

Rigel Multi-Flo

The infusion pump analyser that can double your test capacity

The Rigel Multi-Flo infusion pump analyser offers ease of use, high accuracy readings and productivity improvements right from the start.

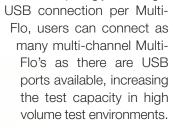
With the choice of single or multi-channel configuration, the Multi-Flo can test up to four infusion devices simultaneously across a range of $10\mu L$ up to 1500mL per hour, with all results being stored in the large internal memory. The Multi-Flo delivers unique accurate and instantaneous flow measurements even at low flow rates, enabling the user to test twice as many infusion devices within the same time period as other volumetric based analysers.

To help save even more time and to reduce the risk of human error, the Multi-Flo can also be programmed with manufacturer specific test routines which can then be automatically executed by the user on the device itself or controlled from a PC using the Med-eBase software solution.

To meet the requirements of IEC 60601-2-24, the Multi-Flo also provides accurate back pressure simulations, occlusion alarm monitoring and bolus (PCA) measurements, and a large colour graphics display presents the data in both numerical and graphical format.

A remote (PC) control interface is available via Rigel's test solution software, Med-eBase, allowing complete control of the Multi-Flo's features from the

comfort of a PC. Requiring just a single





Key Benefits

- Double the test capacity per each channel compared to the nearest competitor.*
- Saves time with accurate and instantaneous flow measurements
- Meet manufacturer's test requirements by creating (or sharing) test protocols for different models or applications
- Fully traceable results storage and automatic data capture reduces time and manual data errors
- Flexible purchase, with 1,2 or 4 channel configuration and optional future upgrade
- Saves time by analysing multiple devices simultaneously
- Improved data analysis with high resolution data storage
- Provides peace of mind with full compliance test capability to IEC 60601-2-24
- Large graphic display with clear data viewing distance exceeding 5 meters
- Increased throughput with Med-eBase remote control function
- Get the most out of the Multi-Flo with Med-eBase test solution software

Analysis Functions

- Real-time flow measurement
- PCA/Bolus
- Back pressure simulation
- Occlusion alarm
- Trumpet curve analysis (Requires Med-eBase)
- Raw data download to MS Excel (Requires Med-eBase)
- Customisable test templates
- Local language options
- Pressure unit options
- Automatic test sequence function
- Remote control testing

Multi-Flo Applications

- Routine analysis of infusion devices
- Calibration of infusion devices
- End of production line testing for infusion devices
- Development tool for infusion device R&D
- Type testing tool for infusion devices
- Evaluation tool for application specific infusion devices

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Instantaneous flow measurement

Instantly determine the accuracy of an infusion device, even at low flow rates, the Multi-Flo provides readings within 1% accuracy from 100 μ L/hr, faster than any alternative testing method or infusion device analyser. It also indicates instantaneous flow behaviour on any infusion device.





1, 2 and 4 channel configurations

The multiple channel configurations enable increased throughput and improved efficiency; and the ability to upgrade to a maximum of 4 channels to meet future circumstances offers flexibility at time of purchase.

► Automatic test and data acquisition

The ability to programme the Multi-Flo with manufacturer-specific test routines and run them automatically as well as capture the results in the internal memory saves time and reduces the risk of data and user error.





■ Fully compliant with IEC 60601-2-24

The compact Multi-Flo is an all-in-one solution to meeting the infusion device testing requirements of IEC 60601-2-24; with back pressure simulations, occlusion alarm monitoring, bolus (PCA) measurement and the creation of trumpet curves, all incorporated into the device.

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Designed for ease-of-use

The Multi-Flo is easy to use and navigate with a large colour display, simple push button operation and intuitive menu driven interface. A dedicated data focus area allows clear viewing of target data from distances exceeding 5 meters, offering flexibility during testing both in the field and in a workshop environment.





Control multiple Multi-Flo analysers on a PC

The Multi-Flo is compatible with Rigel Medical's Med-eBase test solution software, enabling even greater productivity improvements through a remote control interface.

Control as many Multi-Flo analysers as there are USB ports on your PC with Med-eBase software, using the PC screen as a dashboard to aggregate the activity from each of the Multi-Flo analysers. This means that test capacity can be drastically increased for high volume test environments.

Comprehensive data management

Use Med-eBase software to quickly and easily produce real-time and high resolution graphs, including trumpet curves, store test data and create test certificates. Med-eBase builds a complete history for each asset and enables a total solution from test and inspection through to record management and certification.



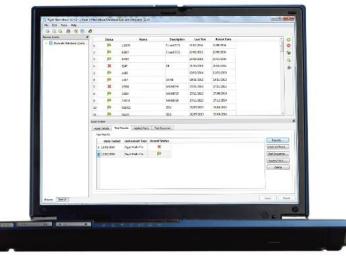
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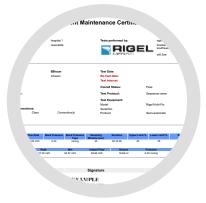


Med-eBase Compatibility

Test solution software

Med-eBase is a universal test solution software that not only allows the download and management of test result history, it also allows for easy scheduling of workload based on (re)test dates, configuration of test equipment protocols, comparing and analysing of downloaded data, and creation of customisable test certificates to give you flexibility in the way you want to manage your assets.





Customisable test certificates

Produce customisable test certificates with logos and electronic signatures for individual assets or multiple results. The certificates can be produced in PDF or HTML format and printed or saved for future reference.

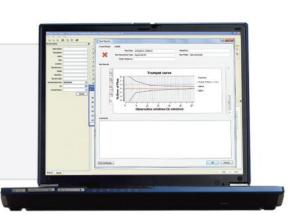
Multi-Flo remote control

Med-eBase V2.4 incorporates a remote control feature for use with the Rigel Multi-Flo, enabling the user to operate the Multi-Flo using a PC as a control dashboard.



► Real time data analysis

Real time graphical and numerical data during remote testing enables the user to see instantaneous readings with specific limits indicated and provides data for analysis of results and trumpet curves.



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Automatic test sequences

Creating test sequences in Med-eBase reduces setup time and increases accuracy and efficiency of working practices when testing multiple devices. Test sequences can be easily shared between testers and PCs or across multiple channels to remove duplication, ensuring greater flexibility and accuracy for those who conduct repetitive testing on the same infusion pump types.



Export to MS Excel

Raw test data can be exported to a Microsoft Excel file for specific and detailed inspection and analyses of particular aspects of the infusion process, leading to unsurpassed quality assurance.



Automatic data collection

The option for volume, time or user-based test durations provides an easy way to automatically record test data at the completion of each test without human interaction. A choice of pressure units allows testing in accordance with specific infusion manufacturers.



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Technical Specifications

Flow Measurement

Display range 0.010 to 1500ml/h

Max. display resolution $10\mu l/h$

0.100 to 1450ml/h Measured range ± 1% of the reading after Accuracy

> 100µl volume at 0mmHg backpressure applied.

-500 to 2500mmHg

-200 to 600mmHg

0.001 to 9999ml Volume

Flow update rate 1H₂

Occlusion / back pressure measurement

Pressure measurement range Back pressure setting range

Unit selection

mmHg, PSI, Bar, kPa (1023 steps) \pm 1% of the reading up to

1500mmHg)

Accuracy Max. resolution 1mmHg PCA / Bolus measurements (Volume)

Display Range 0.1 to 100ml Measuring Range 0.5 to 100ml \pm 1% of the reading Accuracy

Max. resolution 10µl

1ml to 30ml/h Basal flow rate Pressure Max. 2500mmHg

General Specifications

360h of testing at 1 second Storage:

sampling rate

Dimensions: 300mm x 204mm x 220mm

5kg (1 channel) Weight:

6kg (2 channel) 8kg (4 channel)

90 - 264 VAC, 50/60 Hz, Mains supply:

60W

Mains cable: Standard IEC 10A

connector

Storage environment: 0°C to +50°C +15°C to +40°C Operating conditions:

Environmental protection: IP40 PC Communication: USB B Keyboard Communication: USB A

Display: LCD color graphic display 1/4" VGA



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.

Disclaimer: While every care has been taken in ensuring the accuracy of the information in this document, Rigel Medical accepts no responsibilty for errors or omissions.

Rev 1

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