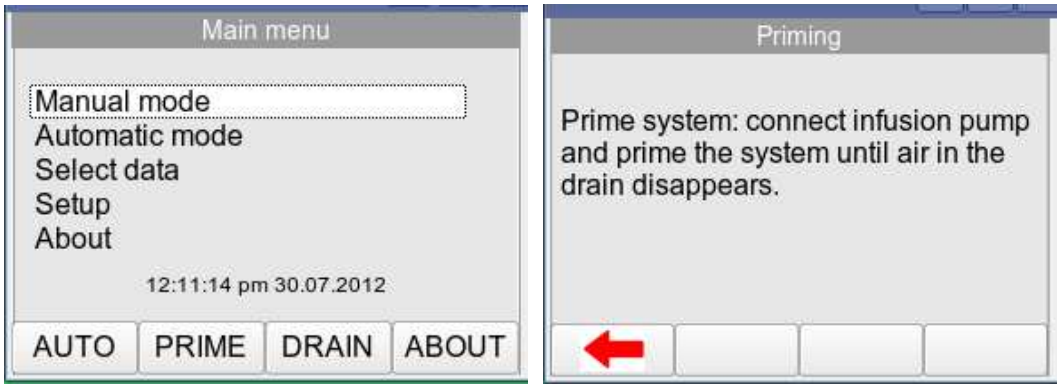
2.1 Connecting an Infusion Device to the Multi-Flo



Ensure the flow direction is as per diagram above. The flow inlet is the top connection whilst the flow outlet is positioned below the inlet for each channel.

2.2 Priming the Channels

Upon power-up the Multi-Flo is in automatic priming mode however, should priming be required at any other stage, select the PRIME from the main menu;

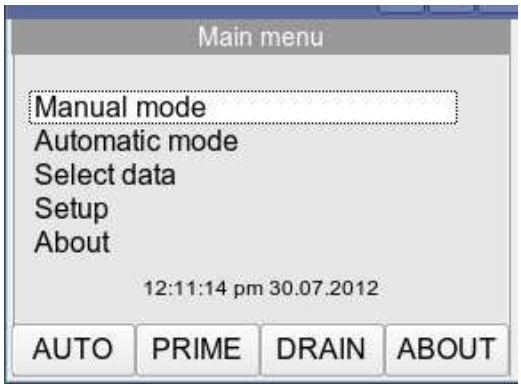


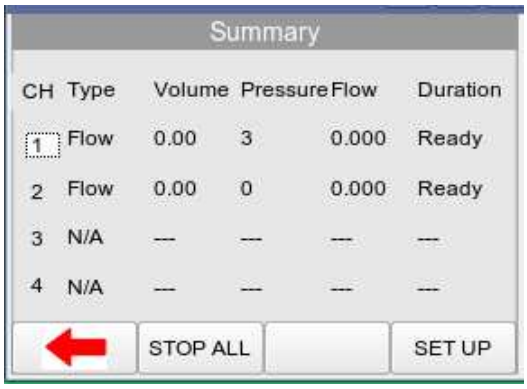
Prime the system until the drain is clear of air bubbles. Press ← to return to the main menu.

2.3 Patient Controlled Analgesia (PCA) test

The PCA test determines the additional volume delivered on top of the basal flow rate set by the user. The additional volume or sometime referred to as BOLUS, is an indication of the correct safety settings of an infusion device.

From the main menu, select Manual mode. This will take you to the channel summary screen.

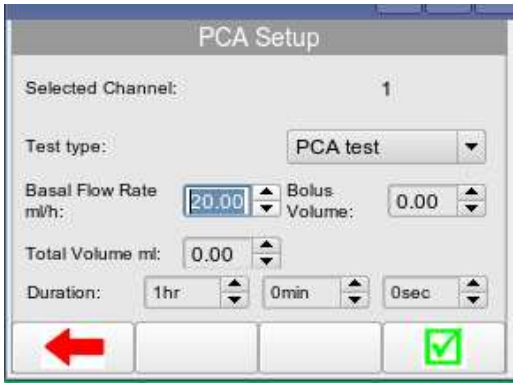




Highlight the required channel and press **SET UP**. Use the rotary encoder to highlight Test type, press the encoder to access the sub-menu. The Test type box will now be highlighted in white.

Use the rotary encoder to select PCA test and press the rotary encoder to confirm. The PCA Setup screen will now be displayed.

Use the rotary encoder to edit the basal flow rate, bolus volume, total volume and test duration.



NOTE: The basal flow rate setting is used to determine the additional volume being delivered ie the BOLUS. Therefore an incorrect setting of the basal flow rate will lead to an inaccurate BOLUS detection.

Press ☑ to save and advance to the PCA test summary screen, or ← to exit without saving.

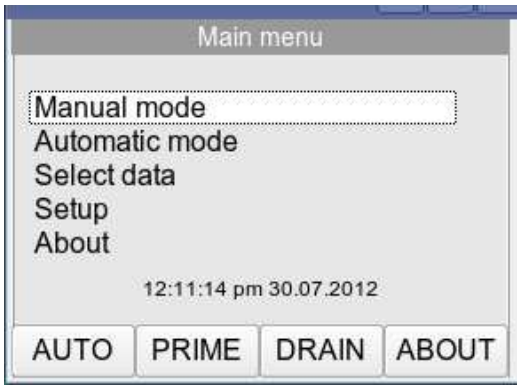
Press the green START button to begin the test.

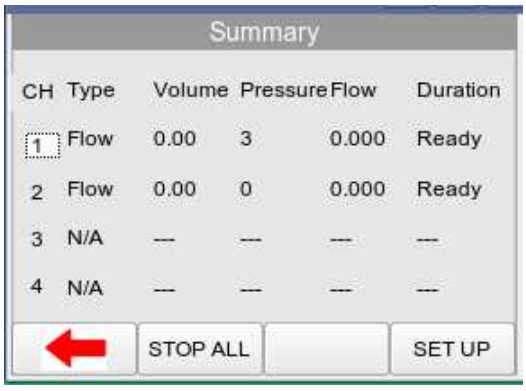
Safety - Press the red STOP button at any time to stop the test.

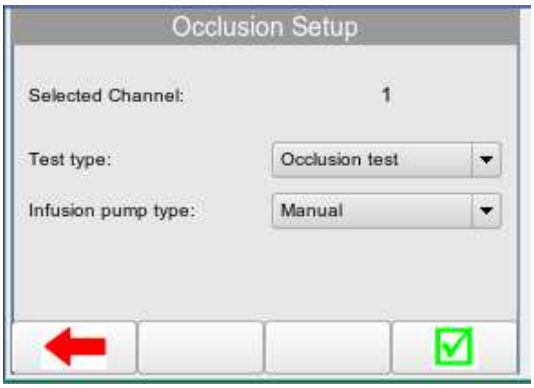
2.4 Occlusion test

The Occlusion test simulates an obstruction in the infusion process. Most infusion devices have the ability to detect this obstruction and provide an occlusion alarm. The occlusion test is able to test this alarm feature in infusion devices.

From the main menu, select Manual mode. This will take you to the channel summary screen. Highlight the required channel and press **SET UP**. This will take you to the Occlusion Setup screen.





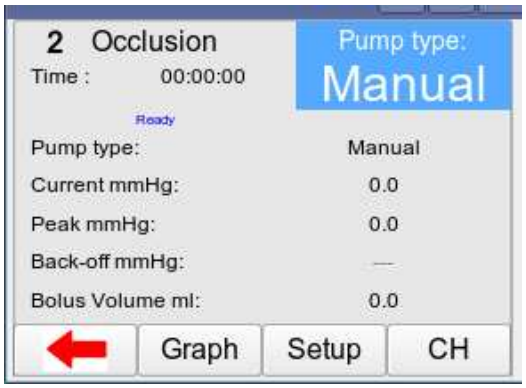


Use the rotary encoder to select Occlusion test and press the rotary encoder to confirm. The Occlusion Setup screen will now be displayed.

Infusion Pump Type

The manual pump setting refers to an infusion device that does not provide for an automatic back-off of pressure. As such, the green button available during the test, must be pressed as soon as the occlusion alarm sound.

The automatic pump setting refers to infusion devices that do provide an automatic pressure back-off function. The Multi-Flo will detect the occlusion alarm when the line pressure decreases after alarm.



Press ☑ to save and advance to the Occlusion test summary screen, or ⬅ to exit without saving.

Press the green START button to begin the test.

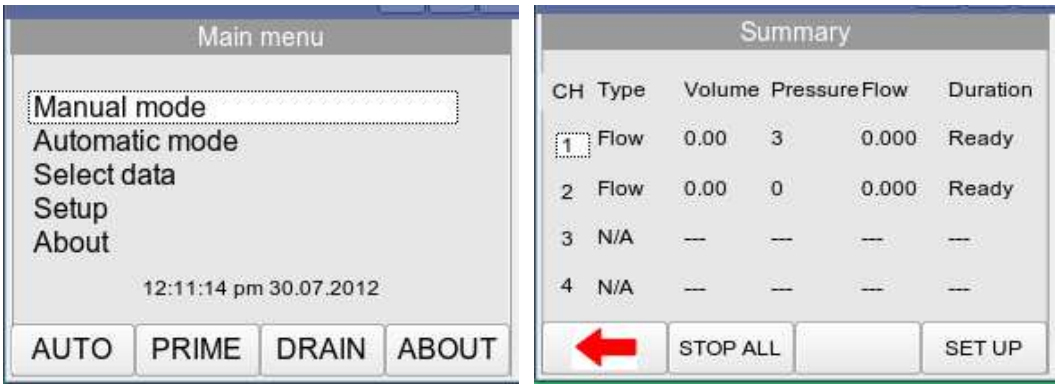
Use the rotary encoder during the test, to change the highlighted (blue) field holding the main measurement parameter.

⚠ **Safety** - Press the red STOP button at any time to stop the test.

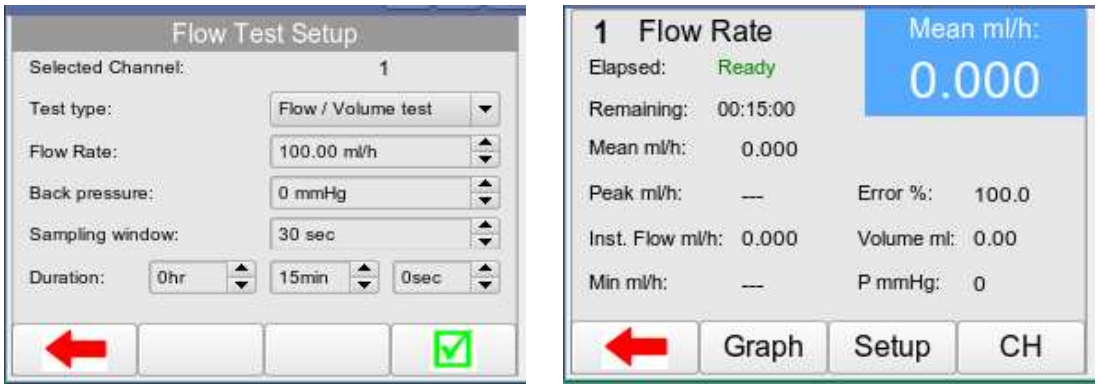
2.5 Flow Rate/Volume test

The Rigel Multi-Flo is capable of measuring the instantaneous flow at a resolution of 10µl/hr. In addition, the flow rate can be viewed based over an average period (user selectable) as well as detecting peak and minimal flow rates.

From the main menu, select Manual mode. This will take you to the channel summary screen.



Use the rotary encoder to select Flow Rate and press the rotary encoder to confirm.



The Flow Test Setup screen will now be displayed.

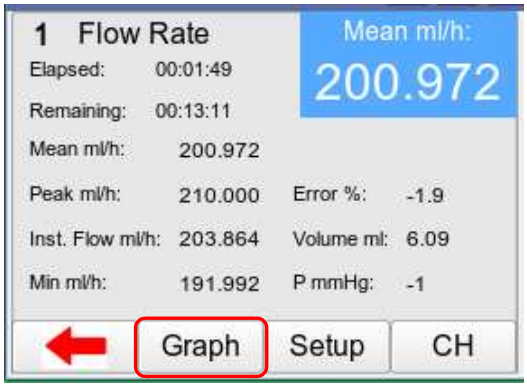
Press ☑ to save and advance to the Flow Rate test summary screen, or ← to exit without saving.

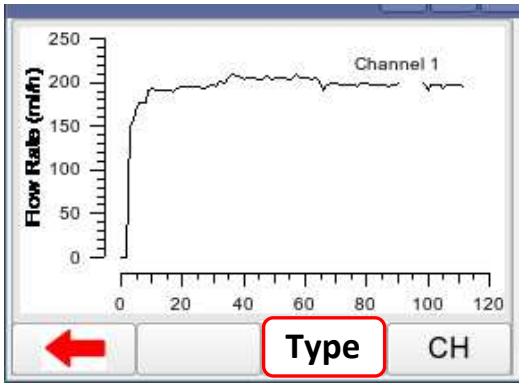
Press the green START button to begin the test.

Use the rotary encoder during the test, to change the highlighted (blue) field holding the main measurement parameter.

Safety - Press the red STOP button at any time to stop the test.

Viewing the flow graph



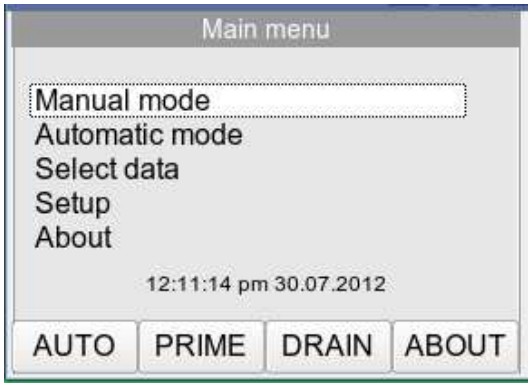


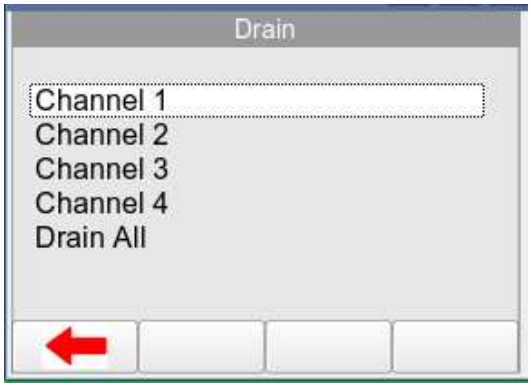
From the summary screen select Graph to view the graph of instantaneous flow rate against time.

The graph can switch between instantaneous flow and volume by pressing the TYPE button.

2.6 Draining the Channels

From the main menu, select DRAIN. This will take you to the Drain function screen.





Either select the individual channel to drain or select Drain All.

Once the fluid has been drained, press ← to stop the draining process.

⚠ Warning; Once the fluid is drained, do not leave the drain pump facility running longer than necessary.

3 Maintaining the Rigel Multi-Flo

3.1 Cleaning

Ensure that the Multi-Flo is operated with the **distilled or de-ionised water** only.

Always ensure you drain the Multi-Flo after use to avoid build-up of contamination of the internal flow channels.

Clean the external case of the Rigel Multi-Flo with a clean dry cloth.

Avoid using solvents and abrasive scouring agents to clean the external case of the Rigel Multi-Flo.

If the Multi-Flo is subject to liquid ingress in a manner other than intended, the unit should be returned for repair, stating clearly the cause for repair.

3.2 User Maintenance

The Rigel Multi-Flo is a rugged quality instrument. However, care should always be taken when using, transporting and storing this type of equipment. Failure to treat the product with care will reduce both the life of the instrument and its reliability.

Always check the Multi-Flo and all accessories for damage and signs of wear before use.

Do not attempt to open the Multi-Flo. Maintenance should only be carried out by authorised personnel.

The Multi-Flo contains no user serviceable parts.

Keep the Multi-Flo and accessories clean and dry.

The recommended calibration period for this unit is 12 months.

3.3 Return Instructions

For repair or calibration of the Multi-Flo, please contact Calibration House.

Calibration House

11 Bracken Hill

Southwest Industrial Estate

Peterlee

County Durham

SR8 2LS

United Kingdom

Tel: +44 (0) 191 587 8739

Fax: +44 (0) 191 518 4666

Email: info@calibrationhouse.com

Prior to returning your unit, please contact Calibration House to obtain a RMA.

By obtaining a RMA your service request can be booked in advance, allowing for a quicker turnaround time of your equipment.

Please have your instrument **make**, **model** and **serial number** available.

4 Accessories

4.1 Optional Accessories

The 1 and 2 channel Multi-Flo configurations are field upgradeable to a maximum of 4 channels.

- USB keyboard
- USB download lead
- Med-eBase PC download and remote control software

4.2 Replacement Spare Parts

44B122 - IEC mains lead

27B044 - Mains fuse, 20 x 5mm T3.15A 250V

5 Specifications

5.1 Technical Specifications

Flow Measurement

Test Duration: Programmable up to 24 hours for memory storage.

Display range	0.010 ml/h to 1500 ml/h
Max. display resolution	10 µl/h
Measured range	0.500 ml/h to 1450 ml/h
Accuracy	± 1% of the reading after 100µl volume at 0 mmHg backpressure applied.
Volume	0.001 ml to 9999 ml
Flow update rate	1 Hz

Occlusion / back pressure measurement

Pressure measurement range	-500 to 2500 mmHg
Back pressure setting range	-200 to 600 mmHg
Unit selection	Bar, PSI, mmHg, mmH2O
Accuracy	± 1% of the reading up to 1500 mmHg
Max. resolution	1 mmHg

PCA / Bolus measurements (Volume)

Display Range	0.1 ml to 100 ml
Measuring Range	0.5 ml to 100 ml
Accuracy	± 1% of the reading
Max. resolution	0.01 ml
Basal flow rate	1 ml to 30 ml/h
Pressure	Max. 2500 mmHg

5.2 General Specifications

Dimensions	300mm x 204mm x 150mm
Weight	5kg (1 channel)
	6kg (2 channel)
	8kg (4 channel)
Mains supply	90 - 264 VAC, 50/60 Hz, 60W
Mains cable	Standard IEC 10A connector
Storage environment	0°C to +50°C
Operating conditions	+15°C to +40°C
Environmental protection	IP40
PC Communication	USB B
Keyboard Communication	USB A
Display	LCD colour graphic display ¼" VGA

5.3 Environmental Conditions

The Rigel Multi-Flo has been designed to perform tests and measurements in a dry environment.

Maximum barometric elevation for making measurements is 2000m.

Protective system IP40 according to IEC 60529.

Electromagnetic compatibility (EMC). Interference immunity and emitted interference conforming to IEC 61326-1.

Operating temperature range of 15°C to 40°C, without moisture condensation.

The Multi-Flo can be stored at any temperature in the range 0°C to +50°C.

6 Support

6.1 Contact Us

Rigel Medical Contact details

Sales and Delivery enquiries

Tel: +44 (0) 191 587 8730

Fax: +44 (0) 191 586 0227

Email: sales@rigelmedical.com

Technical enquiries

Tel: +44 (0) 191 587 8701

Email: support@rigelmedical.com

Rigel Medical Address details

Rigel Medical

15 - 18 Bracken Hill

South West Industrial Estate

Peterlee, County Durham

SR8 2SW, United Kingdom

CalibrationHouse Contact details

Service, Calibration and Repair

Tel: +44 (0) 191 587 8739

Fax: +44 (0) 191 518 4666

Email: info@calibrationhouse.com

CalibrationHouse Address details

CalibrationHouse

11 Bracken Hill

South West Industrial Estate

Peterlee, County Durham

SR8 2SW, United Kingdom

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