MICROLAB Elettronica s.a.s.

di Bergamo Giorgio & C.
Via G. Rossa, 35 – 35020 Ponte S.Nicolò (PD)
ITALIA
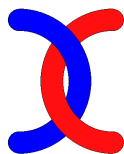www.microlabitalia.it info@microlabitalia.it

PicoFlow Device: Main Features

The PicoFlow **M-1800** air plethysmograph is a Medical Device certified according to the 93/42/EEC Directive as a Class IIa Device. Here below are the main features of the device.

- Picoflow is a portable device equipped with rechargeable batteries. The continuous operating period amounts to 8 hours with fully charged batteries. The full charge cycle is about 2 hours long.
- PicoFlow can be worn by the patient using a shoulder strap. It allows the patient to walk completely free from any constraints to fixed equipment.
- The connection to the boot stirrup is made with a single 40cm long flexible silicon tube. The pneumatic connections are made with Luer Lock connectors.
- The boot stirrup is equipped with a zipper for easy fitting on the patient's leg and is inflated to the working pressure by a compressor incorporated in the device.
- PicoFlow has an automatic volumetric calibration system (reference 100 ml) thanks to a flowmeter incorporated in the device. The PicoFlow does not require the use of a calibration syringe by an operator.
- PicoFlow is equipped with a Bluetooth© transmission system (BLE, Bluetooth Low Energy) with a protocol reserved for the BLED receiving dongle (supplied) to exclude any type of connection / disturbance from other Bluetooth© devices nearby.

PicoFlow Device: Technical Specifications

Manufacturer	Microlab Elettronica s.a.s. Via Guido Rossa 35- Ponte San Nicolò- Italia
Allowed Accessories	
Microlab PicoFlow	Code : M-1800
Boot Stirrup	Code: M-1830
Dongle Bluetooth BLED 112	Code: M-1835
Battery charger	Code: T5889ST (M-1840)
Coax pneumatic pipe	Code: M-1845
Pen Drive USB	Code: M-1850
Electrical characteristics (device)	
Supply Voltage	5V from 4 internal batteries NI-MH , 1.2V, 1.200 mA
Max .drained current (during	600 mA +- 20mA

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| batteries charge)	
Protection fuse	3000 mA, self resettable
Power @ 230V	12W during batteries charge
Dimensions	Lenght=200mm x Width =110mm x Height=43mm
Weight	700 g
Battery charger electric features	
Supply Voltage	Type T5889ST :100-240Vac; 50-60Hz
Max. absorbed Current	0.6 A
Output Voltage	12Vdc
Max. output Current	1A
Storage	
Temperature	Da - 5° a +40°
Humidity	max 70% Rh @ +30°
Electromedical Characteristics	
Device Type	Risk class: IIa secondo Direttiva 93/42/CE e s.m.i.
Applied part	BF Type, as IEC EN 60601-1
Insulation	Class II (Charging the batteries) Inernal supply (during normal usage)
Liquid protection	IPX0 (IEC/EN 60529)
Method of use	Continuous operation
Essential performance	
Measuring range	from 0 to 400 ml (from 0 to 20 mmHg)
Precision	+-10%
Mex. Pressure	50 mmHg
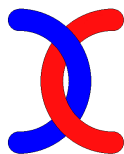
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PicoFlow Software : Main Features

The **PicoFlow M-1800** air plethysmograph bundles with the **Microlab PicoFlow Software** (supplied), whose main functions are:

- Multilingual User Interface (available languages: Italian, English, French, German, Spanish - additional languages available upon request).
- Storage of personal information and examination results on a database (the Patient's Records folder).
- Compile the patient's medical history (Anamnesis), with the date of writing, during the repeated examination sessions.
- Annotate the Pathologies diagnosed in the patient, with the date of writing, during the repeated examination sessions.
- Annotate the Conclusions and any therapeutic recommendations at the end of each examination session.
- Execute the scheduled examinations with real-time representations of the Volume/Time trace in scroll mode (charting). The patient 's operating intervals are highlighted with different background colors for immediate recognition of the various steps of the tests in progress.
- Use a "Voice" function (voice synthesis) outlining the different steps of the test in progress in the language (among those available) selected by the operator.
- At the end of an examination, a single-screen view of the entire examination trace, with the possibility of enlarging single parts of the examination. The duration of the examination is not predetermined and it is possible to perform examinations over longer time periods.
- Automatic positioning of the sliders on the Volume/Time trace in correspondence to the main steps of the examination, with the possibility to manually move each single slider when artifacts (patient movements, etc.) are displayed on the trace.
- Automatic calculation of volumes, times, and characteristic indices per specific test (APG, VOP), with automatic recalculation in case of manual movement of the sliders.
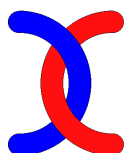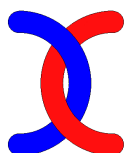
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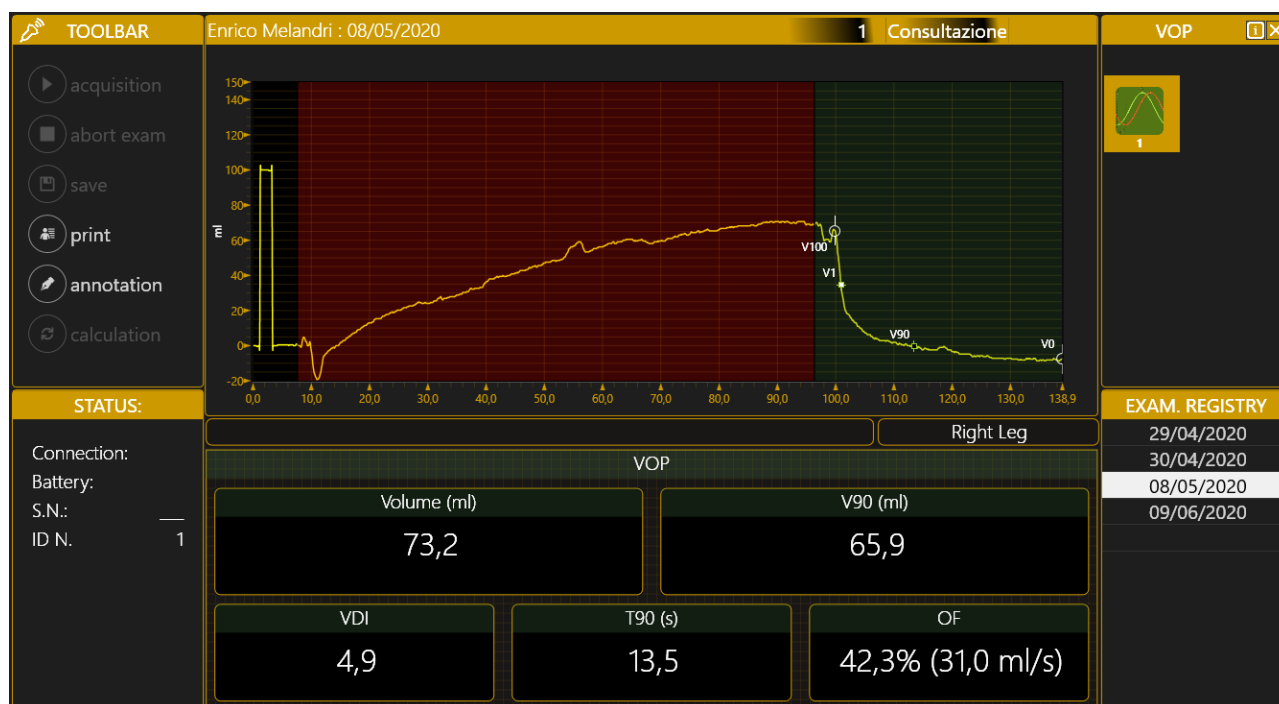www.microlabitalia.it info@microlabitalia.it

- **APG exam:** The following sliders are automatically positioned:
  - o V0: Identifies the volumetric value taken as reference (Volume 0) when the patient is supine with the limb in a raised position with respect to the pelvis (emptying).
  - o V100: Identifies the volumetric value taken as the maximum (Volume 100) value of the plateau when the patient is in the orthostatic position.
  - o V90: Identifies the volumetric value at 90% of the Total Volume, the latter calculated as V100-V0.
  - o EV: Identifies the minimum volumetric value calculated in the time interval in which the patient performs the single exercise.
  - o RV: Identifies the minimum volumetric value calculated in the time interval in which the patient performs free walking.
- **APG exam:** The following values / indices are automatically calculated:
  - o Total Volume (VV) in ml: The value of the Total Volume.
  - o V90 in ml: 90% of the Total Volume VV.
  - o T90 in sec: The time interval elapsed between the beginning of the phase in which the patient goes from the supine position to the orthostatic one and the achievement of the volume value V90.
  - o VFI in ml/sec: **V**olume **F**raction **I**ndex: The ratio between the results V90/T90.
  - o EV in ml: **E**jection **V**olume: The time interval in which the patient performs the single exercise is considered and the minimum value (EV_{min}) of the volumetric curve in that interval is calculated. The Ejection Volume is calculated as $EV = V100 - EV_{min}$.
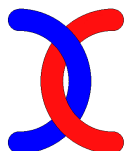 - o EF (%): **E**jection **F**raction**:** Calculated as $100 * EV/VV$.

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- o RV: **R**esidual **V**olume: The time interval in which the patient performs free walking is considered and the minimum value (RV_{min}) of the trace in that interval is calculated. The Residual Volume is calculated as RV=VV-(V100-RV_{min}).
- o RF (%): **R**esidual **F**raction: Calculated as 100*RV/VV.

- **VOP exam:** The following sliders are automatically positioned:
  - o V100: Identifies the volumetric value taken as the maximum (Volume 100) value of the plateau during the occlusion phase of the patient's limb.
  - o V0: Identifies the volumetric value taken as reference (Volume 0) at the end of the occlusion discharge phase (removal of the occlusion) of the limb.
  - o V90: Identifies the volumetric value at 90% of the Total Volume, the latter calculated as V100-V0.
  - o V1: Identifies the volumetric value after 1 sec from the moment of the occlusion discharge (removal of the occlusion).
- **VOP exam:** The following values / indices are automatically calculated:
  - o Volume in ml: The volume value of the limb at the end of the occlusion interval.
  - o V90 in ml: The decay (expulsion) of 90% of the Volume (V100-V0).
  - o T90 in sec: The time elapsed between the beginning of the occlusion drain and the achievement of the V90 volume value.
  - o VDI in ml/sec: **V**enous **D**renage **I**ndex: The ratio between the V90/T90 results.
  - o OF (%): **O**utflow **F**raction: Calculated as a percentage of the volume of blood expelled from the limb after 1 sec from the moment of discharge of the occlusion with respect to the Volume (V100-V0).

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ITALIA
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Giuseppe Verdi

Private Clinic Salus S.p.A.

Main Street - Someware 1243 - Neverland
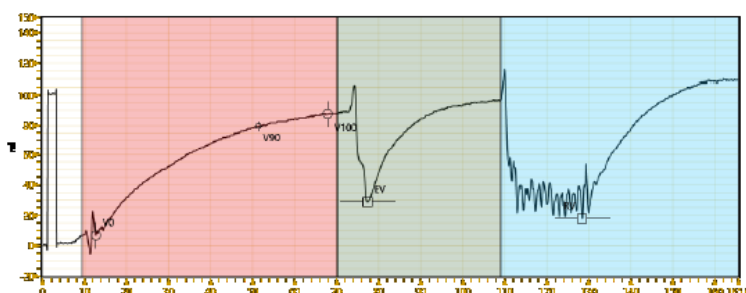Tel.: 0663543667 - eMail : Salus@salus.com

1/1   APG/VOP - Exam. Date :   16/05/2020

Patient Name: Enrico Melandri	Gender:M	Date of Birth 24/04/1955

Patient ID: 66

Filling

Volume	80,5 ml
V90	72,5 ml
T90	38,7 s
VFI	1,9

Exercise

Ejection volume	58,7 ml
Ejection fraction	72,9 %

10 exercises

Residual volume	10,9 ml
Residual fraction	13,5 %

Left Leg

Patient History

29/04/2020
First patient history entry

08/05/2020
Patient history update after a further exam session

List of pathologies found

29/04/2020
Patient pathologies initially found

08/05/2020
Pathologies update after a further exam session

Conclusions and Recommended Therapy

Recommended therapy specifications...

Signature:

- **Final Report** : compile a Report, selecting which of the APG and/or VOP test traces should be part of it. The selected traces are complete of their results. The Report is then complemented by the patient's medical history (Anamnesis), the Pathologies diagnosed and the Conclusions, all freely editable.
- Print the Report and/or produce a PDF file to be stored on an external support (e.g. USB Pen Drive).
- Export the data of an examination in a CSV file format, containing all the test results as well as the values of the Volume/Time trace. The Volume and Time values are stored in separate columns, allowing the reproduction of the graph in an Excel sheet.
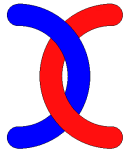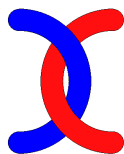
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Minimum Personal Computer Requirements for the PicoFlow Software

- **Operating System**   Windows© 10 or later version
- **Processor**   Core i5 or higher
- **RAM**   512 MB (min.) available after OS and processes
- **Minimum space on HD**   5 GB available for the Application and the patients' Records
- **HW interfaces**   USB 2.0 or higher
- **Other information**   The minimum requirements refer to use without any additional background software. Some SW (e.g. Antivirus) may impact these Requirements.

PLEASE NOTE: **the Personal Computer is not part of the supply.**

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PicoFlow : Components and Accesories

The Microlab PicoFlow "suite" includes:

Component / Accessory	Code
PicoFlow Device	M-1800
Standard-size boot stirrup	M-1830
Coaxial pneumatic tube with double Luer Lock socket	M-1845
Battery charger T5889ST	M-1840
USB Bluetooth© dongle	M-1835
PicoFlow Software User License (in USB Pen Drive)	M-1896
PicoFlow Software EN Manual (in USB Pen Drive)	M-1821
PicoFlow Device EN Manual (in USB Pen Drive)	M-1820
100 ml syringe (periodic checks)	M-299
Pneumatic hose with T fitting (periodic checks)	M-1846
Occlusion hose	
Aneroid sphygmomanometer (manual occlusion)	
Fast manual drain valve	
CE Declaration of the Manufacturer	DCEPF01
Electrical Safety Report	According to EN62353
PicoFlow and Accessories case container	M-1895