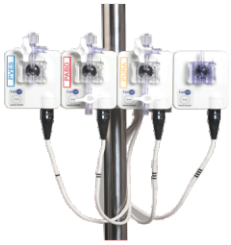
Pico Smart

The Handy Urodynamics

PICO SMART is based on an advanced acquisition module called **SAU-URO**, with powerful capabilities

It can be based on one trolley (all-in-one-system) or upon 2 units connected via **Bluetooth**



PRESURE CHANNELS

Pico Smart is compatible with perfused catheters, air-charged and solid-state catheters like those manufactured by Unisensor, Gaeltec and others

PULLER

The mechanical catheter puller is controlled via software or infrared remote control

UROFLOWMETER

The uroflowmeter is connected to acquisition board either by means of a cable 8 m long or by a wireless module so that it can be put in a private place to make the patient more comfortable

TROLLEY

In all-in-one configuration, the trolley has 4 pivot wheels (all with brakes) and 2 shelves plus 1 sliding top for keyboard and mouse. It is provided with an IV shaft to hold the acquisition unit, the catheter withdrawer and the pressure transducer module

COMMODE CHAIR

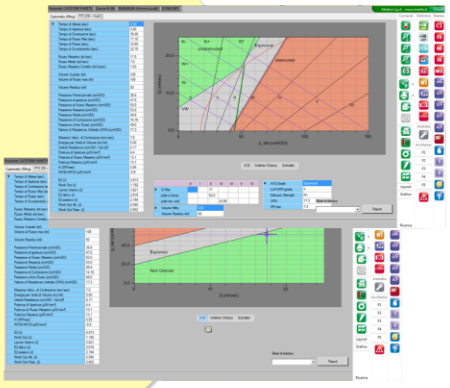
Adjustable and easy to clean

ACQUISITION UNIT

The Acquisition unit has up to 16 channels: Pressure, Electromyography, Flow, Volume and Leak Point Detector; It includes a peristaltic pump with 4 rollers. The microprocessor has high sampling rate capability

PICO SMART WORKS WITH THE SOFTWARE PACKAGE PICO3000

PICO3000 is a program that carries out and analyses all the urodynamic studies in few stage. It includes the following features:
- Database (MS Access and SQL compatible)
- Automatic Medical Reports based on pre-set and customized templates
- Studies results, graphs and raw data available on MS Office application (Excel, Power Point, Word)



Advanced Analysis of Pressure Flow Studies, Cystometry and Flowmetry. It includes the most important nomograms such as ICS, Schafer's nomograms, Abrams and Griffith's plot, Gohniem, Liverpool nomograms, Siroky nomograms, Blaivas and Groutz

RISK-FREE STUDIES:

Thanks to the automatic save & resume feature, the study interrupted for any reason, also for a blackout of the mains, can easily be resumed

SURFACE IMPEDANCE (KOHM)

Electromyography with checking of the skin Impedance to ensure good electrodes contact

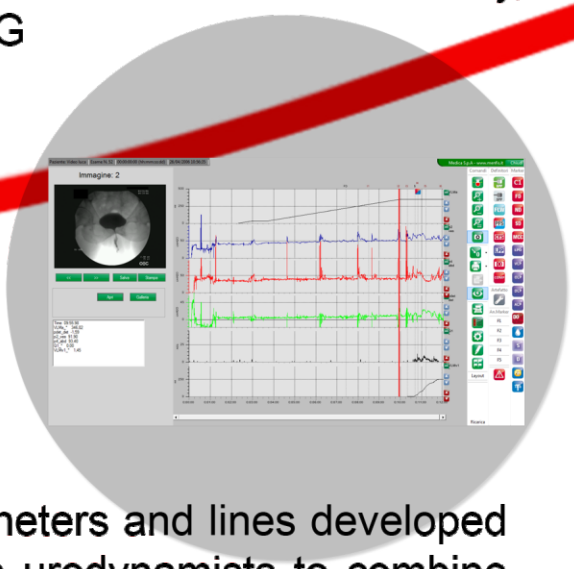
MORE FEATURES

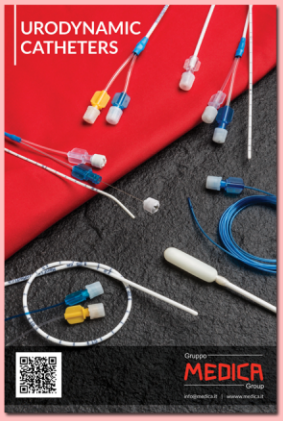
Advanced statistics function. To compare several tests and/or to export the data to MS Excel.
Automatic artefact rejection facility allows the detection and cancellation of the false data, which could lead to uncorrected evaluation. Thanks to the capability to review the history of the study, the operator can recall the acquired traces while performing the study.
PICO3000 is designed to be part of a network. It is compatible with DICOM, HL7 and other standards

A DIAGNOSTIC SYSTEM THAT GROWS ACCORDING TO YOUR NEEDS

PICO SMART can be expanded with the following options:

- Video-urodynamics to combine x-ray or ultrasound images and short movies with the urodynamic tracings
- Biofeedback for the pelvic floor rehabilitation in case of urinary incontinence
- Oesophageal and Anorectal motility: to assess the gastrointestinal motility
- Whitaker test to study the functioning of the upper urinary tract
- Cavernosometry to study the erectile disorders (not available in USA)
- Module of Neurophysiology; It studies Pudendal Motor Nerve Latency, Sacral Refles, simple EMG and quantitative EMG





CATHETERS

We offer a wide range of catheters and lines developed in close cooperation with the urodynamists to combine the maximum comfort of the patient with the best possible measurements. The catheters are made in high quality materials like PEBAX and PVC, widely tested to meet the needs of the Urodunamic studies. Require the catalogue “Urodynamic catheters and lines” or visit our web site www.menfis.it

** Technical data can be change without any notice*

Menfis Division

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www.menfis.it

MEDICA

Via degli Artigiani, 7
41036 - MEDOLLA- MODENA- ITALY

CE 0476 rev. 1.0 Mar ‘18

TECHNICAL CHARACTERISTICS

General technical characteristics

Definition of safety class: the equipment has been constructed in compliance with standard IEC 60601-1 with protection class: I, type BF.

The equipment performs the following studies:

- Flowmetry
- Cystometry
- Pressure- Flow Study
- Urethral Pressure Profile ,
- Conductance
- Valsalva and Cough Leak Point Pressure
- Electromyography
- Cavernosometry
- Biofeedback
- Anorectal and oesofageal manometry

- Acquisition unit medical grade power supply SNP-A129-M: 100-250VAC, 3 A, 47-63 Hz
- A fuse is mounted on the SAU70001 board inside the acquisition unit. The fuse has following technical features: 5x20mm fuse 3A-F.
- Product certification: CE mark in compliance with MDD 93/42 as modified of 2007/47/CE directive.
- Quality system: UNI EN ISO 9001 / UNI EN ISO 13485
- Minimum characteristics that must have the Personal Computer on which to install the software: Windows 7, 4GB RAM, 128GB hard drive.

Environmental conditions

- Utilization condition of the device:
  - Environment temperature: from +15 to +35 °C
  - Relative Humidity of the air: from 35 to 75 % without condensation
  - Atmospheric pressure: from 700 to 1060 hPa

- Transport and storage condition of the device:
  - Environment temperature: from -10 to +50 °C
  - Relative Humidity of the air: from 35 to 85 % without condensation
  - Atmospheric pressure: from 500 to 1060 hPa
  - Keep dry
  - Keep away from sunlight

- The system not intended for use in an OXYGEN RICH ENVIRONMENT; therefore, no protection is offered in this respect.

Cod. UHK

- USB Dongle for software protection;
- Enclosures protection degree: IP20

Cod. REM-CONT2

Infrared Remote Control

- Up to 5 meters
- Enclosures protection degree: IP20

Cod. SAU-URO

Acquisition module with peristaltic pump and the following features:

SAU-URO power supply: SKYNET ELECTRONIC SNP-A129-M

- SAU-URO Enclosures protection degree: IP20

Size and weight:

- High : 32 cm;
- Large : 13 cm;
- Depth: 29 cm;
- Weight: < 5 Kg

Peristaltic pump

- 4 rolls;
- Adjustable from 0 to 200 ml/min;
- It works with the pump line *cod. WTP-SET*

Unit Display :

It shows the Unit status, the working peripherals and alarm codes

Cod. SAU-PRS:

Pressure Module

- Module of 4 pressure channels
- Maximum 2 Modules
- Sampling : max 100 Hz per channel
- Range: -80 mmHg up +400 mmHg;
- Sensitivity: 0,1 mmHg;
- Accuracy: 1% full scale;
- A/D Converter : 16 bit;
- Enclosures protection degree: IP20

Pressure transducers:

Cod. BDPT-9300;

- Range di : da --300 a +400 mmHg;
- Max overpressure : +4000mmHg;
- Sensitivity: 5µV/V/mmHg (+/- 1%);
- Sensitivity on temperature : ≤ 0,1%/°C;
- Drift of the zero point for temperature: ≤0,2 mmHg/°C;
- Hysteresis: < 1,66%;
- Voltage deviation (offset): ≤25 mmHg;
- Output Impedance: 356Ω +/- 1%;

- Operative temperature Range: from +15°C to +40°C;
- Dispersion current: ≤ 10 µA;

Cod. WTH4

Catheter withdrawer :

- Operative length: 35 cm;
- Number of selectable speeds: 24 (from 0,25 mm/sec up to a 50 mm/sec);
- Enclosures protection degree: IP20

Cod. SAU-EMG:

Electromyographic Module with assessment of contact

- Max Sampling rate: 6 KHz;
- Range : -2000, +2000 µ V;
- Sensitivity: 1 µ V;
- Accuracy 1% full scale;
- Enclosures protection degree: IP21

To this module the following cables can be plugged:

- Cable for needle electrodes ***cod. MF-C001***;
- Cable for surface electrodes ***cod. MF-C004;***

Cod. SAU-EMG/LS:

Electromyographic channel without impedance for surface electrodes

- Max Sampling rate: 1 KHz;
- Range : -2000, +2000 µ V;
- Sensitivity: 1 µ V;
- Accuracy 1% full scale;
- Enclosures protection degree: IP21

Cod. SAU-EMG/LN:

Electromyographic channel without impedance for needle electrodes

- Max Sampling rate: 1 KHz;
- Range : -2000, +2000 µ V;
- Sensitivity: 1 µ V;
- Accuracy 1% full scale;
- Enclosures protection degree: IP21

Cod. FLW4/SAU

Wired Flowmeter::

- Built-in amplifier to elaborate the signals of urine volume
- 12 bit A/D converter ,
- Sampling rate : 10 Hz
- Range: from 1 ml to 2000 ml
- Sensitivity: 0.2 ml
- Cable 8 m long
- Supplied with demountable stand pole with load cell , funnel and graduated beaker of 2000 ml
- Enclosures protection degree: IP21

Cod. SAU/VLM

Infused volume unit:

- Range: from 1 ml to 2000 ml
- Sensitivity: 0.2 ml
- Cable 2 m long
- Enclosures protection degree: IP21

URODYNAMIC Software Ref. PICO3000

- Patient database, MS-Access® compatible with Query function
- Test archive
- Routines archive capable to store up to 100 parameter setting pages.
- Research function according to several keys, user-defined.
- Medical report based on templates custom-made. Report saved in Word, PDF or other formats like JPG etcc
- Automatic calibration (zeroing) at the beginning of the test.
- Software WINSUPE for testing the acquisition board , channels and peripherals. It allows the user to re-calibrated the channels in a very easy way.
- Software for urodynamics provided with Post processing, post filtering. Data Exchange-ICS, Data Export software
- Flowmetry with Siroki and Liverpool nomograms (flow nomograms)
- Cystometry with calculation of the markers and compliance and Ghoniem diagram to evaluate the compliance
- Pressure Flow study (voiding cystometry)
- Advanced Urodynamic Analysis software for advanced elaboration of Pressure-Flow study results including: ICS provisional plot, Schäfer's nomograms, Abrams Griffith plot, Chess classification according to Prof. Höfner, PURR, relationship according to Dr. Schäfer, plots of Detrusor Contraction Speed, Detrusor Contraction Power with calculation of WF . In Female the Blavais nomogram is shown
- Urethral pressure profile at rest and during stress/ coughing with calculation of transmission ratio and Pclo.
- Valsalva Leak Point Pressure and Cough Leak Point Pressure for the evaluation of the incontinence in Gynaecology application
- Parameters analysed: Pves, Pabd, Pdet, Pura, Pclo, Infused volume, Micturition flow, EMG , UPP measurements.
- Artefact detection program and functions to isolate/eliminate intervals with the artefact
- Up to 10 dynamic channels displayed on monitor. The user can select the channels of interest.
- Software package for biofeedback training

MEDICA

DICHIARAZIONE DI CONFORMITA' CE N°
EC DECLARATION OF CONFORMITY NO.

MPDP

QUESTA DICHIARAZIONE E' VALIDA SINO AL
THIS DECLARATION IS VALID UNTIL **15/05/2019**

FABBRICANTE ***MANUFACTURER***	**MEDICA S.p.A.** **Via degli Artigiani, 7** **41036 - Medolla (Modena)** **ITALY**
PRODOTTO ***PRODUCT***	**Apparecchiatura diagnostico/riabilitativa per urodinamica** (vedi elenco allegato) ***Diagnostic/rehabilitation equipment for urodynamic*** *(see attached list)*
CLASSIFICAZIONE (in conformità all'Allegato IX del D.L.vo n° 46/97, regola 11) ***CLASSIFICATION*** *(according to Annex IX of D.L.vo n° 46/97, rule 11)*	**IIb**
CRITERIO DI VALUTAZIONE DELLA CONFORMITA' ***CONFORMITY ASSESSMENT ROUTE***	**Allegato II del D.L.vo n° 46/97** ***Annex II of D.L.vo n° 46/97***

Con La presente noi Dichiariamo che i prodotti sopra menzionati sono conformi alle disposizoni del D.L.vo n° 46/97, recepimento italiano della Direttiva del Consiglio n° 93/42/CEE riguardante i Dispositivi Medici, intesa nella sua versione corrente e compresa di tutte le modifiche successive. Tutta la documentazione applicabile è conservata presso la sede del Fabbricante. Il documento viene rilasciato sotto la totale responsabilità del fabbricante.

Herewith we declare that the above mentioned products meet the provisions of D.L.vo n° 46/97, the Italian acknowledgement of the Council Directive 93/42/CEE concerning Medical Devices, to be intended in the current version, including all subsequent changes. Applicable documents are retained at the Manufacturer head office. The document is issued under the full responsibility of the manufacturer.

LEGGI APPLICATE ***APPLIED LAWS***		**D.L.vo n° 46/97**
NORME APPLICATE ***APPLIED STANDARDS***		**UNI CEI EN ISO 13485:2016** **UNI EN ISO 9001:2015**
CERTIFICAZIONI ***CERTIFICATIONS***	**CERTIFICATO CE** ***EC CERTIFICATE***	**MED 23010 - A**
	UNI CEI EN ISO 13485:2016	**3686 - M**
	UNI EN ISO 9001:2015	**3686 - A**
ENTE NOTIFICATO ***NOTIFIED BODY***	**KIWA CERMET ITALIA S.p.A** **Via Cadriano 23, 40057** **Granarolo dell'Emilia (BO)**	**n° identificazione:** ***identification no.:*** **0476**
LUOGO E DATA DI EMISSIONE ***PLACE AND DATE OF ISSUE***		**Medolla (Modena) - ITALY** **15/05/2018**

FIRMA (NOME E RUOLO)
SIGNATURE (NAME AND POSITION)

Ing. Luciano Fecondini
Direttore Generale
General Manager

Dott. Antonio Rossetti
Responsabile QA/RA
QA/RA Manager

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ALLEGATO ALLA DICHIARAZIONE DI CONFORMITA' CE N°

Il presente documento è parte integrante della Dichiarazione di Conformità CE

ANNEX TO THE EC DECLARATION OF CONFORMITY NO.

this document is an integral part of the CE Declaration of Conformity

MPDP

ultimo aggiornamento:
last update:
15/05/2018

CODICE / CODE	DESCRIZIONE / DESCRIPTION
PICO SMART	Apparecchiatura diagnostico/riabilitativa per urodinamica / Diagnostic/rehabilitation equipment for urodynamic

CERTIFICATE

Reg. Number	3686 - A	Valid From	2021-03-22
First issue date	2003-03-24	Last change date	2021-03-22
Valid Until	2024-03-23	IAF Sector	19, 14, 29
Previous expiry date			

Quality Management System Certificate

ISO 9001:2015

We certify that the Quality Management System of the Organization:

MEDICA GROUP

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Design and production of active medical devices for monitoring, blood treatment and organ perfusion. Design and production of non-active medical devices for urology, gastroenterology, blood treatment and ultrafiltration. Molding of plastic components for medical devices. Sterilization with ethylene oxide of non-active medical devices. Marketing of general non-active, non-implantable medical devices, general active medical devices. Production of filters and components for purification and filtration systems. Design and production of equipment for assembly and testing of medical devices.

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.
This certificate is composed of 2 pages. The following technical datasheet provides details concerning the scope of certification.

MEDICA GROUP

Registered Headquarters
MEDICA S.p.A. - Via degli Artigiani, 7 41036 Medolla (MO) Italy

Certified Sites
MEDICA S.p.A. - Via degli Artigiani, 7 41036 Medolla (MO) Italy
MEDICA S.p.A. - Via della Beverara 46/D 40100 Bologna Italy
MEDICA S.p.A. - Via Posta Vecchia, 23 41037 Mirandola (MO) Italy
MEDICA MÉDITERRANÉE s.a.r.l. - Z.I. Menzel Jemil, lot n. 53 bis 7080 7080 Bizerte Tunisia
SAR-MED S.r.l. - Via Centauro, 16 09016 Iglesias (SU) Italy
SAR-MED S.r.l. - Via Centauro, 6 09016 Iglesias (SU) Italy
TECNOIDEAL S.r.l. - Via L. Cazzuoli 43 41037 Mirandola (MO) Italy

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E-mail: info@kiwacermet.it
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CERTIFICATE

Reg. Number	3686 - A	Valid From	2021-03-22
First issue date	2003-03-24	Last change date	2021-03-22
Valid Until	2024-03-23	IAF Sector	19, 14, 29
Previous expiry date			

Data sheet attached to the Certificate

ISO 9001:2015

Operational Unit	*Application field*
Medica S.p.A.	Design and production of active medical devices for monitoring, blood treatment and organ perfusion. Design and production of non-active medical devices for urology, gastroenterology, blood treatment. Marketing of general non-active, non-implantable medical devices.
Sar-med S.r.l.	Production of non-active medical devices for hemodialysis, catheters and accessories. Production of non-active medical devices for blood treatment and ultrafiltration according to customer specifications. Production of filters for purification and filtration systems.
Medica Mediterranée S.a.r.l.	Molding of plastic components for medical devices according to customer specifications. Assembling of non-active medical devices according to customer specifications. Sterilization with ethylene oxide of non-active medical devices.
Tecnoideal S.r.l.	Design and production of active medical devices for monitoring, blood treatment and organ perfusion according to customer specifications. Design and production of equipment for assembly and testing of medical devices.

Chief Operating Officer
Giampiero Belcredi

Kiwa Cermet Italia S.p.A.
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www.kiwa.it

SGQ N° 007A

CERTIFICATE

Reg. Number	3686 - M	Valid From	2021-03-22
First issue date	2003-03-24	Last change date	2021-03-22
Valid Until	2024-03-23		
Previous expiry date			

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

MEDICA GROUP

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design and production of active medical devices for monitoring, blood treatment and organ perfusion. Design and production of non-active medical devices for urology, gastroenterology, blood treatment and ultrafiltration. Molding of plastic components for medical devices. Sterilization with ethylene oxide of non-active medical devices. Marketing of general non-active, non-implantable medical devices, general active medical devices.

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 2 pages. The following data sheet provides application field details.

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Valid Until	2024-03-23		
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Data sheet attached to the Certificate

ISO 13485:2016

Operational Unit	*Application field*
Medica S.p.A.	Design and production of active medical devices for monitoring, blood treatment and organ perfusion. Design and production of non-active medical devices for urology, gastroenterology, blood treatment. Marketing of general non-active, non -implantable medical devices, general active medical devices.
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