



RIGEL MEDICAL
TESTED, TRUSTED... WORLDWIDE.

Multi-Flo USER MANUAL



Administration sets which may have been used with saline solution or dextrose should not be used with the Multi-Flo unless thoroughly cleaned beforehand



The following test fluids are for use with the Multi-Flo

- Deionised water
- Distilled water
- Deionised/distilled water with approximately 0.1% Micro-90

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.

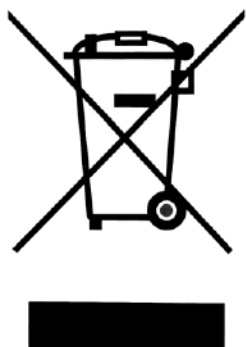
Calibration Statement

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 is 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 into service.

Date received into service; ____ / ____ / ____.

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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.

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.

Environmental Conditions

The Multi-Flo has been designed to be operated for indoor use in a dry environment, at a temperature of 0 to 40 degrees C without moisture condensation, and at an operating altitude 0 – 2000 m.

The Multi-Flo has a protection rating of IP40 and is rated for operation at pollution degree 2 according to IEC 60529.

The following symbols are used in these operating instructions and on the Rigel Multi-Flo

User Notes

These operating instructions are intended for the use of adequately trained personnel.



Ensure that the Multi-Flo is operated with distilled, deionised water or deionised/distilled water with approximately 0.1% Micro-90 cleaning solution.



Do not use saline or dextrose solution as a test fluid



If the Multi-Flo is used with distilled or deionised water without Micro-90 additive, some contamination of the fluid path may occur over time. To maintain optimum measurement performance, the cleaning procedure in Appendix A should be performed after prolonged storage, 3 months of normal use or immediately after accidental contamination with unauthorised test fluids.



Administration sets which may have been used with saline solution or dextrose should not be used with the Multi-Flo unless thoroughly cleaned beforehand.



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



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



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.



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



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



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 visible signs of damage or
- the instrument does not function or
- after extended periods of storage under adverse environmental conditions.

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1. Introduction

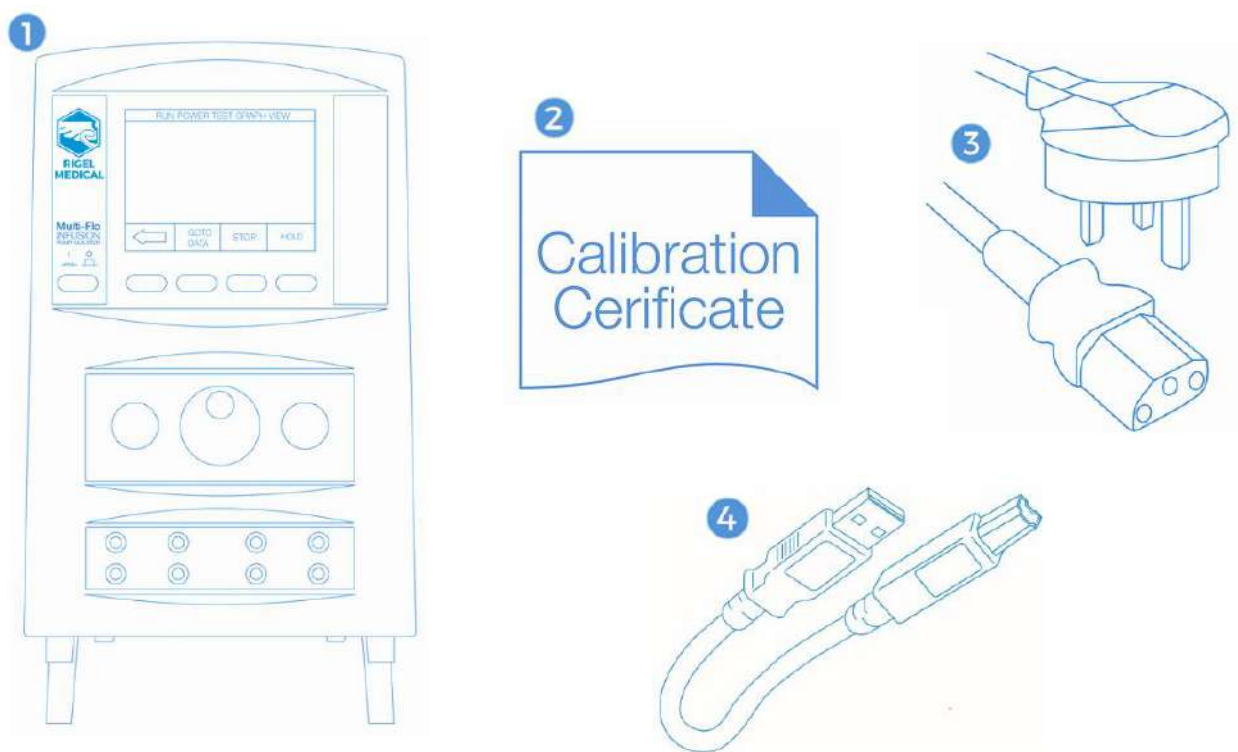
1.1 Rigel Multi-Flo Design Philosophy

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.

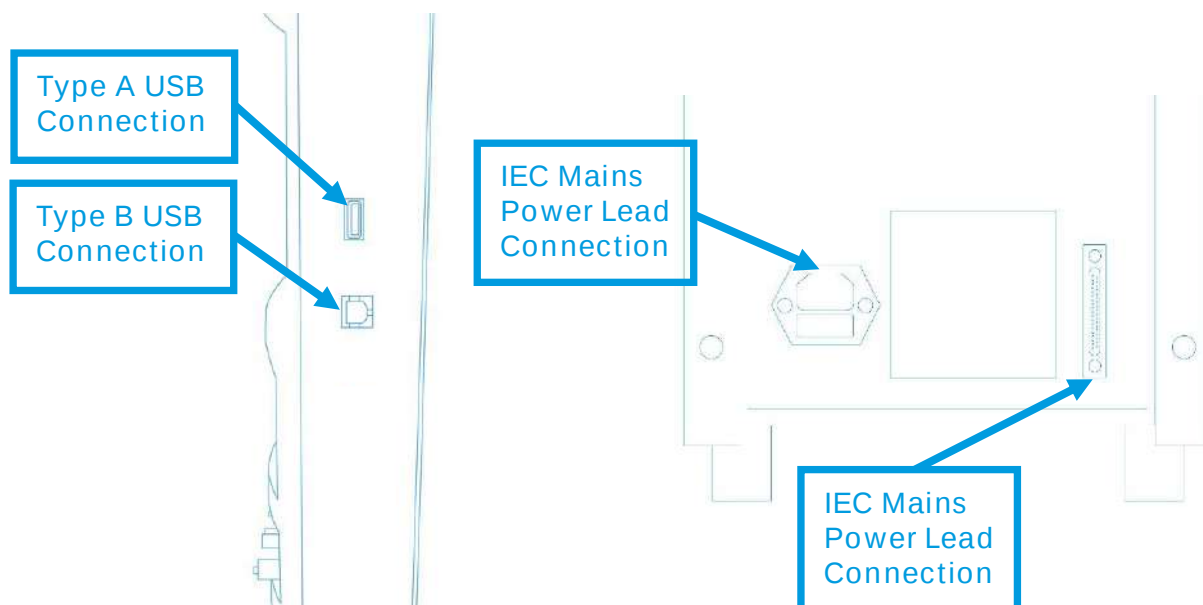
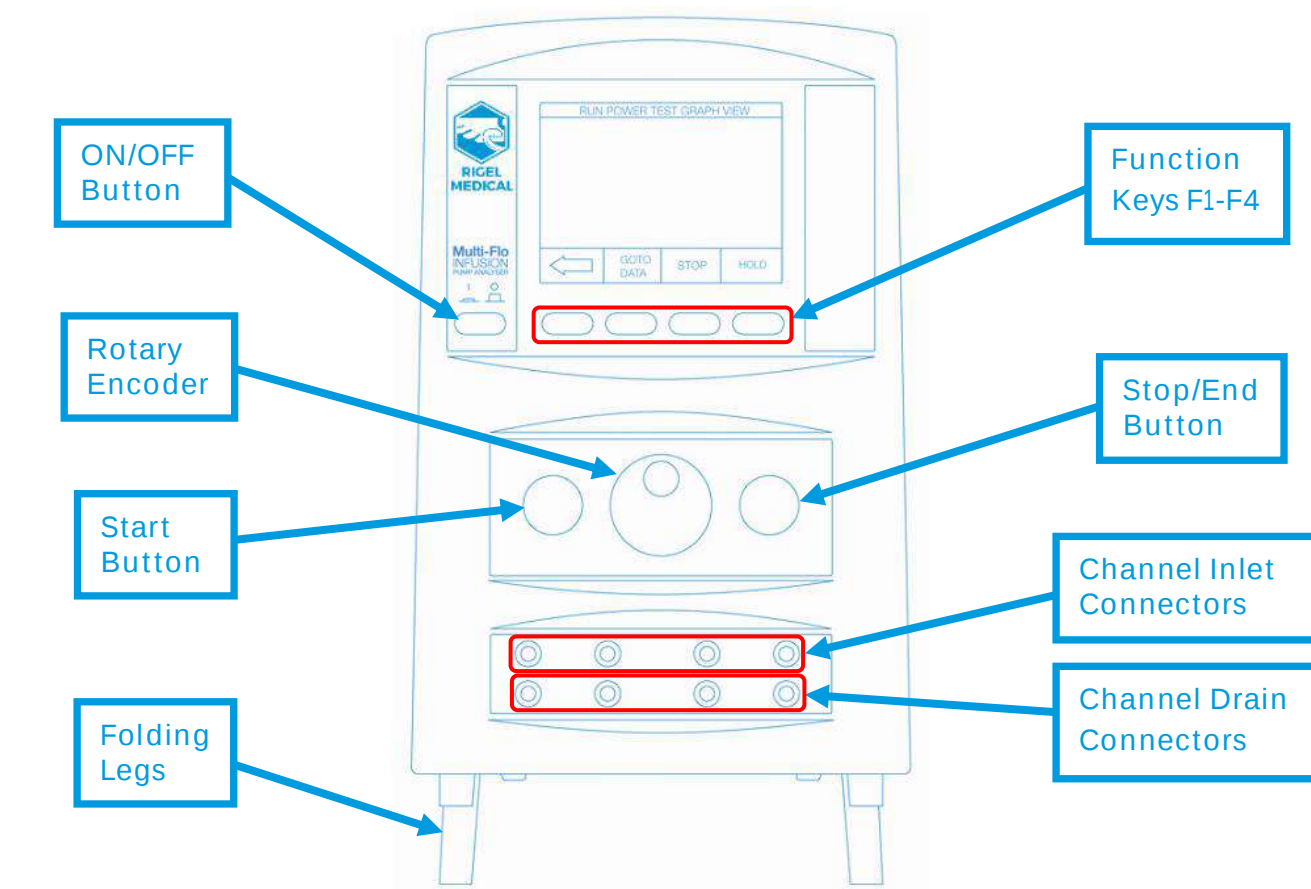
Measuring flow rates, volume and pressure, the Multi-Flo is available in 1, 2 and 4 channel configuration which can be upgraded in the future to include additional channels up to a maximum of 4 channels. The Multi-Flo will ensure it meets your current and future requirements.

1.2. Rigel Multi-Flo Includes:



1. Rigel Multi-Flo
2. Calibration Certificate
3. Mains Power Lead
4. USB Lead

1.3. Interfaces



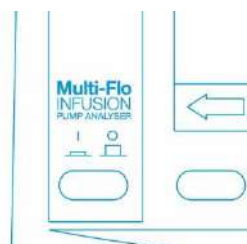
1.4. Before you switch on!

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.



Please follow the guidance in Appendix A. The Multi-Flo is a precision instrument that must be properly maintained to achieve optimum measurement performance.

1.5. Turning the Multi-Flo On and Off

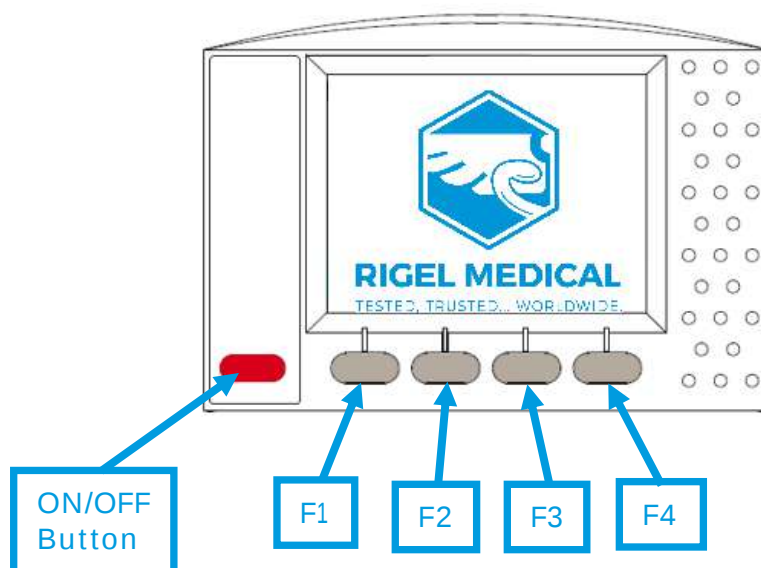


To turn the Multi-Flo ON, press the orange I/O key so it is in the in position.

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

1.6. Home screen

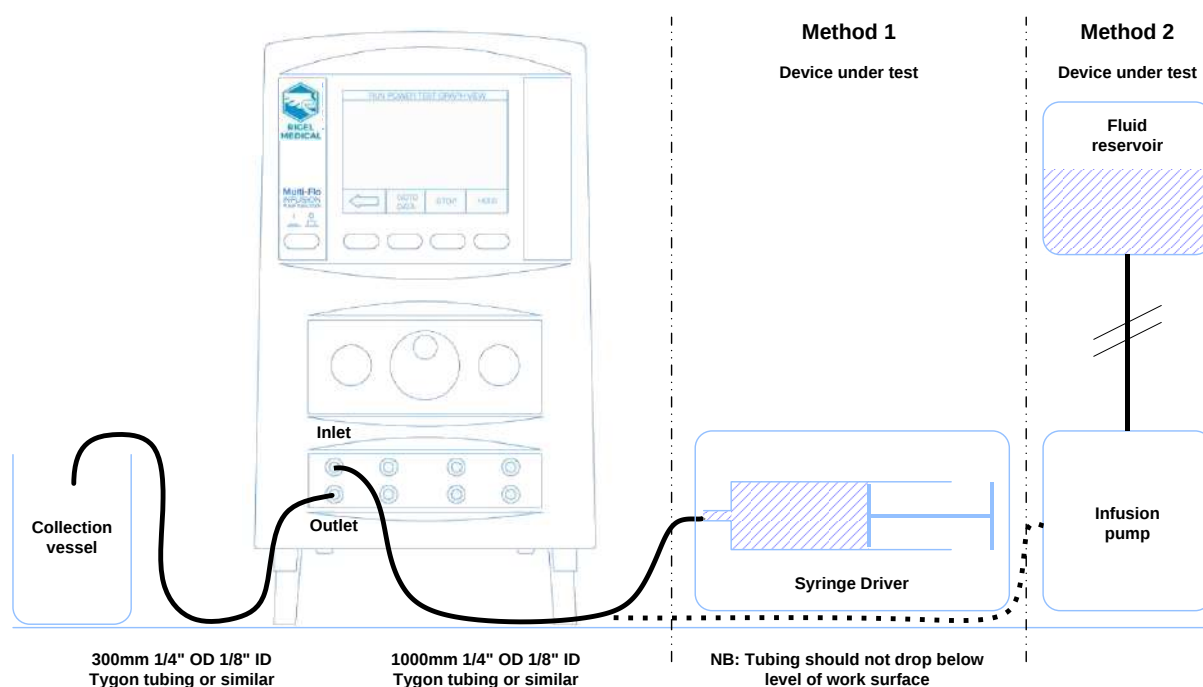
Upon power up of the Rigel Multi-Flo, the display will be showing the HOME SCREEN.



1.7. Connecting to your Multi-Flo Analyser

The Rigel Multi-Flo is a high precision instrument that can provide real-time and high accurate flow measurements subject to following the procedures advised below;" To obtain the highest level of accuracy, we calibrate our Multi-Flo infusion pump analysers using the following practices and procedures;

1. Ensure that the measurements done by the Rigel Multi-Flo are done using distilled or de-ionised water only.
2. To prevent the formation of microscopic air bubbles in the pump chamber, keep the Multi-Flo unit primed unless draining is absolutely necessary.
3. If the Multi-Flo has been drained, to clear any microscopic air bubbles in the pump and pipework that could affect results, prime with 25ml Isopropyl Alcohol, followed by 50 ml deionised water to flush the alcohol from the system.
4. Due to fluid dynamics the inlet and outlet pipe length, diameter and material can affect the results. For best results, avoid any in-line valves or other constrictions and use 1000mm of 1/4" OD/ 1/8" ID tubing on the inlet and 300mm on the outlet. Semi-flexible tubing, such as Tygon, will provide the best results. See setup diagram below;



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.



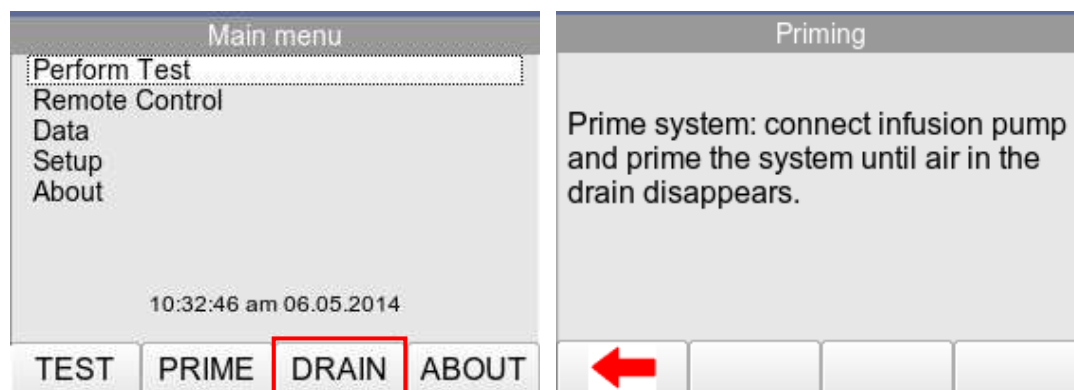
Ensure that the internal diameter of the outlet tubing is 3.2mm or greater.



Ensure that the length of outlet tubing is kept as short as reasonably practicable.

1.8. Priming the Channels

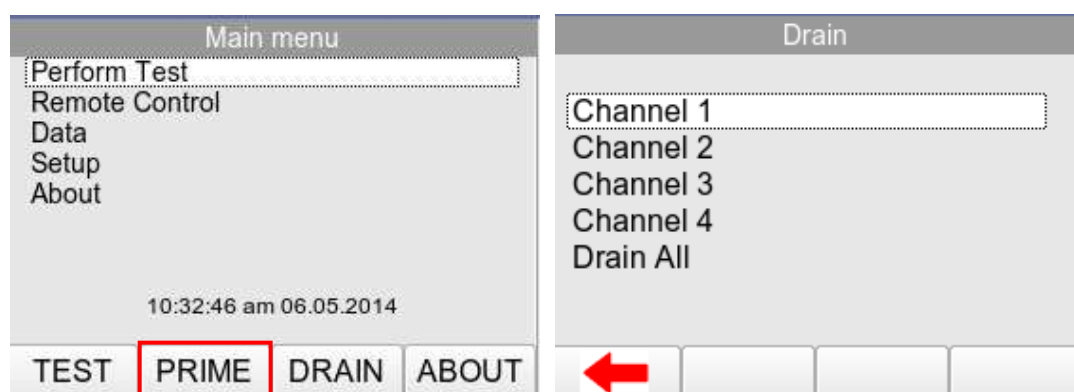
Upon power-up the Multi-Flo is in automatic priming mode however, should priming be required at any stage, select PRIME F2 from the Main Menu;



Prime the system until the drain tubing is clear of air bubbles. Press  to return to the Main Menu.

1.9. Draining the Channels

From the Main Menu, select DRAIN F3. This will take you to the Drain function screen.



Either select the individual channel to drain or select Drain All using the rotary encoder.



Once the fluid has been drained, press  F1 to stop the draining process and return to the Main Menu.



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

2. Manual Mode

To access tests in Manual Mode select TEST F1 from the Main Menu. Highlight the required channel and then select MANUAL F4. Here you can access the Test Setup Menu for each individual channel. (chapters 2.1, 2.2 and 2.3 will go through each individual test in more detail)

Main menu

Perform Test
Remote Control
Data
Setup
About

10:32:46 am 06.05.2014

TEST PRIME DRAIN ABOUT

Summary

CH	Type	Volume	Pressure	Flow	Duration
1	Flow Manual	0.000	2.00	0.00	Ready
2	Flow Manual	0.000	-2.00	0.00	Ready
3	Flow Manual	0.000	0.00	0.00	Ready
4	Flow Manual	0.000	-1.00	0.00	Ready

← SAVE AUTO **MANUAL**

Highlight TEST TYPE and push the rotary encoder to select. This will allow you to toggle between Flow / Volume Test, Occlusion Test and PCA Test.

Flow Test Setup

Selected Channel: 1

Test type: **Flow / Volume test**

Back pressure: 0 mmHg

Sampling window: 30 sec

Duration: 0hr 15min 0sec

Limit Type: Instant Flow

Limit: 0.00 Upper: 0 % Lower: 0 %

← [] [] [] []

PCA Setup

Selected Channel: 1

Test type: **PCA test**

Basal Flow Rate: 10.00 ml/h

Duration: 0hr 15min 0sec

Bolus Volume Limit: 0.0 ml

Upper: 0 %

Lower: 0 %

← [] [] [] []

Occlusion Setup

Selected Channel: 1

Test type: **Occlusion test**

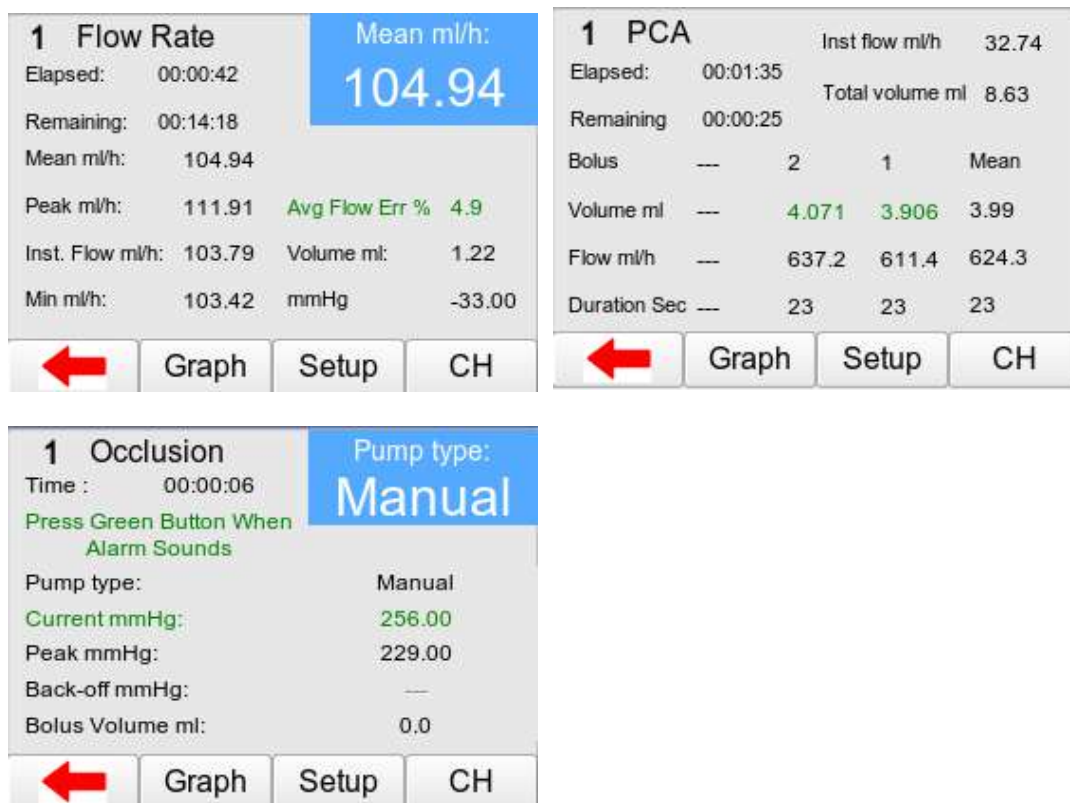
Infusion pump type: Manual

Upper Pressure Limit: 474 mmHg

Lower Pressure Limit: 10 mmHg

← [] [] [] []

Once the test is set up press  to advance to the test screen for the test selected or  to exit without saving and go back to the test summary screen.



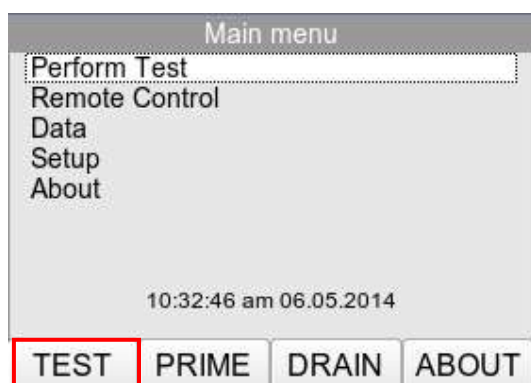
Once a test has finished the ELAPSED time will indicate COMPLETED in blue. Press F1 to go back to the Test Summary screen where the final results and time should be indicated, and Duration set to READY in black for the next test.

2.1. Flow Rate / Volume Test

The Rigel Multi-Flo can measure 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 TEST F1. This will take you to the Test Summary Screen for all individual channels.

Active channels will indicate READY under the Duration column and inactive channels indicate N/A in the Type column.



Highlight the required channel using the rotary encoder and select either MANUAL F4 to enter the manual test setup menu or AUTO F3 to select auto mode to save results in the database.

Summary					
CH	Type	Volume	Pressure	Flow	Duration
1	Flow Manual	0.000	2.00	0.00	Ready
2	Flow Manual	0.000	-2.00	0.00	Ready
3	Flow Manual	0.000	0.00	0.00	Ready
4	Flow Manual	0.000	-1.00	0.00	Ready
					

Once in the Test Setup screen Highlight TEST TYPE and press the rotary encoder to confirm. Using the rotary encoder select FLOW/VOLUME and press to confirm. This will take you to the Flow/Volume Test Setup screen.

Flow Test Setup			
Selected Channel:	1		
Test type:	Flow / Volume test		
Back pressure:	0 mmHg		
Sampling window:	30 sec		
Duration:	0hr	15min	0sec
Limit Type:	Instant Flow		
Limit:	0.00	Upper: 0 %	Lower: 0 %
			

Use the rotary encoder to determine the:

- Back Pressure
- Sampling Window
- Duration
- Error Type (instant flow, average flow or expected volume)
- Upper and Lower Limits

Press the rotary encoder to select the field and then move the encoder to increase or decrease the value required and then press the encoder again to confirm the selection. A USB keyboard can also be used to enter values.

Note: To change the pressure unit measurement please refer to Chapter 0

Note: Upper and lower limits will appear in the graph view provided the limits are greater than 0 or 0%.

Once the test has been setup successfully press  F4 to save and advance to the Flow/Volume Test screen, or  to exit back to the Summary Test screen.



Setup your infusion device to the same settings as entered into the Multi-Flo and start the infusion. Press the green START button on the Multi-Flo to begin the test.

During the Flow/Volume Test

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

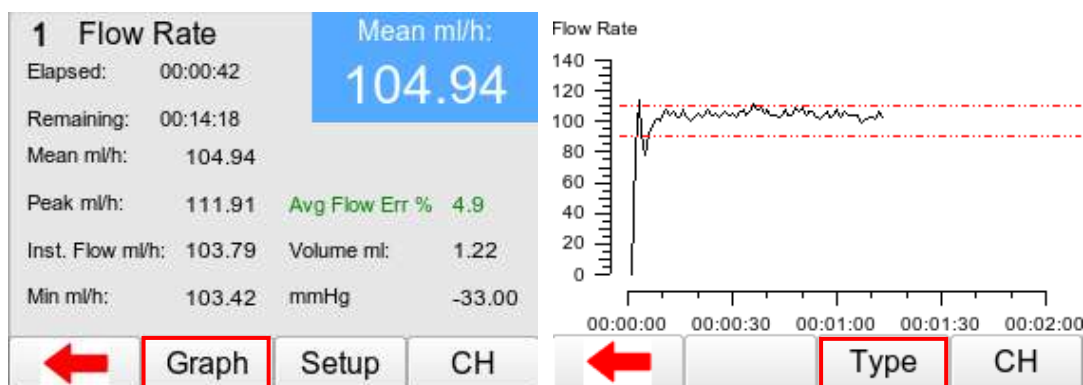
- Mean ml/h
- Peak ml/h
- Error (Instant Flow, Average Flow or Expected Volume)
- Instant Flow ml/h
- Volume ml
- Min ml/h
- Pressure (default mmHg)

Select GRAPH F2 to view the available graphs for this test, SETUP F3 enables the user to see the original Test settings and CH F4 switches between channels which can be run simultaneously.



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

Viewing the Flow Graph



During the flow/volume test select GRAPH F2 to view the graph of the real time results. The red lines depict the set minimum and maximum limits.

The graph can switch between flow and volume against time by pressing the TYPE F3 button.

Pressing CH F4 enables the user to switch between channels which are running simultaneously.



The GREEN and RED buttons on the Multi-Flo are inactive when on the Graph screen.

2.2. Occlusion Test

The Occlusion test simulates an obstruction in the infusion process. Most infusion devices can detect this obstruction and provide an occlusion alarm. The occlusion test can test this alarm feature in infusion devices.

From the Main Menu, select TEST F1. This will take you to the Test Summary Screen for all individual channels.

Main menu		Summary					
Perform Test		CH	Type	Volume	Pressure	Flow	Duration
Remote Control		1	Occ	0.000	-14.00	0.00	Ready
Data			Manual				
Setup		2	Flow	0.000	1.00	0.00	Ready
About			Manual				
10:32:46 am 06.05.2014		3	Flow	0.000	1.00	0.00	Ready
			Manual				
		4	Flow	0.000	0.00	0.00	Ready
			Manual				
TEST PRIME DRAIN ABOUT		← SAVE AUTO MANUAL					

Highlight the required channel using the rotary encoder and select either MANUAL F4 to enter the Manual test setup screen or AUTO F3 to select auto mode to save results in the database.

Once in the Test Setup highlight TEST TYPE and press the rotary encoder to confirm. Using the rotary encoder select OCCLUSION and press to enter. This will take you to the Occlusion Setup screen.

Occlusion Setup				Occlusion Setup			
Selected Channel:		1		Selected Channel:		1	
Test type:		Occlusion test		Test type:		Occlusion test	
Infusion pump type:		Manual		Infusion pump type:		Auto Reverse	
Upper Pressure Limit:		600 mmHg		Upper Pressure Limit:		600 mmHg	
Lower Pressure Limit:		100 mmHg		Lower Pressure Limit:		100 mmHg	
←		✓		←		✓	

Use the rotary encoder to determine the:

- Infusion Pump Type
- Upper Pressure Limit
- Lower Pressure Limit

Press the rotary encoder to select the field and then move the encoder to increase or decrease the value required and then press the encoder again to confirm the selection. A USB keyboard can also be used to enter values.

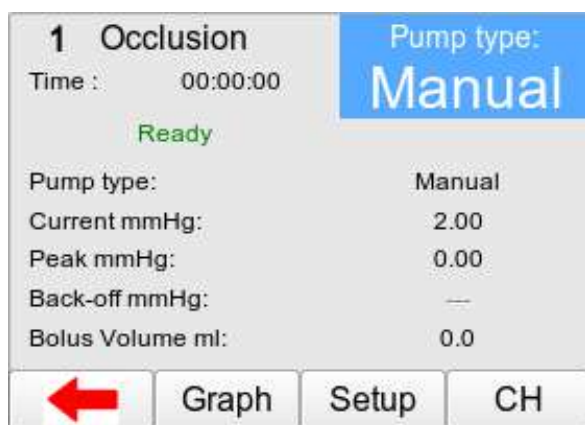
Note: To change the pressure unit measurement please refer to Chapter 7.4.

Infusion Pump Type

The MANUAL setting refers to an infusion device that does not provide for an automatic back-off of pressure. As such, the green START button on the Multi-Flo, must be pressed as soon as the occlusion alarm sound to record the occlusion.

The AUTO REVERSE setting refers to infusion devices that provide an automatic pressure back-off function. The Multi-Flo will detect the occlusion alarm when the line pressure decreases after alarm and no user action is required.

Press  to save and advance to the Occlusion test summary screen, or  to exit back to the Test Summary screen.



The screenshot shows the '1 Occlusion' screen. At the top left, it says 'Time : 00:00:00' and 'Ready' in green. On the top right, a blue box highlights 'Pump type: Manual'. Below this, a table lists parameters: 'Pump type: Manual', 'Current mmHg: 2.00', 'Peak mmHg: 0.00', 'Back-off mmHg: —', and 'Bolus Volume ml: 0.0'. At the bottom, there are four buttons: a red arrow pointing left, 'Graph', 'Setup', and 'CH'.

Parameter	Value
Pump type:	Manual
Current mmHg:	2.00
Peak mmHg:	0.00
Back-off mmHg:	—
Bolus Volume ml:	0.0

Press the green START button on the Multi-Flo to begin the test.

During the Occlusion Test

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

- Pump Type
- Current m mHg
- Peak m mHg
- Back-off m mHg
- Bolus Volume

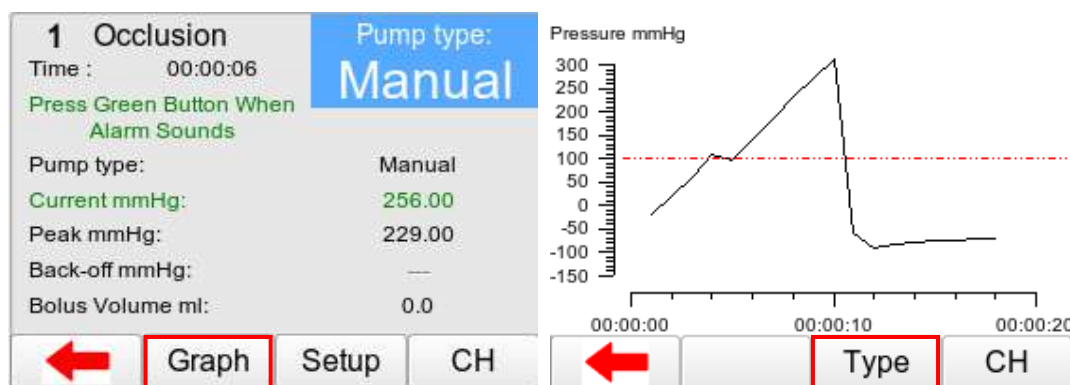
Note: The default pressure measurement is mmHg. Please refer to section 7.4. on how to change pressure units. The bolus volume is the extra volume delivery once the Multi-Flo has released the occlusion.

Select GRAPH F2 to view the available graphs for this test, SETUP F3 enables the user to see the original Test settings and CH F4 switches between channels which can be run simultaneously.



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

Viewing the Occlusion Graph



During the Occlusion test select GRAPH F2 to view the graph of pressure against time.

Pressing CH F4 enables the user to switch between channels which are running simultaneously.



The GREEN and RED buttons on the Multi-Flo are inactive when on the Graph screen.

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 TEST F1. This will take you to the Test summary screen for all individual channels.

The screenshot shows two screens from a device. The left screen is the 'Main menu' with options: Perform Test (highlighted), Remote Control, Data, Setup, and About. The time and date '10:32:46 am 06.05.2014' are displayed at the bottom. The right screen is the 'Summary' screen, which is a table with columns: CH, Type, Volume, Pressure, Flow, and Duration. It lists four entries, all with 'Flow Manual' type and 'Ready' status. At the bottom of the right screen, there are buttons: TEST, PRIME, DRAIN, and ABOUT on the left; a red arrow pointing left, SAVE, AUTO, and MANUAL on the right.

CH	Type	Volume	Pressure	Flow	Duration
1	PCA Manual	0.000	-14.00	0.00	Ready
2	Flow Manual	0.000	1.00	0.00	Ready
3	Flow Manual	0.000	1.00	0.00	Ready
4	Flow Manual	0.000	0.00	0.00	Ready

Highlight the required channel using the rotary encoder and select either MANUAL F4 to enter the Manual test setup screen or AUTO F3 to select auto mode to save results in the database.

Once in the Test Setup highlight TEST TYPE and press the rotary encoder to confirm. Using the rotary encoder select PCA Test and press to confirm. This will take you to the PCA Setup screen

PCA Setup

Selected Channel: 1

Test type: PCA test

Basal Flow Rate: 10.00 ml/h

Duration: 0hr 15min 0sec

Bolus Volume Limit: 0.0 ml

Upper: 0 %

Lower: 0 %

Navigation icons: Back (red arrow), Home (house icon), Stop (stop icon), Confirm (green checkmark).

Use the rotary encoder to determine the Infusion the:

- Basal Flow Rate
- Test Duration
- Bolus Volume Limit
- Total Volume
- Upper and Lower Limits

Press the rotary encoder to select the field and then move the encoder to increase/decrease the value required and then press the encoder again to confirm the selection. A USB keyboard can also be used to enter values.

Note: The basal flow rate setting is used to determine the additional volume being delivered i.e. the BOLUS. Therefore, an incorrect setting of the basal flow rate will lead to an inaccurate BOLUS detection. The minimum bolus limit is the expected volume for each bolus delivered.

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

1 PCA				
Elapsed:	Ready		Inst flow ml/h	0.000
Remaining	00:15:00		Total volume ml	0.00
Bolus	---	---	---	Mean
Volume ml	---	---	---	0.00
Flow ml/h	---	---	---	0.000
Duration Sec	---	---	---	0


Graph
Setup
CH

Set up your infusion device to the same settings as entered into the Multi-Flo and start the infusion.

Press the GREEN START button on the Multi-Flo to begin the test.

During the PCA Test

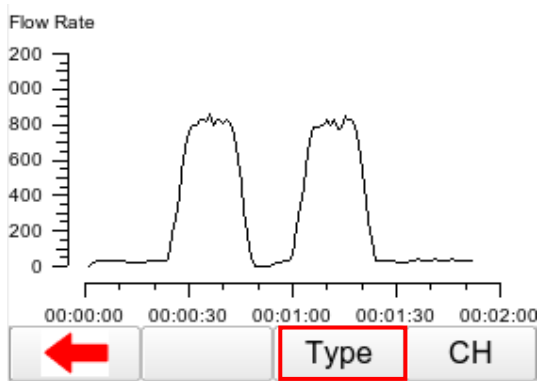
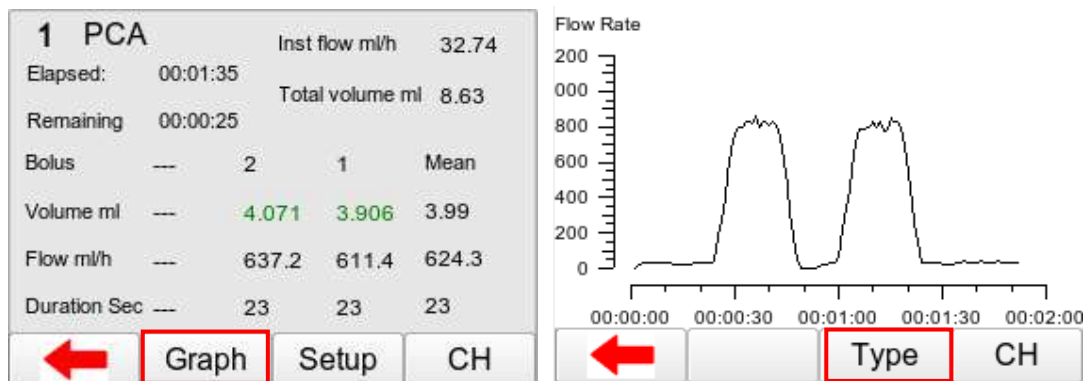
Select the bolus button on the infusion device to administer boluses during testing. Each individual bolus will be recorded to indicate the volume ml, flow ml/h and duration. There is also a mean to show the average of all boluses delivered.



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

Select GRAPH F2 to view the available graphs for this test, SETUP F3 enables the user to see the original Test settings and CH F4 switches between channels which can be run simultaneously.

Viewing the PCA Graph



During the PCA test select GRAPH F2 to view the graph of the real time results.

The graph can switch between flow and volume against time by pressing the TYPE F3 button.

Pressing CH F4 enables the user to switch between channels which can run simultaneously.



The GREEN and RED buttons on the Multi-Flo are inactive when on the Graph screen.

2.4. Saving Manual Results

Once a test has completed press  F1 to go back to the Test Summary screen where the final results and time should be indicated and Duration set to READY in black for the next test.

Summary					
CH	Type	Volume	Pressure	Flow	Duration
0	Occ Manual	0.000	-14.00	0.00	Ready
2	Flow Manual	0.000	1.00	0.00	Ready
3	Flow Manual	0.000	1.00	0.00	Ready
4	Flow Manual	0.000	0.00	0.00	Ready

Navigation buttons:  **SAVE** (highlighted with a red box) AUTO MANUAL

Manual Asset Details	
Channel:	1
Asset ID:	
Make:	
Model:	
Serial Number:	
Status:	Pass 

Navigation buttons:  

Highlight the required channel and then select SAVE F2 to save the manual test results. Parameters and asset details can then be added to the results:

- Asset ID
- Make
- Model
- Serial Number
- Status

Select  F4 to save the results under the inserted asset details. A dialog box will appear to confirm the results have saved. Select OK using the rotary encoder to go back to the Test Summary screen.

Manual Asset Details	
Channel:	1
Asset ID:	31425
Make:	
Model:	
Serial Number:	43567
Status:	Pass 

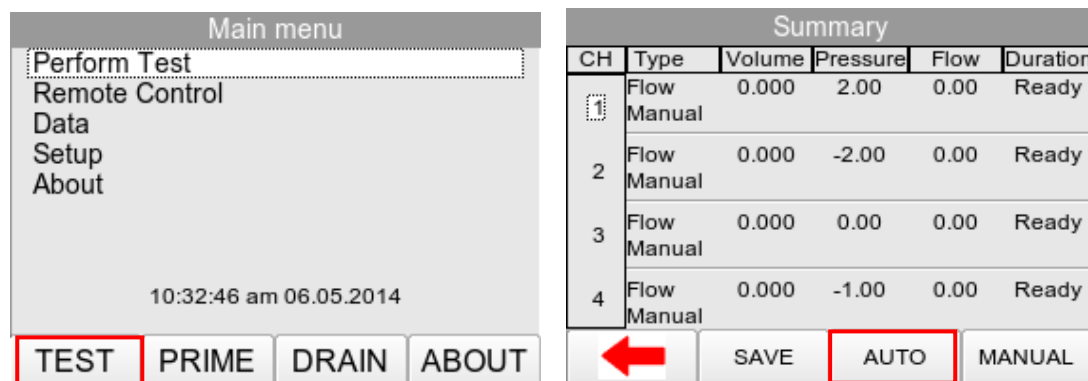
Navigation buttons:  

Manual Asset Details	
Save Asset  Asset Saved Successfully Ok	
Channel:	1
Asset ID:	31425
Make:	
Model:	
Serial Number:	43567
Status:	Pass 

Navigation buttons:  

3. Auto Mode

The automatic mode allows the user to select a test sequence which will carry out a pre-determined set of tests against user definable limits. Test results are stored at the end of the test for future reference. To view or transfer stored data, please refer to Chapter 5 Data.



To enter the automatic mode, select TEST F1 from the Main Menu and then AUTOMODE F3 to enter the ASSET DETAILS Menu.

In the following screen, an asset ID number can be entered using the rotary encoder, barcode scanner or a USB keyboard. Enter data with the rotary encoder (push to select character) or keyboard (note that the enter key is not required).

Asset Details

Channel: 1

Asset ID: 120

Protocol: Sequence_1

Make: Infusion device

Model:

Serial Number: 12345

← [] [] [] [] ✓

When using the barcode scanner, ensure the barcode scanner is paired with the Rigel Multi-Flo, see Chapter 6. When the barcode is ready to scan, the word "OK" will appear in the asset ID field.

Note: The Rigel Multi-Flo will only support the Seaward barcode scanner, Part Number 339A923.

Use the rotary encoder to then highlight PROTOCOL to scroll through the available Test Sequences and push to make a selection. For more on creating Test sequences see Chapter 3.2.

The make, model and serial number of the infusion device being tested can also be entered into the Asset Details screen prior to starting the test sequence.

From the Asset Details screen, press  F4 to confirm the entered details and move to the first test within the sequence.

The following procedure describes the setup and completion of an automatic test sequence. In the example below, Sequence1 will be used which was created in Chapter 3.2. The first test in Sequence 1 is the Flow Test.

1 Flow Rate		Mean ml/h:	
Elapsed:	00:00:42	104.94	
Remaining:	00:14:18		
Mean ml/h:	104.94		
Peak ml/h:	111.91	Avg Flow Err %	4.9
Inst. Flow ml/h:	103.79	Volume ml:	1.22
Min ml/h:	103.42	mmHg	-33.00
		Graph	Setup
		CH	

Once the test has successfully completed the test should indicate COMPLETED in blue and then move onto a custom test to instruct the user to change the flow rate.

1 Flow Rate		Mean ml/h:	
Elapsed:	Completed	102.14	
Remaining:	00:01:00		
Mean ml/h:	102.14		
Peak ml/h:	106.79	Avg Flow Err %	2.1
Inst. Flow ml/h:	103.54	Volume ml:	1.70
Min ml/h:	97.12	mmHg	18.00
		Graph	Setup
		CH	

User Test Settings	
change flow rate to 50ml/h	
Unit:	
	

For the User test, either press PASS F4 or the GREEN button to continue, or the RED button to indicate that the user test could not be completed. If it is not completed the Failure menu would appear, see Chapter 3.1 for more details.

This is followed by another flow test at the new flow rate specified in the User Test.

1 Flow Rate		Mean ml/h:	
Elapsed:	00:00:19	47.84	
Remaining:	00:01:41		
Mean ml/h:	47.84		
Peak ml/h:	---	Avg Flow Err %	-4.3
Inst. Flow ml/h:	47.84	Volume ml:	0.252
Min ml/h:	---	mmHg	2.00
		Graph	Setup
		CH	

The next step in Sequence 1 is the PCA Test;

1 PCA				
Inst flow ml/h	32.74			
Elapsed: 00:01:35	Total volume ml 8.63			
Remaining 00:00:25				
Bolus	---	2	1	Mean
Volume ml	---	4.071	3.906	3.99
Flow ml/h	---	637.2	611.4	624.3
Duration Sec	---	23	23	23
 Graph Setup CH				

During the PCA test the user will need to press the bolus button on the infusion device to deliver boluses to meet the settings of the PCA Test. Once the PCA Test has completed the test will indicate COMPLETED in blue. This test is then followed by an Occlusion test.

1 Occlusion		Pump type: Manual	
Time :	00:00:06	Manual	
Press Green Button When Alarm Sounds			
Pump type:	Manual		
Current mmHg:	256.00		
Peak mmHg:	229.00		
Back-off mmHg:	---		
Bolus Volume ml:	0.0		
	Graph	Setup	CH

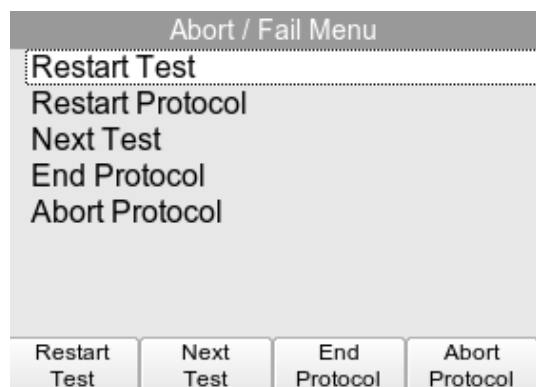
For manual occlusion ONLY the user must press the GREEN button to register the occlusion alarm of the infusion device. Once the Occlusion test has successfully finished COMPLETED will be indicated in Blue and the Multi-Flo will go to the Summary Test screen indicating COMPLETED and SAVING in green to indicate the end of the sequence. The channel then indicated READY in black to start another test.

Summary					
CH	Type	Volume	Pressure	Flow	Duration
0	Flow Manual	0.000	2.00	0.00	Ready
2	Flow Manual	0.000	-2.00	0.00	Ready
3	Flow Manual	0.000	0.00	0.00	Ready
4	Flow Manual	0.000	-1.00	0.00	Ready
 SAVE AUTO MANUAL					

3.1. Abort/Failure Menu

During the test, the sequence can be interrupted or cancelled. Press the red button on the front panel.

When a specific test fails, the user will also be provided with several options depending on the nature of the fault. The Failure Menu will enable the user to:

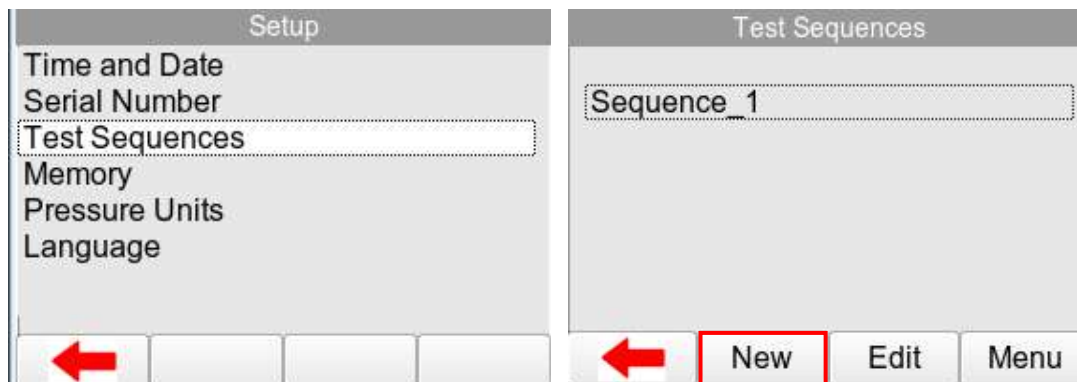


- Restart Test will continue the test sequence from where it was interrupted by restarting the failed test.
- Restart Test Sequence will start the sequence from the beginning.
- Next Test will skip the current test and move to the next test (note that a no results will be reported for the skipped test).
- End Test Sequence will stop the test sequence and store the results (fail).
- Abort Test Sequence will stop the test sequence. No data is stored. Multi-Flo will go back to summary screen.

3.2. Test Sequences

3.2.1. Create a Test Sequence

Select Test Sequences from the SETUP menu;



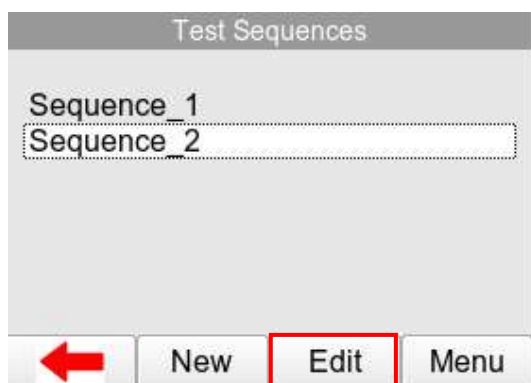
Select NEW F2 to open a new test sequence and enter a name, use the rotary encoder or USB keyboard to enter data. For the example Sequence 1 will be created.

Select KEYBOARD to change the format from QWERTY to ABCD style;

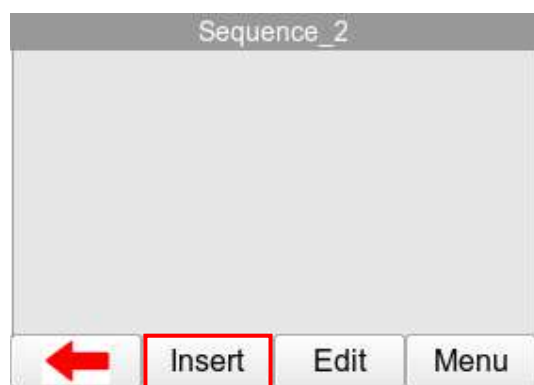


Press the GREEN button to confirm or RED button to cancel.

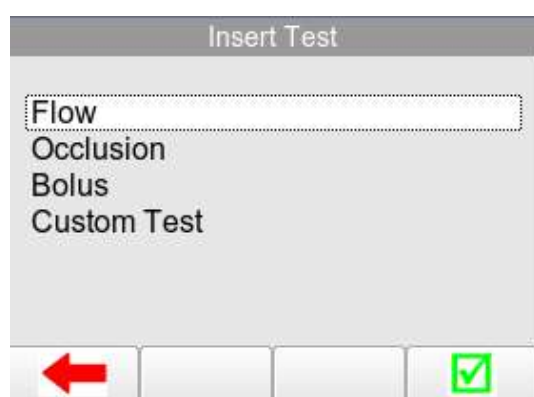
The new sequence name should now appear in the Test Sequence Menu.



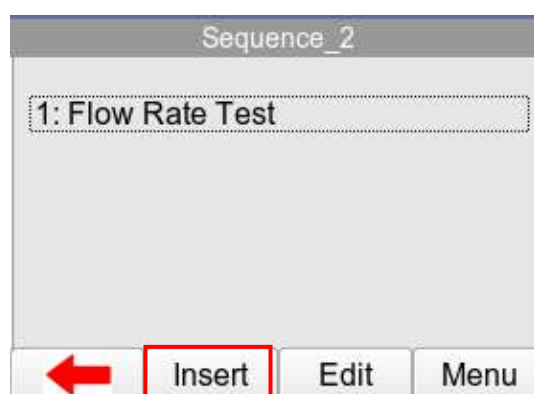
Press the EDIT F3 button to open the new test sequence for editing;



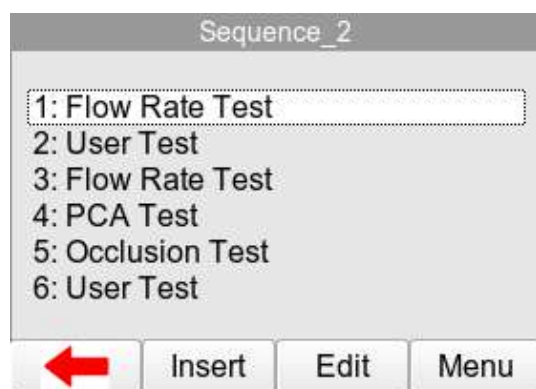
The newly created Test Name now appears in the Test Sequence menu and can be modified to include the required individual tests. Press the INSERT F2 button to open the sequence for editing and start adding individual tests to the test sequence by pressing the button.



Highlighted the required test (in this example FLOW) using the rotary encoder and press to select or  F4 to add test to sequence.

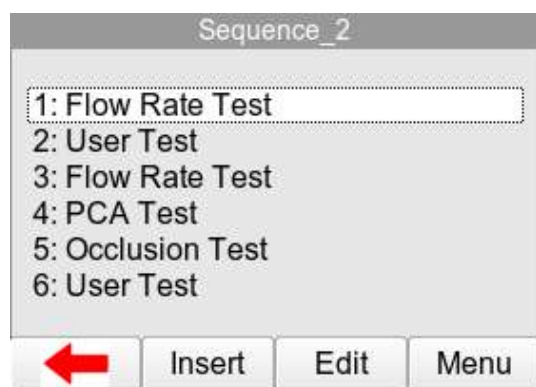


Repeat the above steps until the required test sequence is completed. Additional tests can be inserted in the test sequence by highlighting the position in the sequence and press the ADD F2 button. The test will be inserted AFTER the highlighted position.

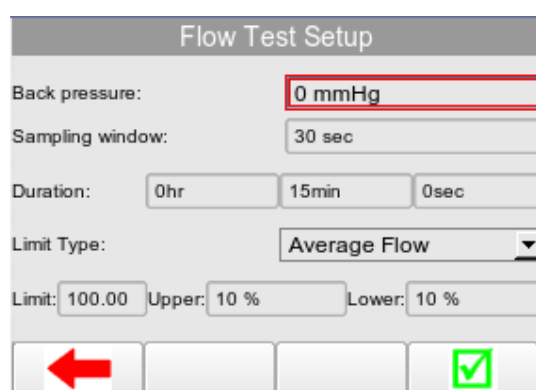


Edit an Individual Test

The individual tests can now be edited / configured to the specific requirements. Once an individual test has been configured, they can be copied and pasted repeatedly by selecting the OPTIONS button.



Edit individual tests by selecting the required test and press EDIT F2 on the Edit Test Sequence Menu.



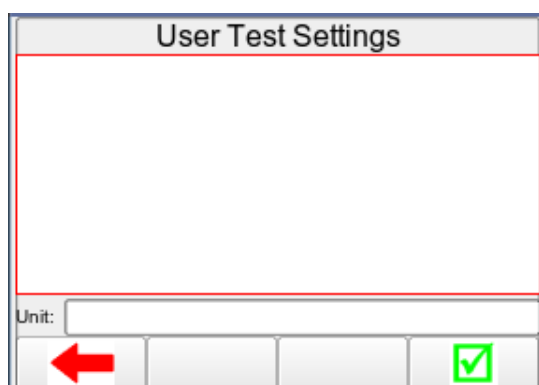
Once the selected criteria have been set, confirm by pressing  F4.

Note: To change the pressure unit measurement please refer to Chapter 0.

Insert a User Test

User tests can be inserted and used for providing instructions to the test engineer. Select the user test and press EDIT.

In the user test screen, select the main field highlighted with a red border in below image. Press the rotary encoder to open the field for editing.



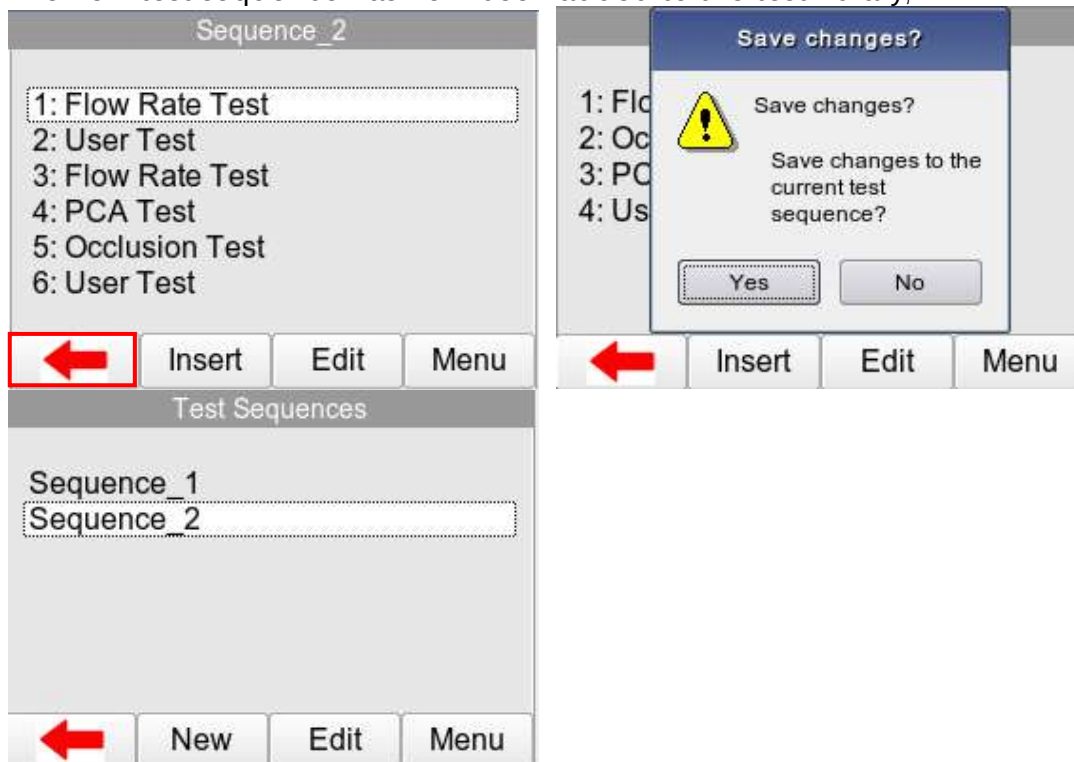
In case the user test requires data entry such as a result, the user test can also include an engineer unit such as Ohms, Watts, and Celsius etc. Confirm the entry by pressing the confirm by pressing  F4.



Save a Test Sequence

Once the test sequence is completed, press  F1 from the edit test sequence menu and confirm the changes by pressing the rotary encoder when the save changes dialog box appears

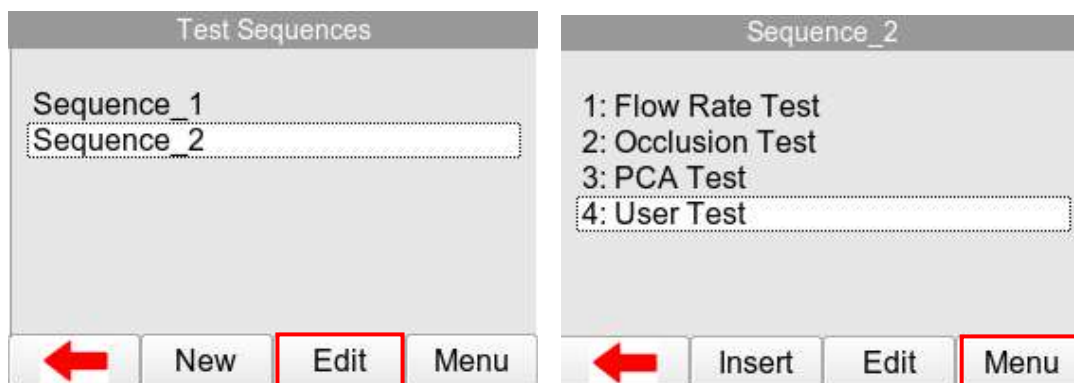
The new test sequence has now been added to the test library;



3.2.2. View, Copy, Deleted and Rename Sequence

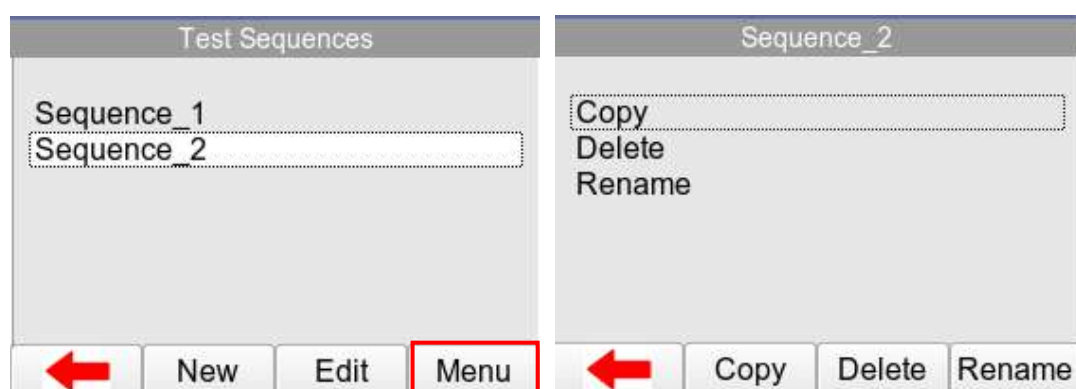
Users can view rename sequences, copy, or delete test sequences.

From the Test Sequences menu, highlight the sequence required and select EDIT F3. From within the sequence the user can view the sequence and then select Edit F3 to edit or Menu F4 to copy or delete the individual test.





To copy, rename or delete a Test Sequence; from the Test Sequences menu, highlight the sequence required using the rotary encoder and select MENU F4.



- To copy a test sequence, press COPY F2
- To delete a test sequence, press DELETE F3
- To rename a test sequence, RENAME F4

Copied Test Sequences will appear in the list with an N where N is a number depending on the quantity of sequences with the same name (starting from 2). All Copied test Sequences can be edited.

Deleted Sequences will remove the highlighted test sequence from the memory of the Rigel Multi-Flo.

4. Remote Control Mode

The Rigel Multi-Flo can be operated using a computer running Med-eBase software V2.4 or higher. Remote control allows the user to control and set up test sequence from a PC connected to the analysing device via a USB cable.

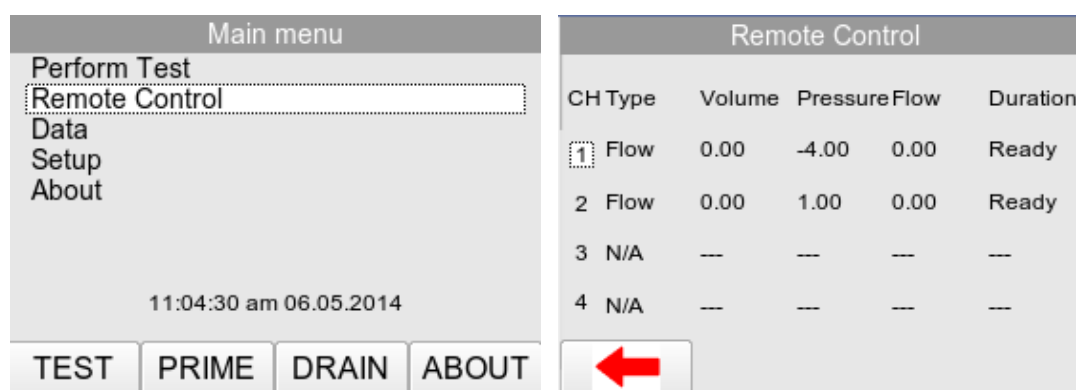
Connect a USB Cable between the Multi-Flo and the computer.



Power up the Multi-Flo and wait for the Main Menu to be displayed.

Make sure Med-eBase Version 2.4 or higher is installed on the computer.

To enter the remote control option select REMOTE CONTROL from the Main Menu.



Once in the remote-control menu the user will need to go onto Med-eBase software and enter the remote-control manager to control the Multi-Flo testing.

Start Med-eBase on the computer, connection should automatically occur after the initial connect. During the first connection the gadget serial driver needs to be installed. Please see Chapter 10.1 of the Med-eBase User Manual for details of this process.

Note: The Multi-Flo need to be in the Remote Control Menu before trying to connect to remote control on the Med-eBase Software as Gadget serial is only activated when Multi-Flo is in remote control mode.

For full functionality and how to use remote control mode please see Chapter 10 Remote Control Rigel Multi-Flo the Med-eBase User Manual.

During testing selecting the RED button will stop all tests and return the channels to prime mode. Alternatively, to exit the remote control mode press  F1 to go back to the Main Menu.

5. Data

Stored data can be viewed and transferred to and from the PC such as Test Results and Test Sequences.

To enter the Data menu, select DATA from the Main Menu.



The available options within the data screen are:

- View (see Chapter 6.1)
- Transfer (see Chapter 6.2)
- Bluetooth Favourites (see Chapter 6.3)

5.1. View Data

Stored data, using both manual and auto testing modes, can be viewed by selecting VIEW F2 from the DATA screen as shown above.

View Results			
	Asset	Date	Status
1	314251	06.05.2014	Pass
2	31425	06.05.2014	Pass
3	31431	06.05.2014	Pass
4	31431	06.05.2014	Pass

At the bottom of the screen, there are four buttons: a red arrow pointing left, 'View', 'Transfer', and 'Sort' (highlighted with a red box).

Data can be sorted using the SORT F4 key which will sort on:

- Asset Number
- Date (Ascending or Descending)

From the view data screen, results and subsequent test sequences can be viewed by pressing the VIEW F2 button and transferred to a PC by pressing TRANSFER F4.

To view data, use the rotary encoder to select the asset ID, press to select or press VIEW F2. This shows the test results for the selected asset ID.

Asset Details	
Asset ID:	31431
Tested On:	06.05.2014 11:42:07 am
Test Sequence:	
Results Seq Delete	

PCA Test Result			
Channel:	1	Duration:	00:02:00
Volume ml:	9.783		
	Volume	Flow	Duration
1	2.971	594.2	00:00:18
2	2.904	418.176	00:00:25
3	2.943	557.621	00:00:19
Pass			
		Graph	

Test results can be viewed by pressing the RESULTS F2 button; test settings can be viewed by pressing TEST SEQ F3 button and the asset result can be deleted by pressing the DELETE F4 button.

5.2. Transfer Data

The Rigel Multi-Flo can transfer data to and from the PC. From the Data screen select TRANSFER F3 to go to the Data Transfer Screen.

Change the data format type by pressing the OPERATION F2 button between:

- Export Results
- Export CSV Summary
- Export Test Sequences
- Import Results
- Import Test Sequences

Change the method of data transfer using the PORT F3 key between;

- USB Cable
- USB Memory Stick
- Bluetooth

When downloading or uploading files from the Rigel Multi-Flo the latest file will contain all previous Results or Sequences stores on the Rigel device and therefore only the last file needs to be used when transferring files between the Multi-Flo and Pc or Med-eBase.

Result files should be in format Results__DATE_TIME.rmfl in Format DDMMYYYY and hhmmss

Sequence files should be in format Sequences_DATE_TIME.fmfl in Format DDMMYYYY and hhmmss

Note: When uploading Results or Sequence to the Multi-Flo make sure that only the type of file required is on the memory stick or in the removable drive as the Multi-Flo cannot distinguish between results and sequence files as they both have the rmfl extension.

If multiple file types are on the memory stick a message indicating 'Incorrect file format' may appear on the Multi-Flo as the unit tries to import all files with that same extensive thinking that they are the same file type. If this message appears it will be associated with the wrong type of file e.g., Results or Sequence which are not being requested. If you go to the Main Menu and then Data and View for results or Main Menu and then Setup and Test Sequences for the Sequence to confirm they have successfully uploaded.

5.3. Download Data (Export)

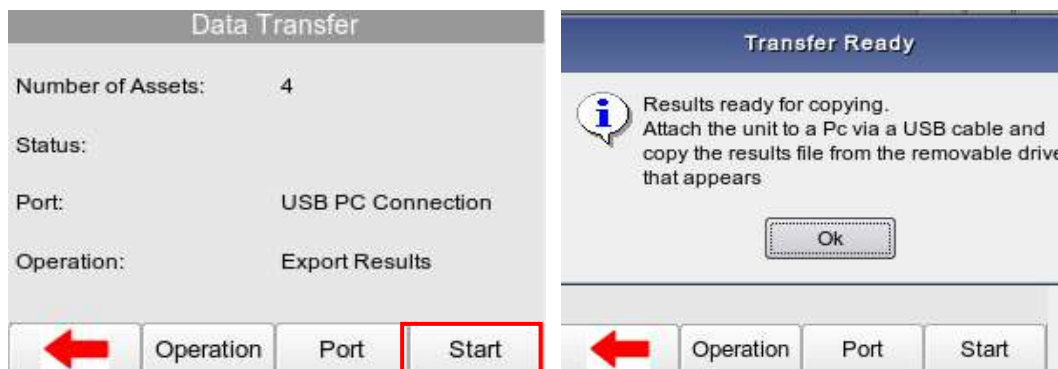
Stored data can be downloaded to the PC in several formats, shown above. From the Main Menu select DATA and then Data Transfer F3 from in the. To download Results or Test Sequences the Multi-Flo OPERATION needs to be EXPORT. To capture data as a text file select CSV format.

Data Transfer	
Number of Assets:	4
Status:	
Port:	USB Memory Stick
Operation:	Export Results
	Operation
	Port
	Start

Data Transfer	
Number of Assets:	4
Status:	
Port:	USB PC Connection
Operation:	Export CSV Summary
	Operation
	Port
	Start

5.3.1. USB Cable

Once the correct operation and port are selected (see Chapter 5.2 for options) start the download by pressing START F4. A Transfer Ready indication message appears on the Multi-Flo screen with OK to select ONLY ONCE the transfer is complete from the PC/Memory stick.



In the Transfer Ready screen connect the Rigel Multi-Flo to the PC using a USB cable.

The Multi-Flo will act as a REMOVABLE DISC data storage device. The data file can be copied from the drive that appears in explorer

Note: When using Med-eBase, the export of data will commence from the software once the Multi-Flo is in the TRANSFER READY state.

For downloading into Med-eBase please see the Med-eBase User Manual Chapter 4 Data Transfer.

Downloaded files can then be stored, transferring between Multi-Flo devices and PC or to colleagues. It also is useful with any technical enquiries if the files can be sent with the enquiry.

5.3.2. USB Memory Stick

When using a USB memory stick it needs to be inserted into the Multi-Flo USB connection prior to selecting START F4 on the Data Transfer screen.



The Memory stick acts as a REMOVABLE DISC data storage device. The data file is copied from the Multi-Flo onto the drive. The files that then be stored, transferred into Med-eBase and between Multi-Flo devices and PCs.

For downloading into Med-eBase please see the Med-eBase User Manual Chapter 4.

Note: When using Med-eBase, the export of data will commence from the software once the Multi-Flo is in the TRANSFER READY state.

5.3.3. Bluetooth

Before selecting to download via Bluetooth the Multi-Flo needs to have stored the PC Bluetooth as a Bluetooth Favourite. See Chapter 6 for Bluetooth Favourites.

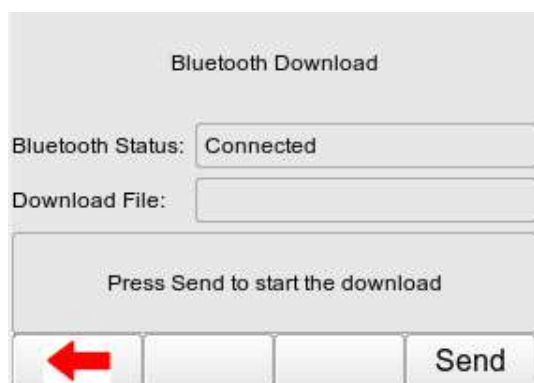
From the Data Transfer screen select PORT Bluetooth and OPERATION to Export results/CSV.



Data Transfer	
Number of Assets:	4
Status:	
Port:	Bluetooth
Operation:	Export Results
 Operation Port Start	

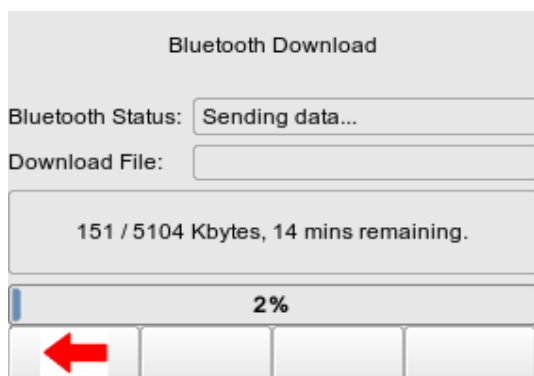
Select START F4

The Bluetooth status will indicate connecting to the selected PC and then Connected when the connection is made successfully.



Bluetooth Download	
Bluetooth Status:	Connected
Download File:	
Press Send to start the download	
   Send	

Press START F4 to begin the download to the PC. A progress bar will move along the bottom of the Multi-Flo screen until the download is complete.



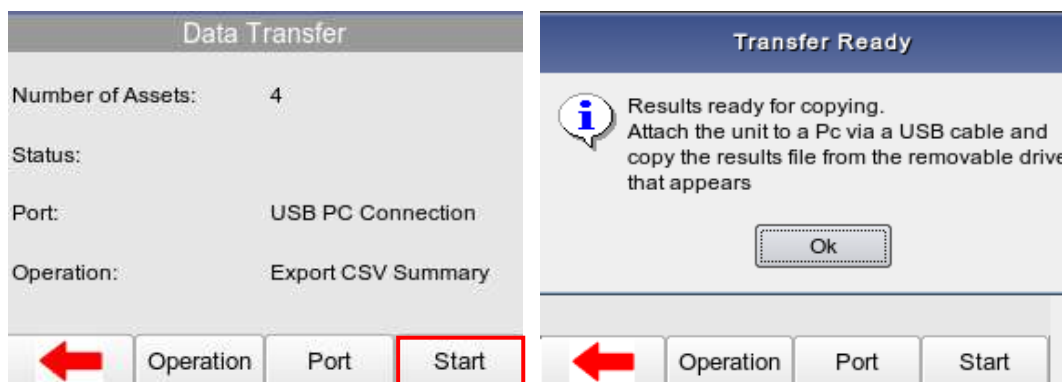
Once the download is complete select ← F1 to go back to the Data Transfer screen. The downloaded file will be saved in your personal Bluetooth location on your PC.

Note: The location of the downloaded file may vary depending on the personal preference or PC system being used.

Note: Make sure that the PC has disconnected the Multi-Flo before trying to download other files via Bluetooth.

5.3.4. CSV Summary

CSV Summary can be downloaded straight from the Multi-Flo as a text file; however, this is only a summary of the test and final results screen. CSV Full Export function is available from the Med-eBase software ONLY. Results therefore must download into Med-eBase in SSS format and then export as a CSV file. CSV summary can be downloaded.



5.4. Upload Data

Test data can be uploaded to the Rigel Multi-Flo by inserting previously downloaded files (see data download above) into the folder that appears in the explorer window (removable disc that is the Multi-Flo) when the Multi-Flo is connected to a PC.

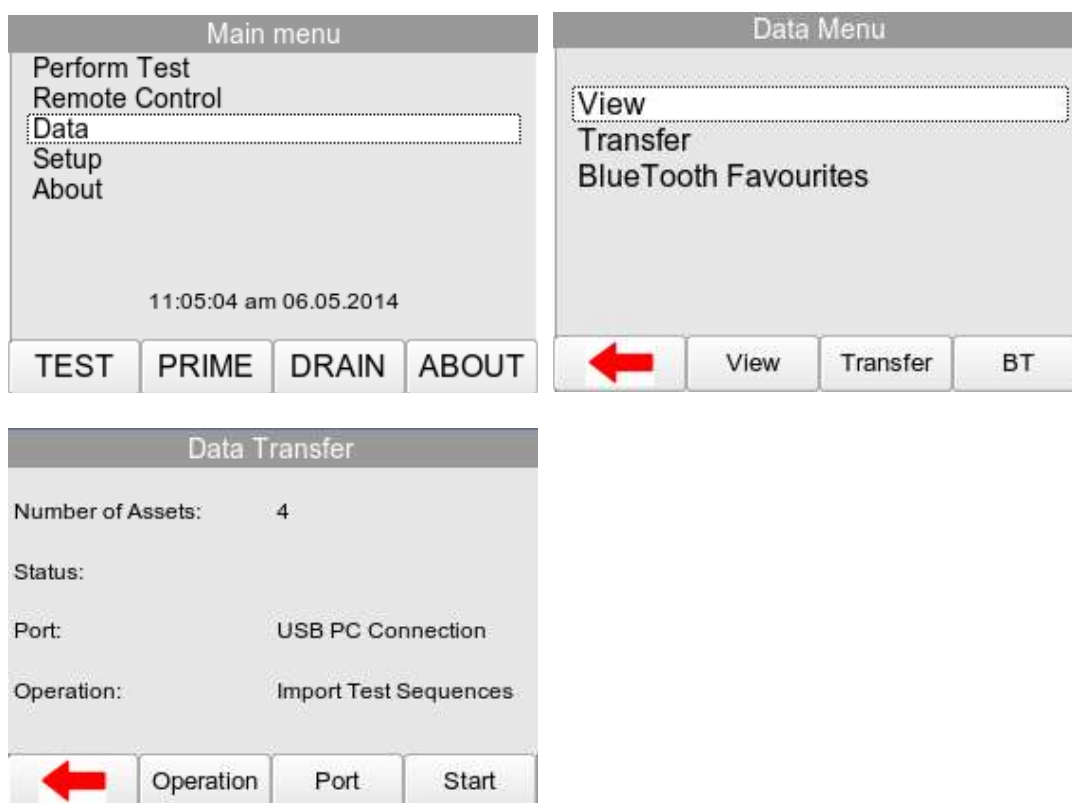
Alternatively, the files can be stored on a USB stick and then plugged into the Multi-Flo.

Using Med-eBase Software, Test Sequence can also be created and uploaded. To create and upload sequences from Med-eBase please see the Med-eBase manual Chapter 8.

From the Main Menu select DATA and then Data Transfer F3. To upload Results or Test Sequences to the Multi-Flo OPERATION needs to be set to IMPORT.

Select START F4 to begin the upload and the Multi-Flo will appear as a REMOVEABLE DISC.

Copy the Test Results or Sequences into the available folder. The data has now been uploaded to the Multi-Flo.



5.5. Transfer Test Sequences

Test sequences can be created on the Rigel Multi-Flo and in the Med-eBase Software. Sequences can then be shared across several Rigel Multi-Flo's in order to have identical configuration of Test Sequences or shared with colleagues at different locations.

When uploading and download sequence between the Rigel Multi-Flo and Med-eBase the latest file will contain all previous Sequences stored on the Rigel device and therefore only the last file needs to be used when transferring files between the Multi-Flo and Med-eBase.

Sequence files should be in format Sequences_DATE_TIME.sss in Format DDMMYYYY and hhmmss



Press START F4 to connect the Multi-Flo as an external drive to the PC.



When using a USB Cable with windows Explorer, locate the REMOVABLE DISC.

Select the Sequence file and copy them to a folder of your choice.

To download sequences into Med-eBase please see the Med-eBase manual Chapter 4 Data Transfer.

The files can then be shared between other PC's and uploaded back into other Multi-Flo's.

Using Med-eBase, import the test sequences by following the instructions in the Med-eBase instruction manual.

To import the Test Sequence(s), put the sequence in the corresponding drive. The new test sequences will now appear in the Multi-Flo test sequence library.

Note: When uploading Sequence to the Multi-Flo make sure that only the type of file required is on the memory stick or in the removable drive as the Multi-Flo cannot distinguish between results and sequence files as they both have the rmfl extension. If multiple file types are on the memory stick a message indicating 'Incorrect file format' may appear on the Multi-Flo as the unit tries to import all files with that same extensive thinking that they are the same file type. If this message appears it will be associated with the wrong type of file e.g. Results or Sequence which are not being requested. If you go to the Main Menu and then Data and View for results or Main Menu and then Setup and Test Sequences for the Sequence to confirm they have successfully uploaded.

6. Bluetooth Favourites

For the Rigel Multi-Flo to automatically connect to the correct Bluetooth accessory, details of that accessory must be entered into the Bluetooth Favourites list on the Rigel device.

The Bluetooth Favourites list comprises of two sub-lists (device types), each of which can store up to 3 accessories of the same type:

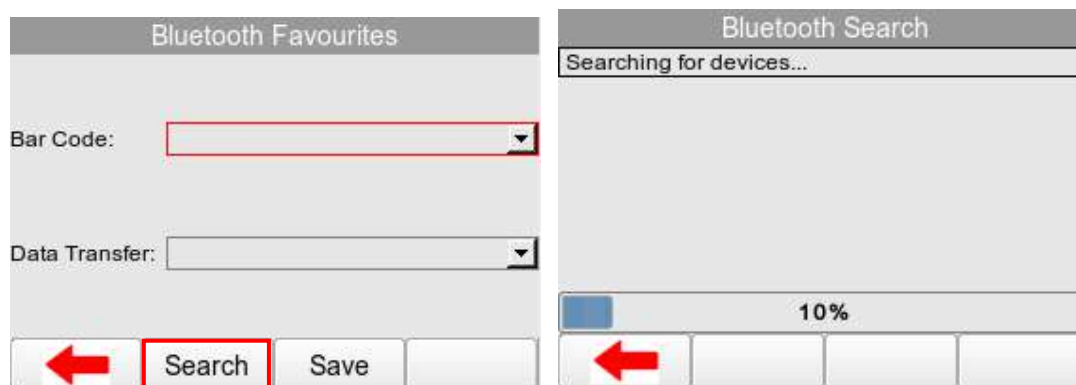
- Barcode
- Data Transfer (Computer)

To select Bluetooth Favourites, select BLUETOOTH FAVOURITES F4 in the DATA menu from the Main Menu.

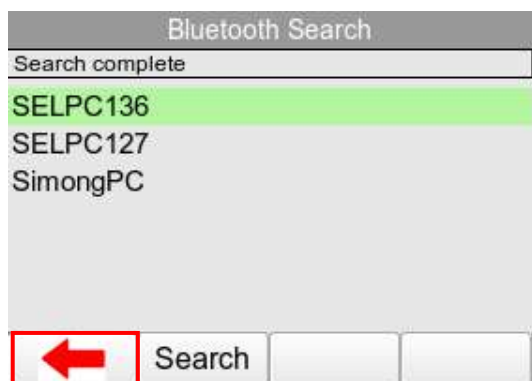


Use the rotary encoder to select the required device type.

Select SEARCH F2 to search for Bluetooth devices. A dropdown box of possible Bluetooth devices will appear in the field.



The devices found in range will be listed. Wait until the search has been completed which can take up to 15 seconds. Once the search is completed, press the back arrow key F1



To pair the appropriate device to the corresponding function, highlight the Bluetooth device type and open the drop-down box using the rotary encoder and press SAVE F3 to save the Bluetooth device for data transfer with either a barcode scanner or Computer.



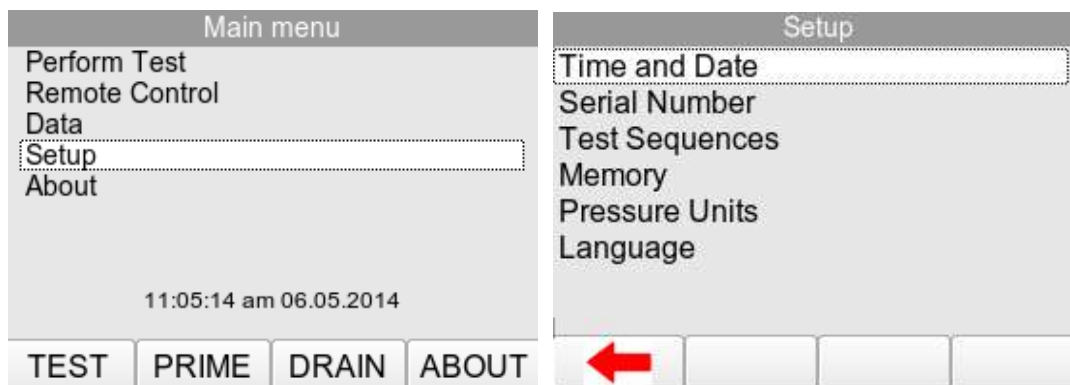
Check that the correct devices are paired for each function and press the back arrow to exit and complete the pairing;

Note: If the required device is not shown, check that it is powered on with the Bluetooth function active then repeat the search. Some Bluetooth devices do not report a recognisable name and may cause confusion when setting up Favourites. Turn off or disable unused Bluetooth devices when configuring Favourites.

Note: Seaward and Rigel accessories do not require a PIN. When the PC requires an authorisation (some Windows version might ask), enter 0000 (four zero's)

7. Setup

To enter the Setup mode, select Setup from the Main Menu using the rotary encoder.



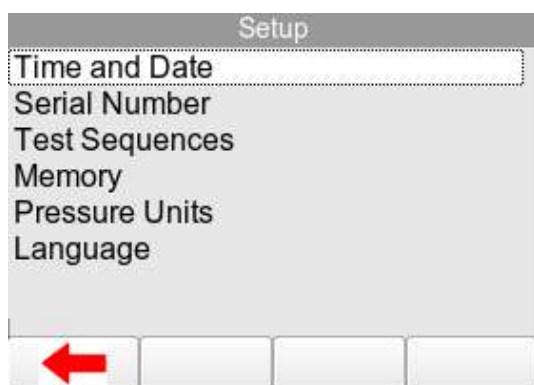
The setup menu allows the user to customise the Rigel Multi-Flo:

- View, edit or create test sequences (see Chapter 7.1)
- Configure the local time and date settings, (see Chapter 7.2)
- Change unit of pressure measurement, (see Chapter 7.3)
- Change the menu language, (see Chapter 7.4)
- View memory option and restore factory settings, (see Chapter 7.5)
- View about screen (see Chapter 7.6)

7.1. Time / Date

To modify the time or date including time format (12 / 24h clock), from the Main Menu, use the rotary encoder to highlight SETUP. Press the rotary encoder to enter the SETUP Menu.

Within the Setup menu select DATE / TIME



Highlight either 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 (am/pm) and 24 hour clock mode.

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

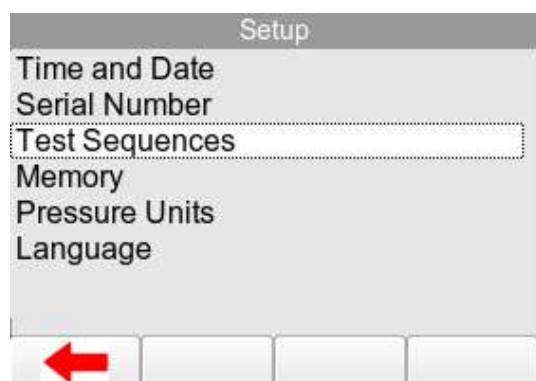
Press  F4 to save the changes, then  F1 to exit.



7.2. Test Sequences

The Rigel Multi-Flo can be set-up to perform automatic test sequences. These can be created by the user and can be specific to for example, manufacturers recommendations. The total number of possible test sequences is 100.

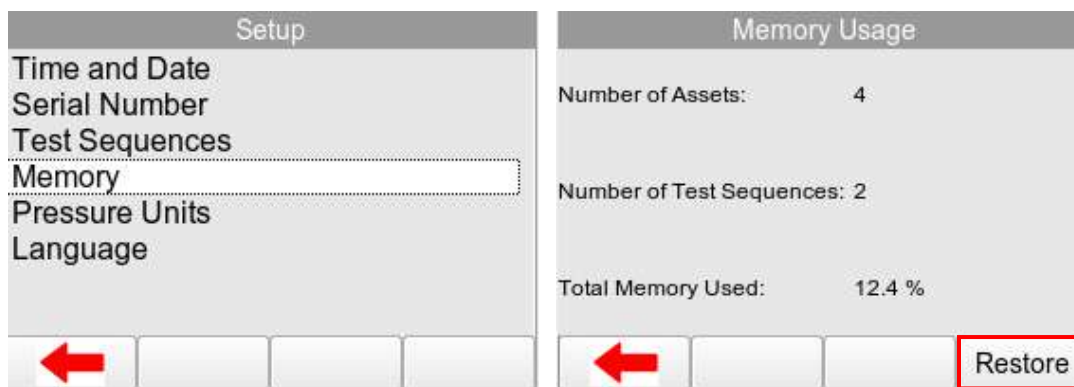
From SETUP menu, select the Test Sequence option. See Chapter 3 Auto Mode on how to create test sequences.



7.3. Memory Options

This feature is used to view information about the Rigel Multi-Flo memory status.

From the Main Menu, use the rotary encoder to highlight SETUP. Press the rotary encoder to enter the Setup Menu. Within the Setup Menu select MEMORY.

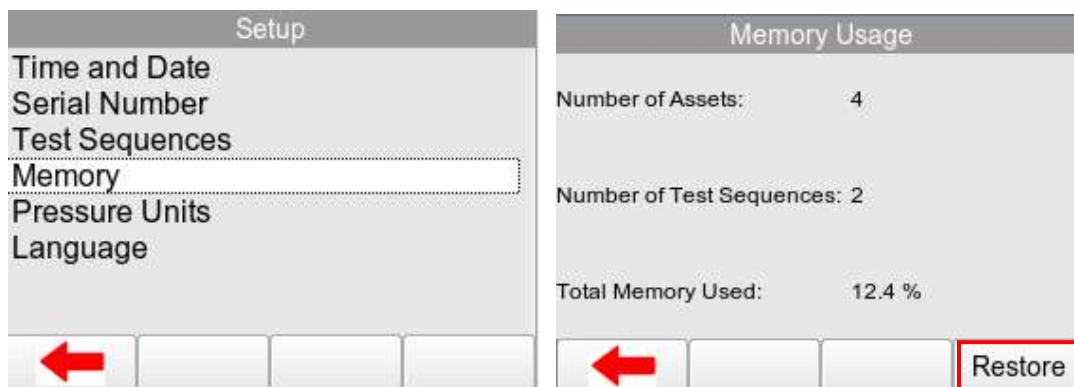


The Memory screen indicates the number of assets and test sequences stores and the total memory used on the Multi-Flo.

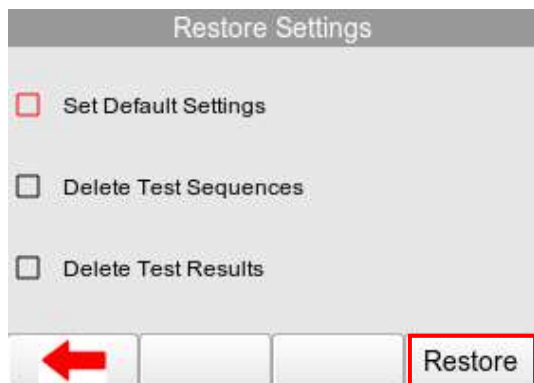
7.3.1. Factory Restore

Restore instrument to factory default settings will delete all user created test sequences and can also be used to clear the memory. The user is given an option to select which part of the memory is being restored to the factory default.

To restore the Multi-Flo to factory settings, select Memory from the Main Menu and then RESTORE F4.



In the Restore Menu use the rotatory encoder to select which part of the memory is being affected. Note: multiple options can be selected);



Select RESTORE F4 and a confirmation box will appear. Press the rotary encoder to select OK. Turn off the Rigel Multi-Flo to allow restore to complete.



 Restore Factory Settings cannot be undone and will remove all the customised items described above.

Individual assets can be deleted from the view data menu, see Chapter 5.1 View Data

7.4. Pressure Measurement Unit

The unit of Pressure measurement can be changed globally from the Main Menu using the rotary encoder to highlight SETUP. Press the rotary encoder to enter the Setup Menu. Within the Setup Menu select PRESSURE UNITS.



The Pressure Unit screen has a list of possible unit measurements.

- mmHg
- PSI
- Bar
- kPa

Use the rotary encoder to select and highlight the unit of measurement required and push to confirm selection.

Once a selection has been made select  F1 to exit.

To confirm that the Multi-Flo has been converted to this pressure unit requested go back to the Main Menu and select TEST F1 and then MANUAL F4. Check that the pressure limits and values in the test configuration screen are for the unit measurement selected.

7.5. Languages

Provides the ability to change the default language in the Rigel Multi-Flo.

From the Main Menu, use the rotary encoder to highlight SETUP. Press the rotary encoder to enter the Setup Menu. Within the Setup Menu select LANGUAGES.



The Languages setup screen has a list of possible languages to use. Highlight the Language required using the rotary encoder and push to enter.

Once a selection has been made select  F1 to exit.

Additional languages can be made available, please contact our support office at +44 (0) 191 5878701.

8. About Menu

The About screen shows the firm ware versions and serial number of your device. Each active channel will have an individual serial number.

Ensure you have this information available when contacting Rigel Medical for Technical Support or Service. See Chapter 9.3 for more information on Service and Calibration.

From the Main Menu, press ABOUT F4. The Main About screen displays telephone, email and website information for the equipment manufacturer.



Press DETAILS F2 to view the firm ware version, hardware version and serial number for the Multi-Flo unit and each individual installed channel.

Details			
Serial #	44E-0664	Version	1.0.0-7-g0f31
Channel	Firmware Ver.	Hardware Ver.	Serial no.
1	6.03	3 0.40A	47E-0329
2	6.03	3 0.40A	47E-0335
3	6.03	3 0.40A	47E-0328
4	6.03	3 0.40A	47E-0331

Press CALIBRATION F3 to view the calibration data of the installed channels.

Calibration Details		
Channel	Cal Date	Verified
1	17 Dec 2013	17 Dec 2013
2	17 Dec 2013	17 Dec 2013
3	17 Dec 2013	17 Dec 2013
4	18 Dec 2013	18 Dec 2013

Press  F4 to view the Service and Calibration contact information.

Contact	
For service / calibration requirements, please contact us using the details below.	
Calibrationhouse	tel; +44(0)191 5878736
11 Bracken Hill	
S.W. Industrial	fax;+44(0)191 5184666
Peterlee	info@CalibrationHouse.com
SR8 2LS	www.CalibrationHouse.com
England	
	Details Calibration

9. Maintaining the Rigel Multi-Flo



Please see appendix A for full details on maintaining and cleaning the Multi-Flo.

9.1. Cleaning the Analyser

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.

9.2. 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.

9.3. Firmware Upgrade

The Rigel Multi-Flo is designed to allow service agents and users to easily upgrade the firmware by using the internet to download: the latest firmware, a loading application, and instructions.

The firmware is installed using a PC via the USB port or via a USB stick.

For the latest firmware, the Rigel Multi-Flo will need to be registered; this will also provide automatic upgrade alerts to the user. Please visit the link below to register your product:
<https://www.rigelmedical.com/gb/support/performance-testing/Multi-Flo/register/>

Note: When downloading firmware from the Rigel medical website, the downloaded file is a self-extracting.exe which will produce the required file.

Equipment required:

- Multi-Flo
- Multi-Flo Manual
- USB Cable or Memory Stick.
- Updater firmware (1_Updater_XXX_firmware_update.tar.bz2)
- Multi-Flo firmware (3_MultiFlo_XXX_firmware_update.tar.bz2)

Note: XXX is any number which varies with each new release.

9.3.1. Firmware Update Stages

When updating the Firmware within the Multi-Flo once each stage is completed the Multi-Flo should be turned off before starting the next stage of firmware update. All stages need to be completed before using the Multi-Flo with the remote control option.

9.3.2. Stage 1 – Updater Firmware Update

If the Seaward Firmware Update Application is earlier than V2.1 it is recommended to update to the latest version. (1_Updater_V2-1_firmware_update.tar.bz2).

9.3.3. Stage 2 – Multi-Flo Library and Firmware Update

This will need to be run to update libraries for the latest release of the Multi-Flo Firmware to work correctly and also includes the remote control firmware.

Note: When updating Stage 2 you will need to check that the upgrade has completed for the Active Channels ONLY within your Multi-Flo. There is only one update file which is set up to update up to four channels. Therefore, if you have only a two channel Multi-Flo you will need to check that channels 1 and 2 has updated successfully. Any inactive channels will come up with a failed to update Pic[x] message for the missing channel(s) which can be ignored.

9.3.4. Updating Firmware via USB Serial Cable

Turn on the Multi-Flo while pressing the power button and holding the F1 button (refer to section 1.6 to identify the F function keys) until the Seaward Firmware Update Application screen appears.

Press F1 to select Update via PC option. Connect the USB Cable between the Multi-Flo and the PC followed by F1 again to attach the Multi-Flo device to the PC.

The Multi-Flo will appear as a removable drive within Windows Explorer.

When upgrading Multi-Flo Firmware make sure only one PIC file is copied onto the driver as the Multi-Flo cannot select between multiple firmware files with the same extension.

Copy the firm ware file on to the removable disc and press F1 to start the update process.

On completion press F1 to return to the main menu and then switch off the Multi-Flo device.

Restart the Multi-Flo in normal mode by pressing the orange power button.

9.3.5. Updating Firmware via USB Memory Stick

When upgrading Multi-Flo Firm ware make sure only one PIC file is copied onto the memory stick as the Multi-Flo cannot select between multiple firmware files with the same extension.

Turn on the Multi-Flo while pressing the power button and holding the F1 button (refer to section 1.6 to identify the F function keys) until the Seaward Firm ware Update Application screen appears.

Press F2 to select the Update via Memory Stick option.

Insert the memory stick into the USB slot and press F1 to start the update process. On completion press F1 to return to the main menu and then switch off the Multi-Flo device.

Restart the Multi-Flo in normal mode by pressing the orange power button.

Note: Registering your product with Rigel Medical enables us to provide you with automatic upgrade alerts when new firm ware versions are released.

9.4. Return Instructions

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

Calibrationhouse
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: service@calibrationhouse.com

Prior to returning your unit for service, please contact our service department to obtain a Returns Number (RMA).

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

When asking for a Returns Number, please quote:

- Instruments name, make and model
- Serial number
- Firm ware version

9.5. Optional Accessories

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

- USB keyboard
- [Med-eBase](#) PC download and remote control software

9.6. Replacement Spare Parts

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

10. Specifications

10.1. Technical Specifications

Flow Measurement

Display range	0.010 to 1500 ml/h
Max. display resolution	10 μ l/h
Measured range	0.100 to 1450 ml/h
Low flow rate Accuracy (0.1-9.9 ml/hr)	1% of reading + 0.005 ml/hr
Midrange flow rate Accuracy (10-700 ml/hr)	1% of reading
High flow rate Accuracy (701 – 1500 ml/hr)	(1+x) % of reading Where $x = 0.0033\% \times (\text{flow rate} - 700 \text{ ml/hr})$
Volume	0.001 to 9999 ml
Flow update rate	1Hz

Occlusion / back pressure measurement

Pressure measurement range	-500 to 2500 mmHg
Accuracy	-500 to 1000 mmHg ± 10 mmHg 1000 to 2500 mmHg $\pm 1\%$ of reading
Back pressure setting range	-200 to 600 mmHg
Unit selection	mmHg, PSI, Bar, kPa
Max. resolution	1 mmHg

PCA / Bolus measurements (Volume)

Display Range	0.1 to 100 ml
Measuring Range	0.5 to 100 ml
Accuracy	$\pm 1\%$ of the reading
Max. resolution	10 μ l
Basal flow rate	1 ml to 30 ml/h
Pressure	Max. 2500 mmHg

10.2. General Specifications

Storage	360h of testing at 1 second sampling rate
Dimensions	300 mm x 204 mm x 220 mm
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
Pollution degree	2
Overvoltage category	CAT II
Environmental protection	IP40
PC Communication	USB B
Keyboard Communication	USB A
Display	LCD colour graphic display 1/4" VGA
Operating conditions	15°C to 40°C, 0 - 90% RH
Storage conditions	0°C to +50°C, 0 - 90% RH

10.3. Environmental Conditions

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

Maximum barometric elevation for making measurements is 2000m.

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

11. Support

Rigel Medical Contact details

Sales and Delivery enquiries
Tel: +44 (0) 191 587 8730
Fax: +44 (0) 191 586 0227
Email: sales@rigelmedical.com

Rigel Medical Address details

Rigel Medical
15 - 18 Bracken Hill
South West Industrial Estate
Peterlee, County Durham
SR8 2SW, United Kingdom

Technical Enquiries

If you require technical support, please
visit rigelmedical.com/support

Calibrationhouse Contact details

Service, Calibration and Repair
Tel: +44 (0) 191 587 8739
Fax: +44 (0) 191 518 4666
Email: service@calibrationhouse.com

Calibrationhouse Address details

Calibrationhouse
11 Bracken Hill
South West Industrial Estate
Peterlee, County Durham
SR8 2SW, United Kingdom

Appendix A Performance and Maintenance Guide

The Multi-Flo is a precision instrument that must be properly maintained to achieve optimum measurement performance. The measurement principle uses a precise volumetric measurement over a known time period to calculate flow rates. Foreign material or air bubbles trapped within the measurement device will influence the volumetric measurement and consequently the flow rate measurement performance.

The volumetric measuring device must be able to rotate freely in order to operate correctly. Using inappropriate test fluids may leave a residue in the fluid path and impede the movement of the measurement device or ultimately cause total seizure.

Please note that damage resulting from the use of unauthorised test fluids is not covered by the warranty.

A.1. Test fluids

The following readily available test fluids are acceptable for use with the Multi-Flo:

- De-ionised water
- Distilled water
- De-ionised/distiller water with approximately 0.1 % Micro-90 cleaning solution

A 0.1 % Micro-90 solution is the preferred test fluid as this will prevent growth of organic material within the fluid path and act as a wetting agent. This will reduce the likelihood of small air bubbles being trapped in the fluid path which could influence the measurement accuracy.

Note: Do not use saline or dextrose solution as a test fluid. IV administration sets which may have been used with saline or dextrose solution should not be used with the Multi-Flo unless thoroughly cleaned beforehand. If saline or dextrose solution is accidentally used with the Multi-Flo, the unit should be cleaned immediately using the process described in section 5.

A.2. Priming

The Multi-Flo must be primed to fill the internal fluid path with test fluid and remove all air to provide accurate measurements. Optimum priming can be achieved using the supplied 3 port valve supplied with the Multi-Flo and a 60 ml syringe.

Follow the steps below to prime the Multi-Flo:

- a. Ensure that the 3-port valve is in the prime position as shown in figure 1 then connect it to a Multi-Flo channel inlet.
- b. Switch on the Multi-Flo.
- c. Fill a clean 60 ml syringe with test fluid.
- d. Ensure that all air is removed from the syringe.
- e. Connect the syringe to the 3-port valve as shown in figure 1.

- f. Slowly discharge the syringe into the Multi-Flo until no air bubbles appear in the Multi-Flo drain.
- g. If air bubbles are still appearing in the Multi-Flo drain when the syringe has been fully discharged repeat steps c to f.
- h. When no air bubbles are present in the Multi-Flo drain the system is ready to make measurements.
- i. Turn the 3-port valve to the position shown in figure 2.

Note: The Multi-Flo measurement device will rotate as the priming fluid is injected

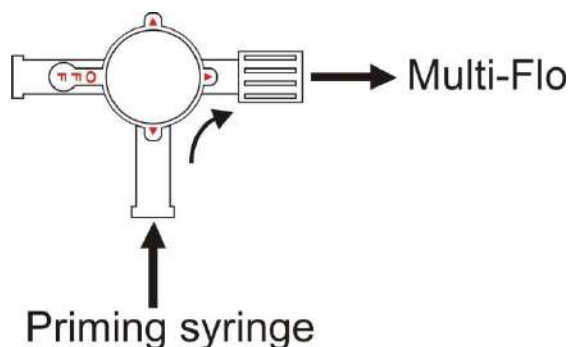


Figure 1

A.3. Making measurements

Always use a new disposable syringe when testing a syringe pump. It is advisable to lubricate the syringe by drawing on the plunger a few times before loading the syringe with test fluid and installing it in the pump.

Note: Administration sets which may have been used with saline or dextrose solution should not be used with the Multi-Flo unless thoroughly cleaned beforehand.

After priming the Multi-Flo, as described in section 3, connect an administration set between the device under test and the 3-port valve as shown in figure 2.

Prime the device under test, administration set and 3-port valve with test fluid according to the manufacturer's instructions for the device under test.

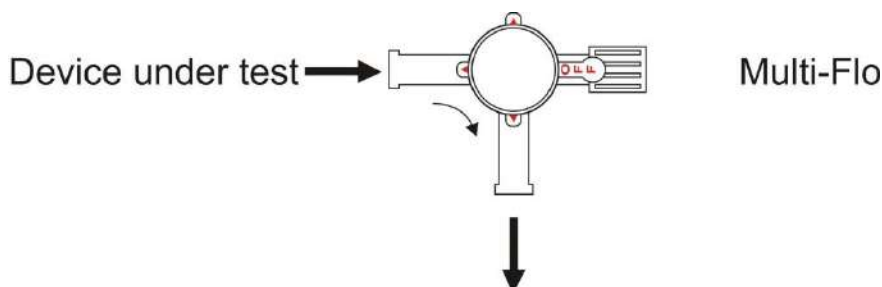


Figure 2

When there is no air in the device under test and administration set the system is fully primed and ready to make measurements.

Turn the 3-port valve to the position shown in figure 3 to direct the flow from the device under test to the Multi-Flo inlet.

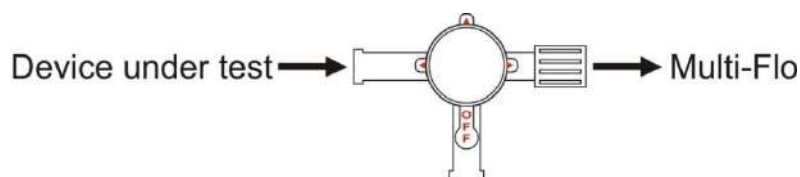


Figure 3

Note: The Multi-Flo channels should be kept primed between tests. After use, set the 3-port valve to the OFF position. Before placing into storage, the Multi-Flo inputs should be sealed using the caps provided.

A.4. Cleaning

If the Multi-Flo is used with distilled or deionised water without Micro-90 additive, some contamination of the fluid path may occur over time. To maintain optimum measurement performance, the following procedure should be used to clean the Multi-Flo:

- After prolonged storage
- After 3 months of normal use
- Immediately after accidental contamination with unauthorised test fluids

Each Multi-Flo channel should be cleaned as follows:

- a. Prepare a 1% solution of Micro-90 using deionised or distilled water.
- b. Fill a disposable 60 ml syringe with the cleaning solution and connect the syringe to the Multi-Flo inlet.
- c. Connect a suitable container to the Multi-Flo drain.
- d. Switch on the Multi-Flo.
- e. Inject the cleaning solution into the Multi-Flo channel to be cleaned.
- f. Leave for approximately 10 minutes.
- g. Flush the Multi-Flo channel with 100 ml of deionised or distilled water at a rate of 200 ml/hr.
- h. Repeat steps 1 to 6 for each Multi-Flo channel.

A.5. Maintenance spares

Replacement priming kit: Part number **385A951**

MICRO-90 Concentrated Cleaning Solution (1 litre): Part number **385A952**



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