Anexa 2 Sistem de impregnare (incluzionare) în parafină, EC500

Amplasare Pe masă Mod de operare Manual Tip suprafață Anticorozivă Material de impregnare a probei Parafină Construcția dispozitivului Modular **Sistemul de parafinare** Rezervor de parafină Minimum 4 litri, cu ajustare a temperaturii Interval de temperatură a rezervorului de parafină 50 – 70 °C Compartiment de depozitare a matricilor Da, cu ajustare a temperaturii Interval de temperatură a compartimentului pentru matrici 50 – 70 °C Compartiment de depozitare a casetelor cu țesut Da, cu ajustare a temperaturii Interval de temperatură a compartimentului pentru caste cu țesut 50 – 70 °C Suprafața de lucru Încălzită Zonă de răcire a matricei Da Sursă de lumină Da, integrată în dispensor Mod de turnare Cu pedală/buton funcțional comode Ajustarea fluxului de parafină Da Interfața cu utilizator Ecran **Sistemul de răcire a blocurilor de parafină** Modalitate de răcire Automat sau ajustat de utilizator Suprafața efectivă Pentru minimum 60 blocuri Temperatura minimă de răcire Maximum -6 °C **Funcționalități speciale** Setarea timpului de lucru Da Setarea temperaturii Da, pentru rezervorul de parafină, zona caldă a dispensorului, zona de răcire a blocurilor, compartimentul de depozitare a casetelor cu țesut, compartimentul de depozitare a matricilor Posibilitate de conectare a pencetelor încălzite electric Da **Sursa de alimentare** Tensiunea de alimentare 220 V, 50 Hz Cablu de alimentare Tip Schuko UPS Minimum o oră de funcționare **Accesorii și consumabile** Parafină în granule 15 kg Pencetă încălzită electric 1 buc Pencete din metal 3 buc Matrice din oțel inoxidabil para free, adîncime de 11-14 mm, dimensiuni laterale 22 x 22 mm ± 2 mm 20 buc Matrice din oțel inoxidabil para free, adîncime de 11-14 mm, dimensiuni laterale 32 x 25 mm ± 2 mm 10 buc Matrice din oțel inoxidabil para free, adîncime de 11-14 mm, dimensiuni laterale 38 x 25 mm ± 2 mm 20 buc Pedală de comandă 1 buc	Amplasare Pe masă Mod de operare Manual Tip suprafață Anticorozivă Material de impregnare a probei Parafină Construcția dispozitivului Modular **Sistemul de parafinare** Rezervor de parafină Minimum 4 litri, cu ajustare a temperaturii Interval de temperatură a rezervorului de parafină 40 – 70 °C Compartiment de depozitare a matricilor Da, cu ajustare a temperaturii Interval de temperatură a compartimentului pentru matrici 40 – 70 °C Compartiment de depozitare a casetelor cu țesut Da, cu ajustare a temperaturii Interval de temperatură a compartimentului pentru caste cu țesut 40 – 70 °C Suprafața de lucru Încălzită Zonă de răcire a matricei Da Sursă de lumină Da, integrată în dispensor Mod de turnare Cu pedală/buton funcțional comode Ajustarea fluxului de parafină Da Interfața cu utilizator Ecran **Sistemul de răcire a blocurilor de parafină** Modalitate de răcire Automat sau ajustat de utilizator Suprafața efectivă Pentru 60 blocuri Temperatura minimă de răcire Maximum -12 °C **Funcționalități speciale** Setarea timpului de lucru Da Setarea temperaturii Da, pentru rezervorul de parafină, zona caldă a dispensorului, zona de răcire a blocurilor, compartimentul de depozitare a casetelor cu țesut, compartimentul de depozitare a matricilor Posibilitate de conectare a pencetelor încălzite electric Da **Sursa de alimentare** Tensiunea de alimentare 220 V, 50 Hz Cablu de alimentare Tip Schuko UPS Minimum o oră de funcționare **Accesorii și consumabile** Parafină în granule 15 kg Pencetă încălzită electric 1 buc Pencete din metal 3 buc Matrice din oțel inoxidabil para free, adîncime de 11-14 mm, dimensiuni laterale 22 x 22 mm ± 2 mm 20 buc Matrice din oțel inoxidabil para free, adîncime de 11-14 mm, dimensiuni laterale 32 x 25 mm ± 2 mm 10 buc Matrice din oțel inoxidabil para free, adîncime de 11-14 mm, dimensiuni laterale 38 x 25 mm ± 2 mm 20 buc Pedală de comandă 1 buc

Rezervor pentru evacuarea reziduurilor de parafină din sistem 1 buc **Cerințe față de producător și furnizor** Garanție Minimum 5 ani Certificate CE certificat european Standarte ISO 9001, ISO 13485 **Logistică** Manuale de utilizare Da, în limba română sau rusă Manual de service Da, engleză Transportare la locul necesar Da Instalare Da Testare Da Training pentru utilizatori Da, pregătire de lucru, mod de utilizare a dispozitivului, întreținerea zilnică Training pentru personal tehnic Ajustarea, calibrarea, înlăturarea defecțiunilor minore, parole de acces	Rezervor pentru evacuarea reziduurilor de parafină din sistem 1 buc **Cerințe față de producător și furnizor** Garanție 5 ani Certificate CE certificat european Standarte ISO 9001, ISO 13485 **Logistică** Manuale de utilizare Da, în limba română sau rusă Manual de service Da, engleză Transportare la locul necesar Da Instalare Da Testare Da Training pentru utilizatori Da, pregătire de lucru, mod de utilizare a dispozitivului, întreținerea zilnică Training pentru personal tehnic Ajustarea, calibrarea, înlăturarea defecțiunilor minore, parole de acces

NSING CONSOLE

d x h)	
	345 x 641 x 405 mm
	340 x 250 mm
	30,5 Kg
erature range	
	40-70 °C
ps wells	40-70 °C
nnesses	60-75 °C
capacity	5 L
ature	5 °C
	Magnifier
	Footswitch

ressers 1, 2 and 4 mm dip

EC500-3: THERMAL CONSOLE

Dimensions (w x d x h)	
Console	340 x 620 x 385 mm
Cassette storage	269 x 510 x 48 mm
Removable trays	262 x 175 x 55 mm
Mold storage	275 x 170 x 180 mm
Weight	18 kg
Adjustable temperature range (via Dispensing Console)	
Cassette storage	40-70 °C
Mold storage	40-70 °C

ONSOLE

x h)

386 x 613 x 394 mm

375 x 207 mm

24,5 kg

ature range de 0 a -12 °C

Especialidades Médicas Myr S.L
ISO 9001 / 13485 certified company
Lleida, 17-23 - P. I. L'Empalme
43713 Llorenç del Penedès - Spain

Phone. +34 977 66 8020
Fax. +34 977 66 8030
Mail. esp.medicas@myr.com.es
www.myr.com.es

Local Distributor. Contact information.

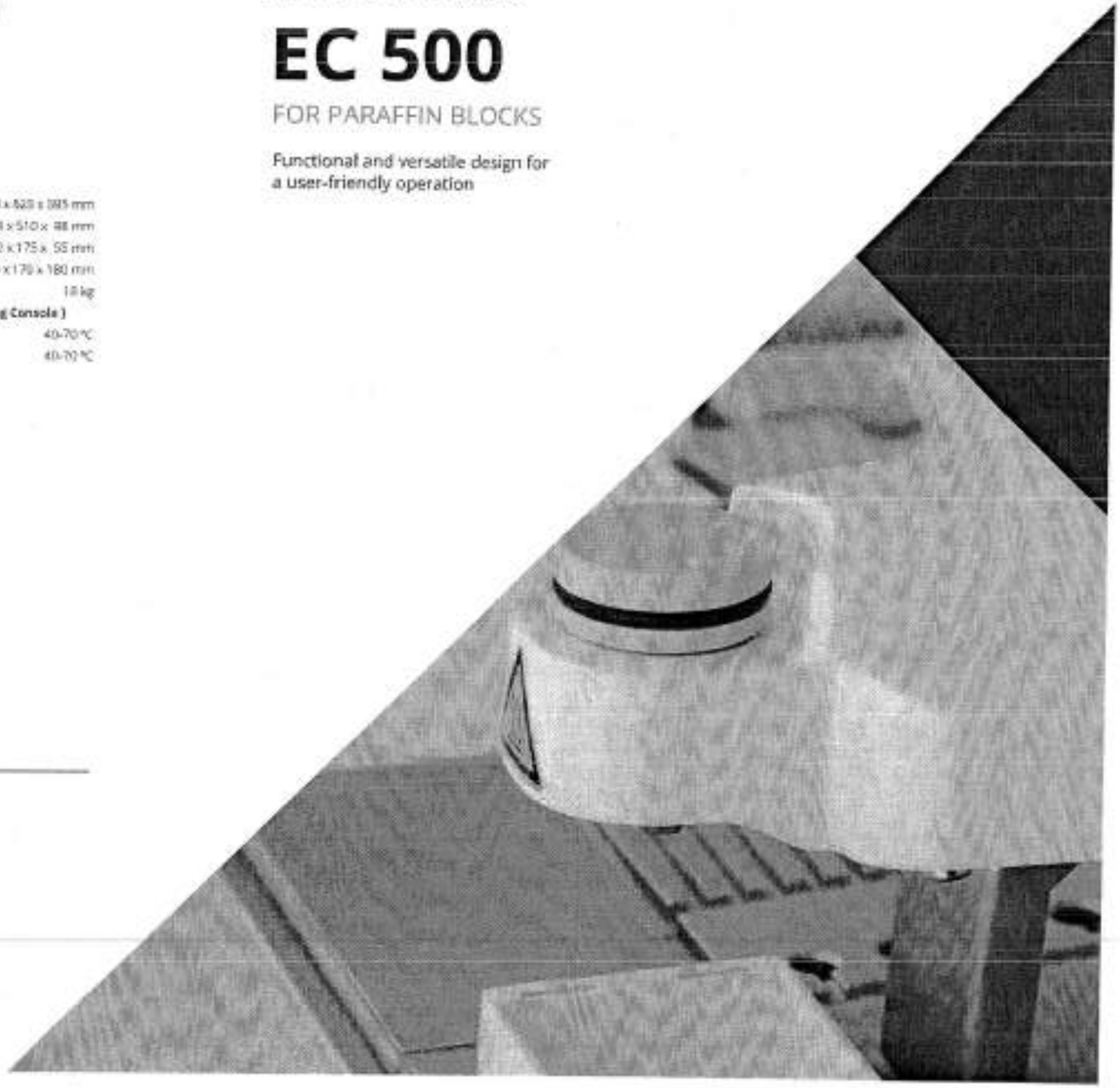
Myr

MODULAR TISSUE EMBEDDING CENTER

EC 500

FOR PARAFFIN BLOCKS

Functional and versatile design for a user-friendly operation

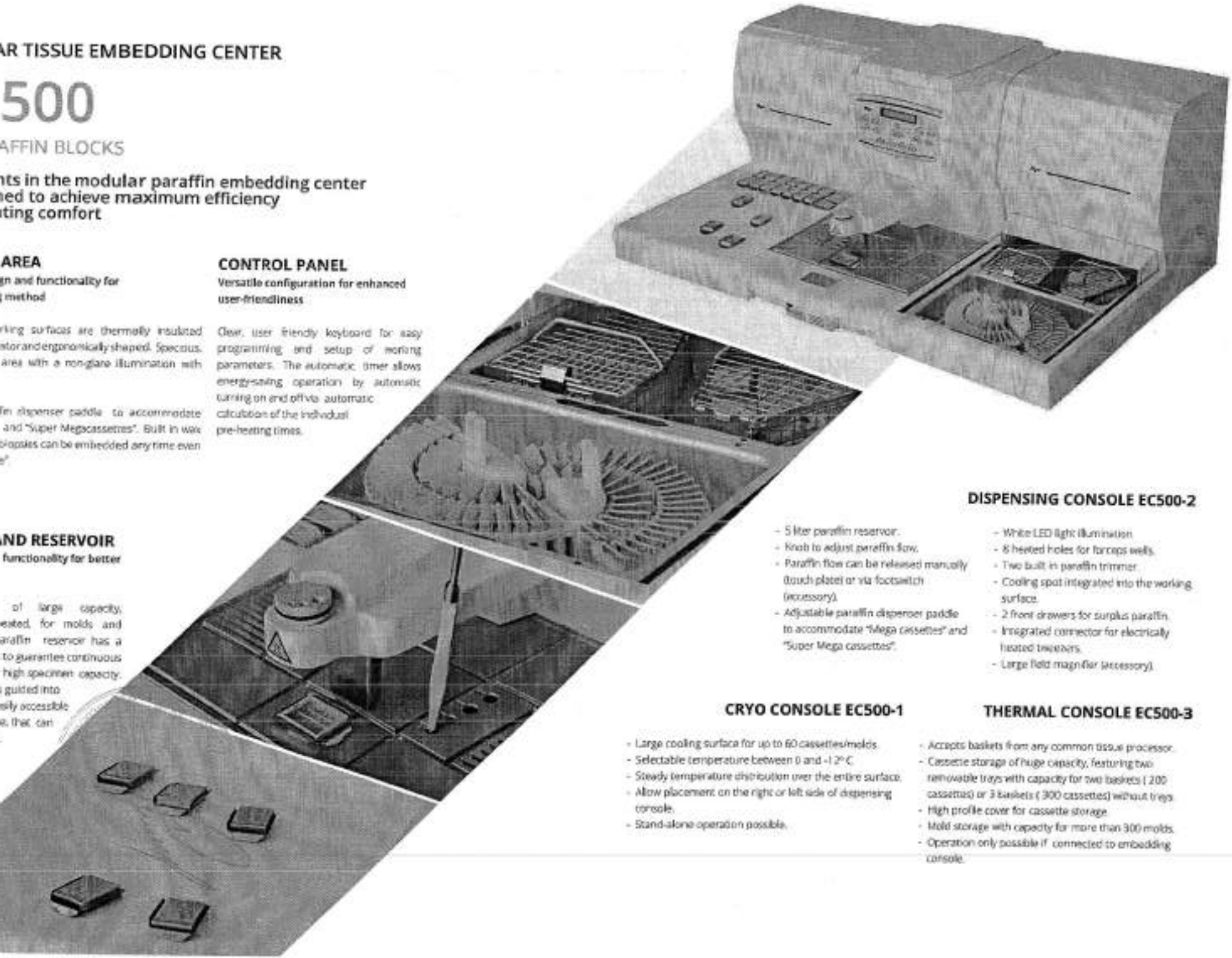


AR TISSUE EMBEDDING CENTER

500

AFFIN BLOCKS

nts in the modular paraffin embedding center
ed to achieve maximum efficiency
ting comfort



AREA

gn and functionality for method

rking surfaces are thermally insulated stor and ergonomically shaped. Specious. area with a non-glare illumination with

fin dispenser paddle to accommodate and "Super Megacassettes". Built in wax bloppies can be embedded any time even e".

CONTROL PANEL

Versatile configuration for enhanced user-friendliness

Clear, user friendly keyboard for easy programming and setup of working parameters. The automatic timer allows energy-saving operation by automatic turning on and off via automatic calculation of the individual pre-heating times.

ND RESERVOIR

functionality for better

of large capacity, eated, for molds and araffin reservoir has a to guarantee continuous high specimen capacity. guided into sily accessible e, that can

DISPENSING CONSOLE EC500-2

- 5 liter paraffin reservoir.
- Knob to adjust paraffin flow.
- Paraffin flow can be released manually (touch plate) or via footswitch (accessory).
- Adjustable paraffin dispenser paddle to accommodate "Mega cassettes" and "Super Mega cassettes".
- White LED light illumination.
- 6 heated holes for forceps wells.
- Two built in paraffin trimmer.
- Cooling spot integrated into the working surface.
- 2 front drawers for surplus paraffin.
- Integrated connector for electrically heated tweezers.
- Large field magnifier (accessory).

CRYO CONSOLE EC500-1

- Large cooling surface for up to 60 cassettes/molds.
- Selectable temperature between 0 and -12° C.
- Steady temperature distribution over the entire surface.
- Allow placement on the right or left side of dispensing console.
- Stand-alone operation possible.

THERMAL CONSOLE EC500-3

- Accepts baskets from any common tissue processor.
- Cassette storage of huge capacity, featuring two removable trays with capacity for two baskets (200 cassettes) or 3 baskets (300 cassettes) without trays.
- High profile cover for cassette storage.
- Mold storage with capacity for more than 300 molds.
- Operation only possible if connected to embedding console.

Especialidades Médicas **Myr** S.L.

EC Declaration of Conformity / *Declaración de Conformidad CE*

Manufacturer / *Fabricante*

Especialidades Médicas MYR S.L.
C/ Lleida 17-23 - 43712 Llorenç del Penedès - Tarragona - Spain

We declare under our own responsibility that the product / *Declaramos bajo nuestra responsabilidad que el producto*

Tissue Embedding Center EC 500 / *Centro de Inclusión EC 500*

meets all the requirements of the following European Directives that are applicable
cumple todos los requisitos aplicables de las siguientes Directivas Europeas

98/79/EC:	In Vitro Diagnostic Devices Directive Classification: General IVD (Other), neither listed in Annex II of IVD 98/79/EC nor IVDs for self-testing purpose
2014/30/EU:	Electromagnetic Compatibility (EMC) Directive
2014/35/EU:	Low Voltage Directive
2011/65/EU:	Restriction of the Use of Hazardous Substances in electrical and electronic equipments (RoHS) Directive

The product is designed and manufactured according to the relevant parts of the following International Standards
El producto está diseñado y fabricado de acuerdo con las partes relevantes de los siguientes estándares

IEC 61010-1: 2010 + A1:2016	**IEC 61010-2-010: 2014**
IEC 61010-2-101: 2015	**EN 61326-1: 2013**
EN 61326-2-6: 2013	**EN ISO 14971: 2012**

In addition, the following standards are applied:
Además, la empresa trabaja de acuerdo con las siguientes normas:

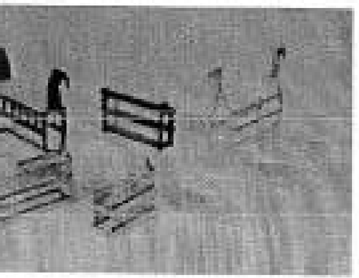
ISO 9001-2015:	Quality Management system
ISO 13485-2016:	Medical Devices - Quality Management system

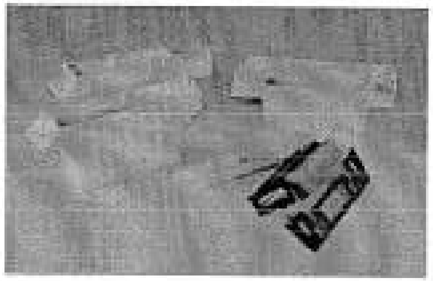
Llorenç del Penedès, 19/06/2019

Francisco Ruiz Robles
Managing Director / *Director General*

Anexa 3 Colorator de lamele, SS 30H

Configuraţia Amplasare pe masă Tip suprafaţă Anticorozivă Mecanismul de translaţie a suportului cu lamele Sistem cu transfer robotic **Sistemul de colorare** Numărul de containere Minim 40 containere Volumul containerului Minim 310 ml Numărul de lamele pe rack Minim 20 de lamele Capacitate totală de colorare pe oră Minim 280 de lamele Uscător de lamele integrat Da **Managementul proceselor** Posibilitate de modificare a programelor de colorare Da Numărul de programe de colorare concomitent Minimum 10 programe Posibilitate de întrerupere manuală a procesului de colorare Da Funcţie de eficientizare a proceselor Da Interfaţa cu utilizatorul Ecran tactil încorporat **Funcţionalităţi speciale** Sistem de filtrare a vaporilor toxici Prin filtru de cărbune Existenţa unui sistem automat de montare a lamelelor pe lamă compatibil Da **Sursa de alimentare** Tensiune de alimentare 220 V, 50 Hz Cablu de alimentare Tip Schuko **Consumabile şi accesorii** Rack pentru lame (26x76 mm) de multiplă utilizare 10 bucăţi Chit de conectare la sursa de apă Da Chit de conectare la sursa de canalizare Da **Cerinţe faţă de producător şi furnizor** Garanţie Minimum 3 ani Certificate CE certificat european Standarte ISO 9001, ISO 13485 **Logistică** Manuale de utilizare Da, în limba română sau rusă Manual de service Da, engleză Transportare la locul necesar Da Instalare Da Testare Da Training pentru utilizatori Da, pregătire de lucru, mod de utilizare a dispozitivului, întreţinerea zilnică Training pentru personal tehnic Ajustarea, calibrarea, înlăturarea defecţiunilor minore, parole de acces Deservire în perioada de garanţie Da	Configuraţia Amplasare pe masă Tip suprafaţă Anticorozivă Mecanismul de translaţie a suportului cu lamele Sistem cu transfer robotic **Sistemul de colorare** Numărul de containere 20 containere Volumul containerului 300 ml Numărul de lamele pe rack 30 de lamele Capacitate totală de colorare pe oră Minim 280 de lamele Uscător de lamele integrat Da **Managementul proceselor** Posibilitate de modificare a programelor de colorare Da Numărul de programe de colorare concomitent 20 programe Posibilitate de întrerupere manuală a procesului de colorare Da Funcţie de eficientizare a proceselor Da Interfaţa cu utilizatorul Ecran tactil încorporat **Funcţionalităţi speciale** Sistem de filtrare a vaporilor toxici Prin filtru de cărbune Existenţa unui sistem automat de montare a lamelelor pe lamă compatibil Da **Sursa de alimentare** Tensiune de alimentare 220 V, 50 Hz Cablu de alimentare Tip Schuko **Consumabile şi accesorii** Rack pentru lame (26x76 mm) de multiplă utilizare 10 bucăţi Chit de conectare la sursa de apă Da Chit de conectare la sursa de canalizare Da **Cerinţe faţă de producător şi furnizor** Garanţie Minimum 3 ani Certificate CE certificat european Standarte ISO 9001, ISO 13485 **Logistică** Manuale de utilizare Da, în limba română sau rusă Manual de service Da, engleză Transportare la locul necesar Da Instalare Da Testare Da Training pentru utilizatori Da, pregătire de lucru, mod de utilizare a dispozitivului, întreţinerea zilnică Training pentru personal tehnic Ajustarea, calibrarea, înlăturarea defecţiunilor minore, parole de acces Deservire în perioada de garanţie Da





...ATIONS:

...	Histological and/or Cytological
...pacity	Up to 5 racks simultaneously depending on protocols, load frequency and instrument configuration
...apacity	30 slides
...programs	Up to 30 programs with max. 50 steps each
...time:	From 1 s to 59 m 59 s per step
...ystem	Independently programmable for each station
...parameters	Depth, number of deeps and speed
...	Minimizes carryover from reagent from one station to the next
...ns	20 vessels with individual lid
...tions	Up to 19
...tions capacity	300 ml
...ns	Up to 9
...ns	Up to 2
...tations	Up to 3 (1 if drying station is available)
...on	1 (optional)
...on temperature	30 to 70° C
...tion system	Charcoal filter
...tage	100-240 VAC / 50-60 Hz
...acity	[illegible]
...	1 300 x [illegible]
...	[illegible]
...	55 [illegible]

ORDERING INFORMATION:

SS-30	Automated slide stainer	100-240v / 50-60 Hz
SS-30H	Automated slide stainer with drying station	100-240v / 50-60 Hz

OPTIONAL ACCESSORIES:

SS30-050	Adapter for THERMO-MICROM rack (30 slides)
SS30-200	Load station LEICA racks
SS30-200B	Lid for load station LEICA rack
SS30-201	Adapter for LEICA plastic rack (30 slides)
SS30-201B	Adapter for LEICA metal rack (30 slides)
SS30-202	Adapter for SAKURA rack (20 slides)
SS30-204	Adapter for MEDITE rack (20 slides)
SS30-205	Adapter for MEDITE rack (30 slides)
SS30-210	Megaslides adapter

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Fax. +34 977 66 8080
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www.myr.com.es

Local Distributor, contact information.

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AUTOMATED
SLIDE STAINER

MYREVA SS-30

Flexible and versatile design for optimized staining results

MATED SLIDE STAINER

YREVA SS-30

UTINE STAINING AND SPECIAL STAINING
COLS IN ANATOMICAL PATHOLOGY LABS

e, optimized and user-friendly

ning flexibility allowing simultaneous and automatic various racks with identical and /or different staining This maximizes efficiency and productivity in labs.

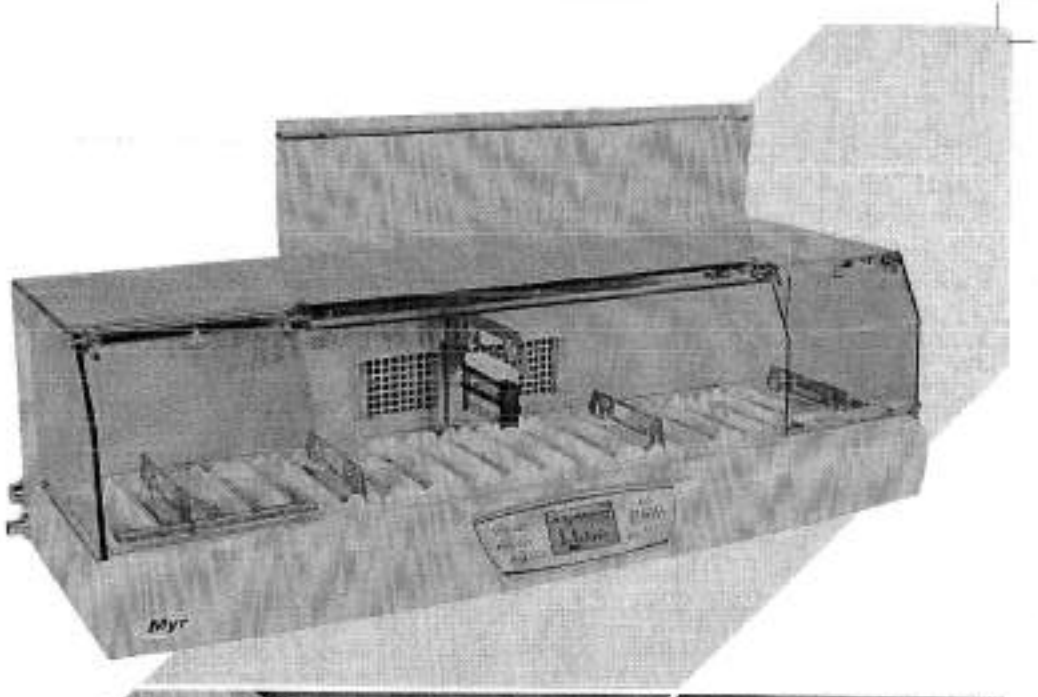
be used for Hemetoxylin and Eosin (H&E), Papanicolau (PAP) and user ining protocols.

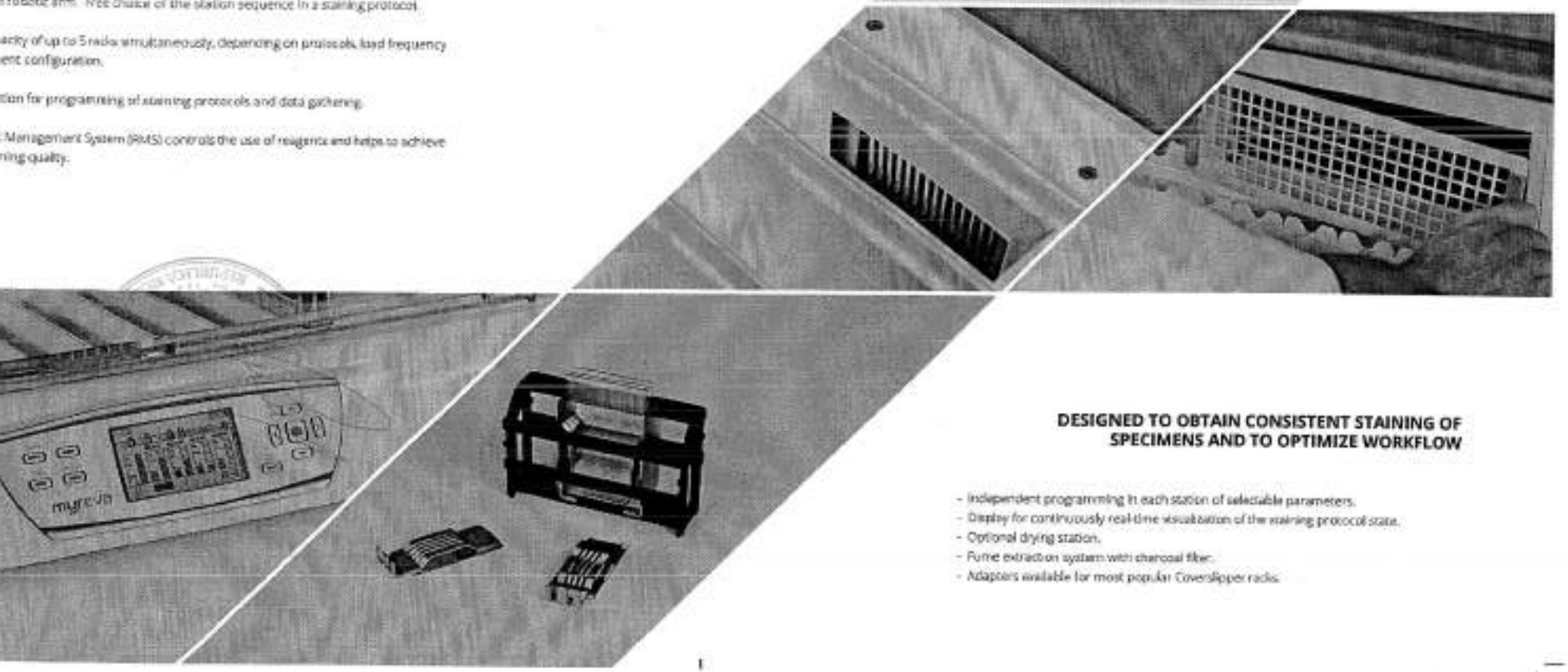
robotic arm. Free choice of the station sequence in a staining protocol.

acity of up to 5 racks simultaneously, depending on protocols, load frequency ent configuration.

tion for programming of staining protocols and data gathering.

Management System (RMS) controls the use of reagents and helps to achieve ning quality.





DESIGNED TO OBTAIN CONSISTENT STAINING OF SPECIMENS AND TO OPTIMIZE WORKFLOW

- Independent programming in each station of selectable parameters.
- Display for continuously real-time visualization of the staining protocol state.
- Optional drying station.
- Fume extraction system with charcoal filter.
- Adapters available for most popular Coverslipper racks.

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EC Declaration of Conformity / *Declaración de Conformidad CE*

Manufacturer / *Fabricante*

Especialidades Médicas MYR S.L.
C/ Lleida 17-23 - 43712 Llorenç del Penedès - Tarragona - Spain

We declare under our own responsibility that the products / *Declaramos bajo nuestra responsabilidad que los productos*

Slide Stainers SS-30 and SS-30H / *Teñidores de Tejidos SS-30 y SS-30H*

meet all the requirements of the following European Directives that are applicable
cumplen todos los requisitos aplicables de las siguientes Directivas Europeas

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IEC 61010-2-101: 2002	**EN 61326-1: 2013**
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ISO 13485-2016:	Medical Devices - Quality Management system

Llorenç del Penedès, 19/06/2019

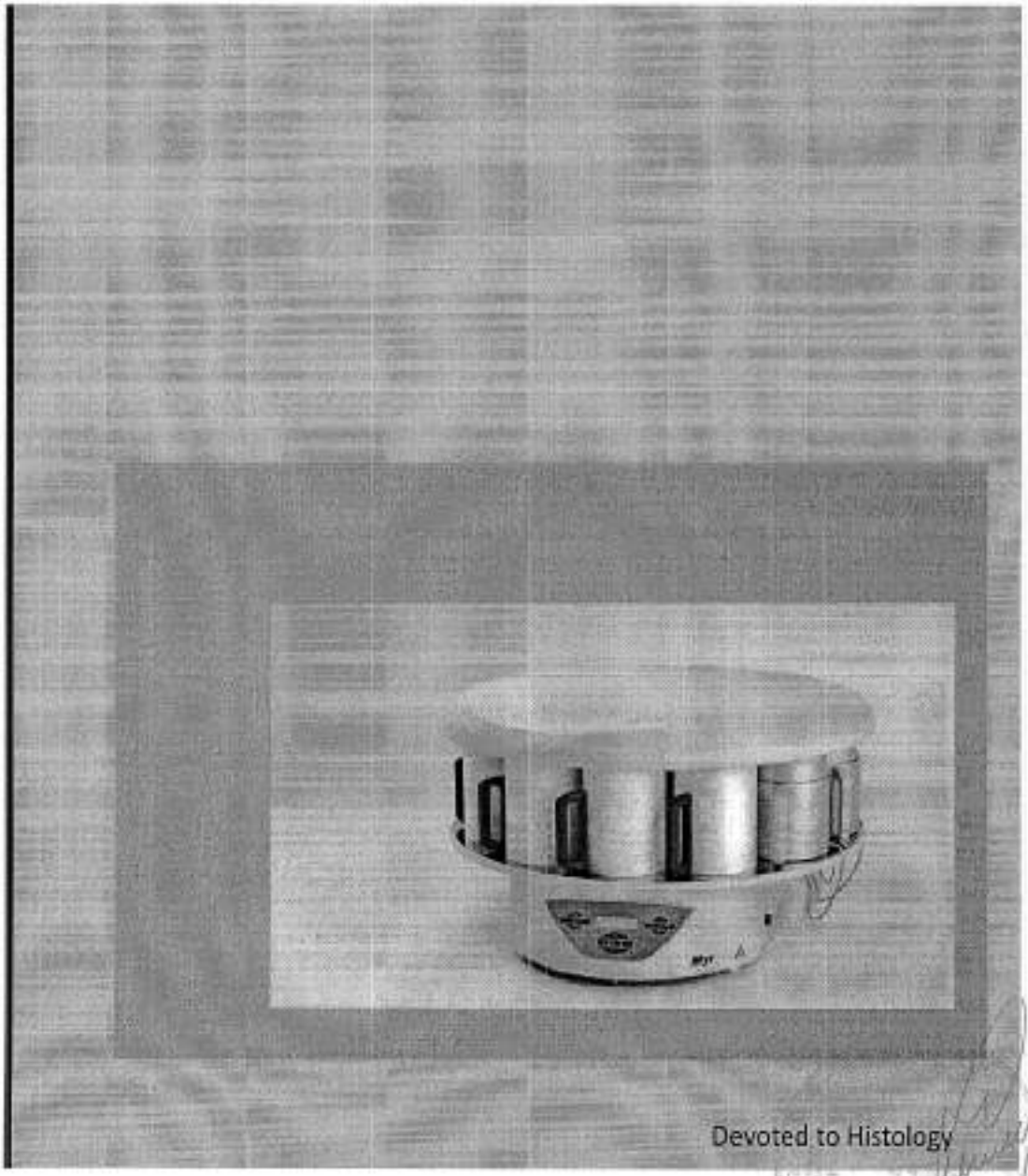
Francisco Ruiz Robles
Managing Director / *Director General*

Anexa 4 Microtom de precizie tip "rotație" inclusiv accesorii și consumabile, M240

Modul de operare Manual	Modul de operare Manual
Tip suprafață Anticorozivă	Tip suprafață Anticorozivă
Material de impregnare a probei Parafină	Material de impregnare a probei Parafină
Greutatea Maximum 30 kg	Greutatea Maximum 33.9 kg
Sistemul de tăiere	**Sistemul de tăiere**
Grosimea feliei tăiate 0,5 – 60 µm	Grosimea feliei tăiate 0,5 – 100 µm
Acuratețea de tăiere a feliei 0,5 – 2 µm / Maximum 0,5 µm; 2 – 10 µm / Maximum 1 µm; 10 – 20 µm / Maximum 2 µm; 20 – 60 µm / Maximum 5 µm.	Acuratețea de tăiere a feliei 0,5 – 5 µm / Maximum 0,5 µm; 5 – 20 µm / Maximum 1 µm; 20 – 60 µm / Maximum 5 µm.
Excursia frontală maximă a sistemului de tăiere Minimum 25 mm	Excursia frontală maximă a sistemului de tăiere Minimum 72 mm
Dimensiunile maxime ale probei Minimum 45 x50 mm	Dimensiunile maxime ale probei Minimum 28 x28 mm
Funcționalități speciale	**Funcționalități speciale**
Retracția probei în procesul de tăiere Da	Retracția probei în procesul de tăiere Da
Sistem de oprire sau de alarmare la finalizarea tăierii probei Da	Sistem de oprire sau de alarmare la finalizarea tăierii probei Da
Blocarea roții de acțiune Da	Blocarea roții de acțiune Da
Posibilitate de modificare a unghiului de tăiere a cuțitului Da	Posibilitate de modificare a unghiului de tăiere a cuțitului Da
Accesorii și consumabile	**Accesorii și consumabile**
Lame de unică utilizare de profil îngust din oțel inoxidabil cu unghiul lamei de 35° (pentru țesut moale) 1000 buc	Lame de unică utilizare de profil îngust din oțel inoxidabil cu unghiul lamei de 35° (pentru țesut moale) 1000 buc
Lame de unică utilizare de profil lat din oțel inoxidabil cu unghiul lamei de 35° (pentru țesut dur) 400 buc	Lame de unică utilizare de profil lat din oțel inoxidabil cu unghiul lamei de 35° (pentru țesut dur) 400 buc
Suport pentru cuțit de profil îngust 1 buc	Suport pentru cuțit de profil îngust 1 buc
Suport pentru cuțit de profil lat 1 buc	Suport pentru cuțit de profil lat 1 buc
Husă de protecție 1 buc	Husă de protecție 1 buc
Ulei pentru lubrifierea angrenajelor 200 ml	Ulei pentru lubrifierea angrenajelor 200 ml
Cerințe față de producător și furnizor	**Cerințe față de producător și furnizor**
Garanție Minimum 5 ani	Garanție 5 ani
Certificate CE certificat european	Certificate CE certificat european
Standarte ISO 9001, ISO 13485	Standarte ISO 9001, ISO 13485
Logistică	**Logistică**
Manuale de utilizare Da, în limba română sau rusă	Manuale de utilizare Da, în limba română sau rusă
Manual de service Da, engleză	Manual de service Da, engleză
Transportare la locul necesar Da	Transportare la locul necesar Da
Instalare Da	Instalare Da
Testare Da	Testare Da
Training pentru utilizatori	Training pentru utilizatori
Da, pregătire de lucru, mod de utilizare a dispozitivului, întreținerea zilnică	Da, pregătire de lucru, mod de utilizare a dispozitivului, întreținerea zilnică
Training pentru personal tehnic	Training pentru personal tehnic
Ajustarea, calibrarea, înlăturarea defecțiunilor minore, parole de acces	Ajustarea, calibrarea, înlăturarea defecțiunilor minore, parole de acces

Myr

Spin Tissue Processor
STP 120
for tissue infiltration



Spin Tissue Processor STP 120

e Processor STP 120 has been developed to meet the requirements of every single e state-of-the-art technology and the unsurpassed processing method of the STP as the most successful Spin Tissue Processors ever. More than 3.000 units installed rld confirm its leading position.

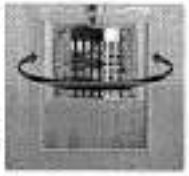
ue technique

a technique that uses alcohols to tissues and replace it with a medium g of tissue. Several methods are used Spin Tissue Processor STP 120 fulfills it ique technique that combines several issue to achieve perfect infiltration le thanks to the world's best spin

TION. The basket with the cassettes e reagent vessel. In this position, 60 rpm and changes the rotational econds. The rotational agitation achieves a perfect infiltration of tissue, an homogeneous mixture of the reagents and a reduction of processing time. To get better results, user can start optionally a shaking process.

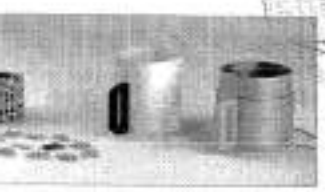
SHAKING. This movement can be optionally activated on the control panel and allows the basket to perform an up-down movement inside the vessel that combined with the rotational agitation fulfills an helicoidal movement that increases infiltration quality at a high degree of precision. At the end of this process, baskets start centrifuging.

CENTRIFUGING. This function is activated as soon as the infiltration time comes to an end. The basket rises above the reagent's level but rests inside the vessel. For a period of 60 seconds it starts whirling at 210 rpm and changes the rotational direction every 15 seconds.
This process allows tissue to be optimally drained and avoids carry-over of reagents from one vessel to another.



cessing achieves by this method almost similar results to those obtained with vacuum systems!

- Standard instrument (basic instrument, 10 reagent vessels, 2 paraffin baths, 1 stainless steel basket for 120 cassettes, 1 tool kit and 1 user manual).
- STP 120-1 + fume extraction system with charcoal filter.
- STP 120-2 + 3rd paraffin station and 2nd basket for another 120 cassettes.



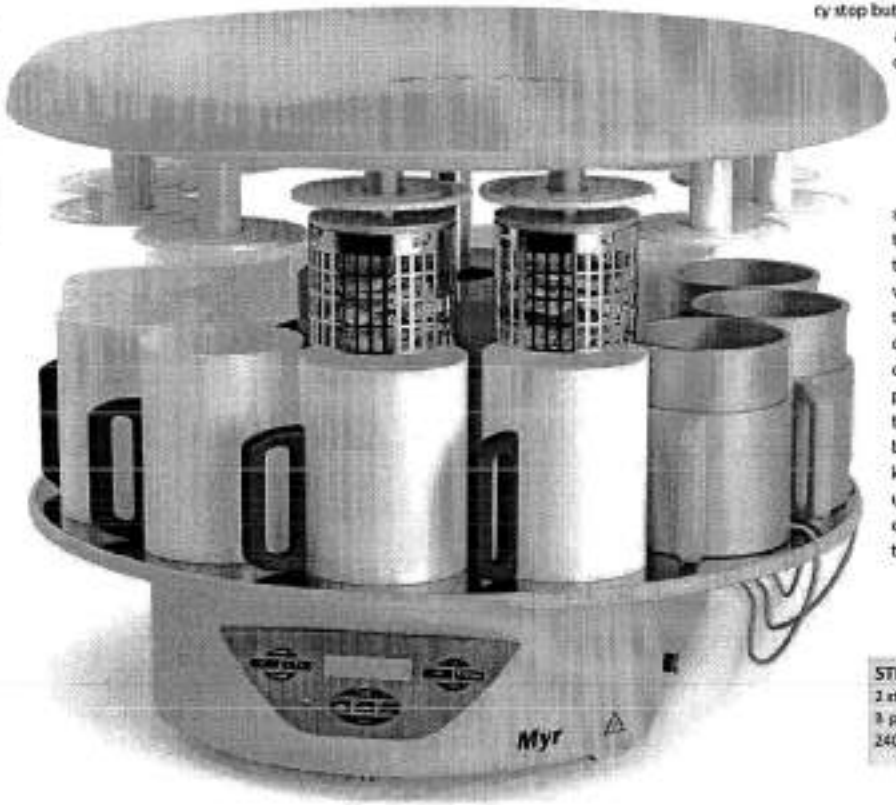
omponents and accessories

Active charcoal filter

Ergonomic control panel
The buttons of the control panel are arranged ergonomically for easy handling. The LCD display shows all the parameters throughout the process, such as programm number, vessel, remaining time, start time, start delay, total duration of the programm, rotational agitation and shaking, basket's centrifuging, temperature of paraffin baths, date and time.

Easy handling
The instrument has capacity to store up to 10 different programs that can be freely set up by the user. Each one of the programs can be started in immediate or delayed mode, without time limit. The instrument can easily be rotated via the four rollers mounted on the base. This allows the user to have fast and safe access to each one of the vessels.

Maximum safety standards for the user and the specimen
The individual cover for each one of the vessels reduce the emission of vapors to a minimum. The STP 120-2 and STP 120-3 versions incorporate a fume extraction system that - through a fan and an active charcoal filter - cleanse the vapors before being discharged into the air.
In case of a power shutdown, the specimens are automatically lowered inside the vessel by means of a battery to protect them against dessication and solid paraffins. Once power is restored, the instrument resumes the program at the same point in which it was interrupted. If it is a long power failure and the paraffin baths become solidified, the safety program will be activated. The instrument will then wait for the baths to be fully liquified before going ahead with the change to the paraffin baths. Emergency motions can be implemented through the battery, such as moving the basket up and down or station change (as long as the basket is not inside a solidified paraffin bath). Instrument is also equipped with an emergency stop button. It is possible to interrupt a program for reloading or advanced unloading of samples.



Alarms during the process
If the specimens remain inside a station for a longer time than the programmed time, e.g. due to a power failure, the display will show a message indicating the station number and the overtime spent in that station compared with the initially programmed time. The acoustic and visual alarms can easily be identified by the user. The keyboard can be locked by the user to avoid an inadvertent change of the process parameters during operation.

STP 120-3:
2 stainless steel baskets +
3 paraffin baths for processing up to 240 cassettes.

In anatomical pathology, tissue processing is a decisive factor. MYR has been offering for more than 25 years a broad range of histology equipment to perform the processing, the embedding and the staining of tissues. Many laboratories are already benefitting from the proven technology, the high reliability and the professional approach of a dedicated team. We meet your requirements. Because we are devoted to Histology.

Technical Data Spin Tissue Processor STP 120

Power requirements

Nominal voltage	100 - 120 V	220-240 V AC (± 10%)
Network's frequency	50/60 Hz	
Consumption	400 VA	
Fuses	115 V (2xT4A)	230 V (2xT2A)
Battery Nickel-Cadmium	12 V 600 mA	

Capacity

Reagent stations	
Number of vessels	10 (9 if 3 paraffin baths are used)
Volume per vessel	1,8 l
Paraffin stations	
Number	2 (optionally 3)
Volume	1,8 l
Nominal voltage	24 V AC
Nominal power per station	100 VA
Temperature setting range	45 - 70 °C in 1°C increments
Overtemperature release	75 °C (± 4 °C)
Cassette baskets	
Number of baskets	1 (optionally 2)
Basket capacity	120 cassettes (optionally 240)

Programming

Number of programs	10 (selectable)
Infiltration time per station	from 1 m to 90 h 59 m
Rotational agitation	selectable
Shaking	selectable
Centrifuging time	selectable
Program start delay	selectable without time limit

Dimensions

Diameter	850 mm
Height	500 - 700 mm
Diameter of the roller's circle	670 mm

Weight

Including packaging	130 kg
Net (fully equipped)	70 kg

Optional equipment

- Spiral support for a second cassette basket (double processing capacity)
- Additional basket
- Additional paraffin bath (necessary when operating the processor with the two baskets)
- Fume extraction system with active charcoal filter

Especialidades Médicas Myr S.L.
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Especialidades Médicas **Myr** S.L.

EC Declaration of Conformity / *Declaración de Conformidad CE*

Manufacturer / *Fabricante*

Especialidades Médicas MYR S.L.
C/ Lleida 17-23 - 43712 Llorenç del Penedès - Tarragona - Spain

We declare under our own responsibility that the product / *Declaramos bajo nuestra responsabilidad que el producto*

Microtome M-240 / *Microtomo M-240*

meets all the requirements of the following European Directives that are applicable
cumple todos los requisitos aplicables de las siguientes Directivas Europeas

98/79/EC:	In Vitro Diagnostic Devices Directive Classification: General IVD (Other), neither listed in Annex II of IVD 98/79/EC nor IVDs for self-testing purpose
2014/30/EU:	Electromagnetic Compatibility (EMC) Directive
2014/35/EU:	Low Voltage Directive
2011/65/EU:	Restriction of the Use of Hazardous Substances in electrical and electronic equipments (RoHS) Directive

The product is designed and manufactured according to the relevant parts of the following International Standards
El producto está diseñado y fabricado de acuerdo con las partes relevantes de los siguientes estándares

IEC 61010-1: 2010 + A1:2016	**IEC 61010-2-101: 2015**
EN 61326-1: 2013	**EN 61326-2-6: 2013**
EN ISO 14971: 2012	

In addition, the following standards are applied:
Además, la empresa trabaja de acuerdo con las siguientes normas:

ISO 9001-2015:	Quality Management system
ISO 13485-2016:	Medical Devices - Quality Management system

Llorenç del Penedès, 19/06/2019

Francisco Ruiz Robles
Managing Director / *Director General*

Anexa 10

Specificație tehnică completată

Ventilator: Hamilton C6, Producător: Hamilton Medical, Țara: Elveția.

Specificație tehnică deplină solicitată	Specificație tehnică deplină propusă
Tip pacient: nou-născut, prematur	**DA** Tip pacient: nou-născut, premature, **adult, copil**
Mobil, pe suport cu rotile	**DA** Mobil, pe suport cu rotile
Brat pentru tuburi, ajustabil	**DA** Brat pentru tuburi, ajustabil
Mîner de transport	**DA** Mîner de transport
Umidificator activ, cu temperatură ajustabilă și măsurarea temperaturii în tubul respirator	**DA** Umidificator activ, cu temperatură ajustabilă și măsurarea temperaturii în tubul respirator
Ecran min. 15 inch, color, touch screen	**DA** Ecran **17 inch**, color, touch screen
Parametrii de ventilare:	**Parametrii de ventilare:**
Mod ventilare: HFO, SIMV, A/C, CPAP, PC	**DA** Mod ventilare: HFO, SIMV, A/C, CPAP, PC
Forma de unda flux: dreptunghiulara, descendentă	**DA** Forma de unda flux: dreptunghiulara, descendentă
Presiunea de insipartie: ≥ 80 cmH2O	**DA** Presiunea de insipartie: - 100 cmH2O
Timpul de inspirate: 0,1-3 s	**DA**Timpul de inspirate: 0,1- 12 s
Volumul tidal: ≥ 2-300 ml	**DA** Volumul tidal: 2-300 ml neonatal si 20-2000 ml adult
Fluxul de inspiratie ≥ 30 lpm	**DA** Fluxul de inspiratie ≥ 30 lpm
PEEP/CPAP ≥ 0-30 cmH2O	**DA** PEEP/CPAP - 0-50 cmH2O **Adult,** 0-25 cm H2O **neonatal**
Frecventa respiratorie in regimuri de ventilare convenționale ≥ 1-150 rpm	**DA** Frecventa respiratorie in regimuri de ventilare convenționale: 1-150 rpm **neonatal**
Frecventa respiratorie in regim de ventilare HFO ≥ 5-16 Hz	**DA** Frecventa respiratorie in regim de ventilare HFO: 5-16 Hz
Amplitudinea HFO ≥ 0-150 cmH2O	**DA** Amplitudinea HFO ≥ 0-150 cmH2O
Trigger presiune	**DA** Trigger presiune
Trigger volum	**DA** Trigger volum
Concentratia de oxigen 21-100 %	**DA** Concentratia de oxigen 21-100 %
Flush O2, ajustabil 21-100 %	**DA** Flush O2, ajustabil 21-100 %
Alarme:	**Alarme:**
Alarme vizuale si sonore	**DA** Alarme vizuale si sonore
Alarme cu prioritate mică, medie și înaltă	**DA** Alarme cu prioritate mică, medie și înaltă
Buton anulare alarmă	**DA** Buton anulare alarmă
Lipsă alimentare gaz aer, oxigen	**DA** Lipsă alimentare gaz aer, oxigen
Lipsă alimentare electrică	**DA** Lipsă alimentare electrică
Eroare de sistem	**DA** Eroare de sistem

Anexa 10

Alarme ajustabile, parametrii ventilatorii	**DA** Alarme ajustabile, parametrii ventilatorii
Parametrii măsurați:	**Parametrii măsurați:**
Presiunea inspiratorie de vîrf	**DA** Presiunea inspiratorie de vîrf
Presiunea medie	**DA** Presiunea medie
PEEP	**DA** PEEP
Rata IE	**DA** Rata IE
Frecventa respiratorie	**DA** Frecventa respiratorie
Volumul tidal	**DA** Volumul tidal
Minut volum	**DA** Minut volum
Scurgerile	**DA** Scurgerile
Complianta	**DA** Complianta
Concentratia O2	**DA** Concentratia O2
Vizualizare grafice:	**Vizualizare grafice:**
Presiune	**DA** Presiune
Flux	**DA** Flux
Volum	**DA** Volum
Presiune-volum	**DA** Presiune-volum
Presiune-flux	**DA** Presiune-flux
Flux-volume	**DA** Flux-volume
Conditiile de functionare:	**Conditiile de functionare:**
Tensiunea 220V, 50 Hz	**DA** Tensiunea 220V, 50 Hz
Presiuena gaz 3-4 bar	**DA** Presiuena gaz 3-4 bar
Furctun cu conectori O2, Aer, tip DIN	**DA** Furctun cu conectori O2, Aer, tip DIN
Accesorii şi consumabile:	**Accesorii şi consumabile:**
Circuite respiratorii reutilizabile nou-născut, 3 buc.	**DA** Circuite respiratorii reutilizabile nou-născut, 3 buc.
Cameră de umidificare reutilizabilă 2 buc.	**DA** Cameră de umidificare reutilizabilă 2 buc.
Filtre antibacteriale 50 buc.	**DA** Filtre antibacteriale 50 buc.
Senzor de debit 2 buc.	**DA** Senzor de debit 2 buc.
Plamăn de test 2 buc.	**DA** Plamăn de test 2 buc.
Cerinţe generale:	**Cerinţe generale:**
Termen de garanţie minim 24 de luni	**DA** Termen de garanţie minim 24 de luni
Timp maxim de intervenţie postgaranţie 24 ore	**DA** Timp maxim de intervenţie postgaranţie 24 ore
Certificat de la producător CE	**DA** Certificat de la producător CE
Certificat de la producător ISO 13485	**DA** Certificat de la producător ISO 13485
Trainingul personalului medical şi tehnic	**DA** Trainingul personalului medical şi tehnic
Instalarea şi punerea în funcţiune la sediul beneficiarului de către reprezentantul autorizat al producătorului .	Instalarea şi punerea în funcţiune la sediul beneficiarului de către reprezentantul autorizat al producătorului .

HAMILTON-C6

Technical specifications for SW version 1.1.x

Ventilation modes

Mode form	Mode name	Mode	Adult/Ped	Neonatal
Volume-controlled, flow-controlled	(S)CMV	Breaths are volume controlled and mandatory, including patient triggered breaths.	✓	--
	SIMV	A fixed rate is set for volume-controlled mandatory breaths. Additional patient triggered breaths between mandatory breaths are spontaneous breaths (with or without pressure support).	✓	--
Volume-targeted, adaptive pressure-controlled	APVcmv / (S)CMV+	Breaths are volume targeted and mandatory.	✓	✓
	APVsimv / SIMV+	Volume-targeted mandatory breaths can be alternated with pressure-supported spontaneous breaths.	✓	✓
Pressure-controlled	PCV+	All breaths, whether triggered by either the patient or the ventilator, are pressure controlled and mandatory.	✓	✓
	P-SIMV+	Mandatory breaths are pressure controlled. Mandatory breaths can be alternated with pressure-supported spontaneous breaths.	✓	✓
	DuoPAP	Mandatory breaths are pressure controlled. Spontaneous breaths can be triggered at both pressure levels.	✓	✓
	APRV	Spontaneous breaths can be continuously triggered. The pressure release between the levels contributes to ventilation.	✓	✓
	SPONT	Every breath is spontaneous, with or without pressure support.	✓	✓
Intelligent ventilation	ASV®	Operator sets %MinVol, PEEP, and Oxygen. Frequency, tidal volume, pressure, and I:E ratio are based on physiological input from the patient.	✓	--
	INTELLiVENT®-ASV	Fully automated management of ventilation and oxygenation based on physiological input from the patient. The underlying mode is ASV.	O	--
Noninvasive ventilation	NIV	Every breath is spontaneous, with or without pressure support.	✓	✓
	NIV-ST	Every breath is spontaneous as long as the patient is breathing above the set rate. A backup rate can be set for mandatory breaths.	✓	✓
	nCPAP-PS	Every breath is spontaneous as long as the patient is breathing above the set rate. A backup rate can be set for mandatory breaths. PS can be set to 0 (= nCPAP).	--	O
Oxygen therapy	HiFlowO2	High flow oxygen therapy. No supported breaths.	O	O

Standard ✓ Option O Not applicable –

Swiss Quality

HAMILTON MEDICAL

Intelligent Ventilation since 1983

Standard configuration and options (in alphabetical order)

Functions	Adult / Ped	Neonatal
Capnography, mainstream (volumetric) and sidestream	O	O
Communication ports: Three COM ports, two USB ports, DVI, Nurse call	✓	✓
Communication protocols: for details see Connectivity brochure	✓	✓
Dynamic Lung (real-time visualization of the lungs)	✓	–
Event log (up to 10,000 events with date and time stamp)	✓	✓
HAMILTON-H900 humidifier control via ventilator	O	O
Inspiratory and expiratory hold maneuver	✓	✓
IntelliCuff® cuff pressure controller control via ventilator	O	O
IntelliSync+ (inspiratory and expiratory trigger synchronization)	O	–
IntelliTrig (leak compensation)	✓	✓
Manual breath / prolonged inspiration	✓	✓
Nebulization (Aerogen®)	O	O
Nebulization (pneumatic)	✓	–
O2 enrichment	✓	✓
On-screen help	✓	✓
P/V Tool® Pro	O	O
Paramagnetic O2 sensor	O	O
Patient group	✓	O
Print screen	✓	✓
Screen lock	✓	✓
Second battery	O	O
SpO2 monitoring	O	O
Standby with timer	✓	✓
Suctioning tool	✓	✓
Transpulmonary pressure monitoring	✓	✓
TRC (tube resistance compensation)	✓	✓
Trends/Loops	✓	✓
Trigger, flow and pressure selectable	✓	✓
Vent Status (Visual representation of ventilator dependancy)	✓	[illegible]

Standard ✓ Option O Not applicable –

"GBG-MLD"

Technical performance data (in alphabetical order)

Description	Specification
Automatic expiratory base flow	Fixed at 6 l/min
Inspiratory pressure	0 to 100 cmH2O
Maximum inspiratory flow	260 l/min
Means of inspiratory triggering	Flow trigger control, pressure trigger control, or optional InnoSync® control
Means of expiratory triggering	Flow cycle (ETS), or optional InnoSync® control
Minimum expiratory time	20% of cycle time; 0.2 to 0.8 s
O2 input flow	150 l/min (at 2.8 bar/280 kPa / 41 psi input pressure)
Oxygen mixer accuracy	± (Volume fraction of 2.5% + 2.5% of actual reading)
Preoperational checks	Tightness test, flow sensor/O2 sensor/CO2 sensor calibration
Tidal volume	Adult/Ped: 20 to 2000 ml Neonatal: 2 to 300 ml

Standards and approvals

Classification	Class IIb, continuously operating according to EC directive 93/42/EEC
Certification	EN 60601-1:2006/A1:2013, IEC 60601-1-2:2014, ANSI/AAMI ES60601-1:2005/(R)2012, ISO 80601-2-12:2011, CAN/CSA-C22.2 NO. 60601-1:14, EN ISO 5356-1:2015, ISO 80601-2-55:2011
Declaration	The HAMILTON-C6 was developed in accordance with pertinent international standards and FDA guidelines. The ventilator is manufactured within an EN ISO 13485 and EN ISO 9001, Council Directive 93/42/EEC, Annex II, Article 3 certified quality management system. The ventilator meets the Essential Requirements of Council Directive 93/42/EEC, Annex I.
Electromagnetic compatibility	According to IEC 60601-1-2:2014
Safety Class	Class I, Type B applied part (ventilator breathing system, VBS), type BF applied parts CO2 sensor including CO2 module connector, humidifier, Aerogen® system, nebulizer, and SpO2 sensor including SpO2 adapter, continuous operation according to IEC 60601-1

Pneumatic specifications

O2	Input pressure	2.8 to 6 bar / 41 to 87 psi
	Connector	DISS (CGA 1240) or NIST
Air supply		Integrated turbine with lifetime warranty
Inspiratory outlet (To patient port)	Connector	ISO 15 mm ID/22 mm OD conical
Expiratory outlet (From patient port)	Connector (on expiratory valve)	ISO 15 mm ID/22 mm OD conical

Electrical specifications

Input power	100 to 240 VAC ±10%, 50/60 Hz	
Power consumption	60 W typical, 310 W maximum	
Battery	Electrical specifications	14.4 V, 6.6 Ah, 98 Wh, 35 W typical, 115 W maximum
	Type	Lithium-ion
	Normal operating time	≥ 90 min with one battery / ≥ 180 min with two batteries

Graphical patient data

Graphic type/Tab name	Options
Waveforms	Pressure, Flow, Volume, Off, PCO2[1], FCO2[1], Plethysmogram[1], Ptrachea, Pes, Ptranspulm
Intelligent panels	Dynamic Lung[1], Vent Status, ASV Graph[1], SNPs (Secondary monitoring parameter)
Trends	1-, 6-, 12-, 24-, or 72-h trend data for a selected parameter or combination of parameters
Loops	Pressure/Volume, Pressure/Flow, Volume/Flow, Volume/PCO2[1], Volume/FCO2[1], Pes/Volume, Ptranspulm/Volume

Alarms[4]

Priority	Alarm
High priority	Apnea time (s), ExpMinVol high/low (l/min), Oxygen high/low (%), Pressure high/low (cmH2O), Flow sensor calibration needed, Exhalation obstructed, Disconnection, Oxygen supply failed
Medium priority	fTotal high/low (b/min), PetCO2 high/low (mmHg), Pressure limitation (cmH2O), Vt high/low (ml), SpO2 high/low, SpOC high/low, %leak, High PEEP, Loss of PEEP, Pulse high/low
Low priority	High SpO2, Loss of external power, Cuff leakage

[1] CO2 + SpO2 option required / [2] For adult/pediatric patients only / [3] Only available in nCPAP mode / [4] For complete list of alarms see user manual

Control settings and ranges[5]

Parameter (units)	Range Adult/Ped	Range Neonatal
Apnea backup	On, Off	On, Off
Cuff pressure (cmH2O)	0 to 50	0 to 50
Expiratory trigger sensitivity ETS (%)	5 to 60	5 to 80
Flow for HiFlowO2 therapy (l/min)	2 to 80	2 to 12
Flow pattern	Square, 50% decelerating, Sine, 100% decelerating	--
Flow trigger (l/min)	0.5 to 20, off	0.1 to 5.0, off
Gender	Male, Female	--
I:E	1:9 to 4:1	1:9 to 4:1
%MinVol (%)	25 to 350	--
Oxygen (%)	21 to 100	21 to 100
P high (cmH2O) (only in DuoPAP and APRV)	0 to 100	0 to 60
P low (cmH2O) (only in APRV)	0 to 50	0 to 25
PasvImit (cmH2O)	5 to 100	5 to 100
Pat. height (cm) (in)	30 to 250 / 12 to 98	--
Pause (%)	0 to 70	--
Pcontrol (cmH2O)	5 to 100	3 to 60
Peak flow (l/min)	1 to 195	--
PEEP/CPAP (cmH2O)	0 to 50	0 to 25
Pinsp (cmH2O)	3 to 100	0 to 60
P-ramp (ms)	0 to 2000	0 to 600
Pressure trigger (cmH2O)	-0.1 to -15.0, off	-0.1 to -15.0, off
Psupport (cmH2O)	0 to 100	0 to 60
Rate (b/min)	1 to 80	1 to 150
Sigh	On, Off	--
T high (s) (only in DuoPAP and APRV)	0.1 to 40	0.1 to 40
T low (s) (only in APRV)	0.2 to 40	0.2 to 40
Ti (s)	0.1 to 12	0.1 to 12
Ti max (s)	1 to 3	0.25 to 3.0
Tip (s)	0 to 8	--
Tpause (s)	0 to 30	0 to 30
TRC compensation (%)	0 to 100	0 to 100
Vt (ml)	20 to 2000	2 to 300
Weight (kg)	--	0.2 to 30.0

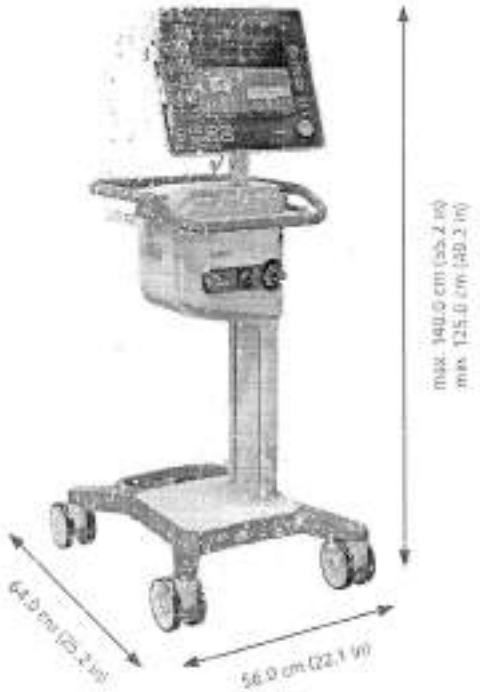
5 Parameter setting and ranges can change depending on the mode

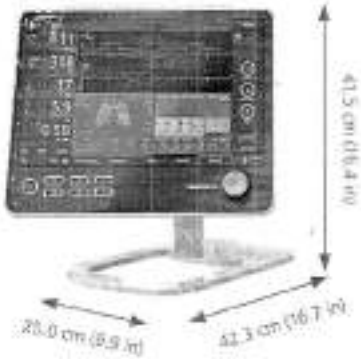
Monitoring parameter

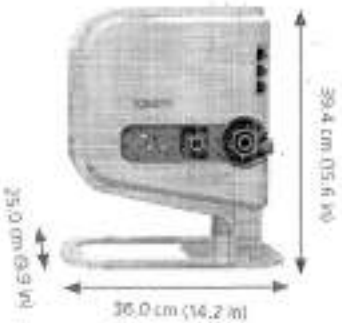
Parameter (units)		Description
Pressure	AutoPEEP (cmH2O)	Unintended positive end-expiratory pressure
	Paw (cmH2O)	Airway pressure
	ΔP (cmH2O)	Driving pressure
	P0.1 (cmH2O)	Airway occlusion pressure
	PTP (cmH2O*s)	Inspiratory pressure time product
	Pcuff (cmH2O)	Cuff pressure
	Ptrans I (cmH2O)	The arithmetic mean value of Ptranspulm over the last 100 ms of the last inspiration.
	Ptrans E (cmH2O)	The arithmetic mean value of Ptranspulm over the last 100 ms of the last expiration.
	PEEP/CPAP (cmH2O)	PEEP (positive end-expiratory pressure) and CPAP (continuous positive airway pressure)
	Pinsp (cmH2O)	Inspiratory pressure
	Pmean (cmH2O)	Mean airway pressure
	Ppeak (cmH2O)	Peak airway pressure
	Pplateau (cmH2O)	Plateau or end-inspiratory pressure
	Pes min (cmH2O)	See PEEP. The pressure is measured through the Pes port instead of using airway pressure.
	Pes max (cmH2O)	See Ppeak. The pressure is measured through the Pes port instead of using airway pressure.
	Pes plateau (cmH2O)	See Pplateau. The pressure is measured through the Pes port instead of using airway pressure.
	Pes PTP (cmH2O)	See PTP. The pressure is measured through the Pes port instead of using airway pressure.
	Pes P0.1 (cmH2O)	See P0.1. The pressure is measured through the Pes port instead of using airway pressure.
Flow	Control Flow (l/min)	The set flow of gas to the patient. HFlowO2 mode only.
	Insp Flow (l/min)	Peak inspiratory flow, spontaneous or mandatory
	Exp Flow (l/min)	Peak expiratory flow
Volume	ExpMinVol or MinVol NIV (l/min)	Expiratory minute volume
	MVSpont or MVSpont NIV (l/min)	Spontaneous expiratory minute volume
	VTE or VTE NIV (ml)	Expiratory tidal volume
	VTESpont (ml)	Spontaneous expiratory tidal volume
	VTI or VTI NIV (ml)	Inspiratory tidal volume
	VTIBW	Tidal volume according to ideal body weight (IBW) for adult and child patients and
	VTIWeight (ml/kg)	according to the actual body weight for neonatal patients
	VLeak (%) or MVLeak (l/min)	Leakage percent or total minute volume leakage

Monitoring parameter (continued)

Parameter (units)		Description
CO2	FetCO2 (%)	Fractional end-tidal CO2 concentration
	PetCO2 (mmHg)	End-tidal CO2 pressure
	slopeCO2 (%CO2 / l)	Slope of the alveolar plateau in the PetCO2 curve, indicating the volume/flow status of the lungs
	Vtalv (ml)	Alveolar tidal ventilation
	V'alv (l/min)	Alveolar minute ventilation
	V'CO2 (ml/min)	CO2 elimination
	VDaw (ml)	Airway dead space
	VDaw/VTE (%)	Airway dead space fraction at the airway opening
	VeCO2 (ml)	Exhaled CO2 volume
	ViCO2 (ml)	Inspired CO2 volume
SpO2	SpO2 (%)	Oxygen saturation
	Pulse (1/min)	Pulse
	Plethysmogram	The waveform that visualizes the pulsating blood volume; it is delivered by the pulse oximeter.
	SpO2/FiO2 (%)	The SpO2/FiO2 ratio (%) is an approximation of the PaO2/FiO2 ratio, which, in contrast to PaO2/FiO2, can be calculated noninvasively and continuously.
	PI (%)	Perfusion index
	PVI (%)	Pleth variability index
	SpCO (ml/dl)* (%)*	Carboxyhaemoglobin saturation
	SpMet (%)	Methaemoglobin saturation
	SpHb (g/dl) (mmol/l)	Total haemoglobin
	SpOC (ml/dl)	Oxygen content
Oxygen	Oxygen (%)	Oxygen concentration of the delivered gas
Time	I:E	Inspiratory:expiratory ratio
	fControl (b/min)	Mandatory breath frequency
	fSpont (b/min)	Spontaneous breathing frequency
	fTotal (b/min)	Total breathing frequency
	TI (s)	Inspiratory time
	TE (s)	Expiratory time
	Pause (s)	Inspiratory pause or plateau
Lung mechanics	Cstat (ml/cmH2O)	Static compliance
	P0.1 (cmH2O)	Airway occlusion pressure
	PTP (cmH2O*s)	Pressure time product
	RCexp (s)	Expiratory time constant
	Rinsp (cmH2O/l/s)	Inspiratory flow resistance
	RSB (1/l*min))	Rapid shallow breathing





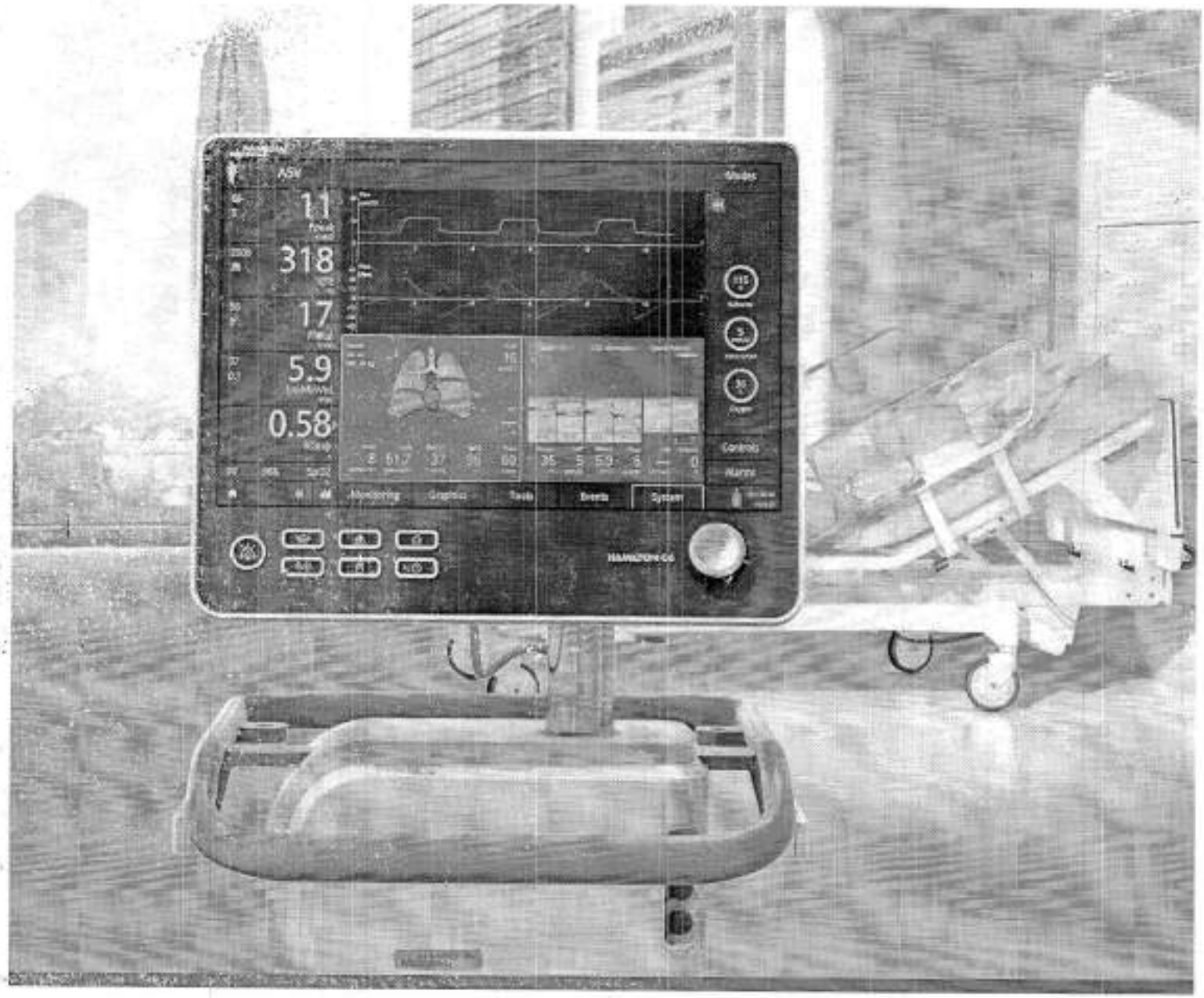


Physical characteristics

Weight	Monitor (interaction panel) 7.8 kg (17.2 lb), with shelf mount: 10.0 kg (22.0 lb)
	Ventilation unit, shelf mount: 10.5 kg (23.15 lb)
	46 kg (101 lb) with trolley, monitor, ventilation unit
	The trolley can accommodate a maximum safe working load of 80 kg (176 lb)
Dimensions	See graphic above
Monitor	Type: Color TFT, Size: 1920 x 1200 pixels, 17 in (431.8 mm) diagonal
Monitor mounting options	VESA, pole mount, rail mount, handle mount
Trolley accessories	Basket for suctioning catheter, O2 bottle holding system, HAMILTON-H900 mounting system

Manufacturer:
Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz, Switzerland
☎ +41 (0)58 610 10 20
info@hamilton-medical.com
www.hamilton-medical.com

HAMILTON-C6



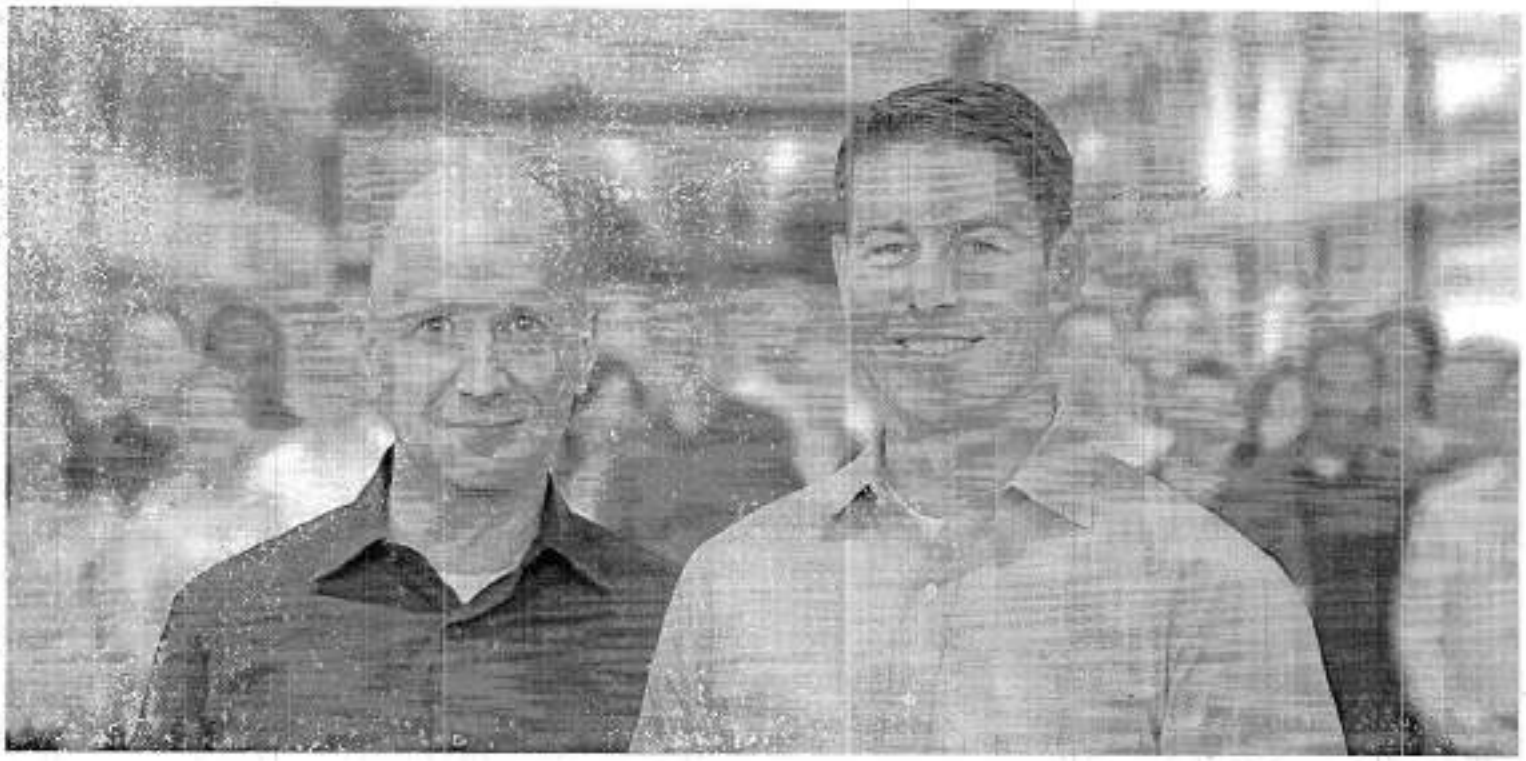
HAMILTON-C6

The next generation of intelligent ICU ventilators

Swiss Quality

HAMILTON MEDICAL

Intelligent Ventilation since 1983



We live for ventilation technology

We live for ventilation technology that helps caregivers improve the lives of their critically ill patients. We believe that innovation is essential to meet the demands of critical care. To us, innovation is about realizing visionary new ideas and continuously improving existing products, always keeping patient safety and ease of use in focus.

We learn from our customers and from multi-disciplinary experts. And we invest in long-term research and development. We develop Intelligent Ventilation solutions: devices and consumables for the ventilation of all critically ill patients – from neonates to adults.

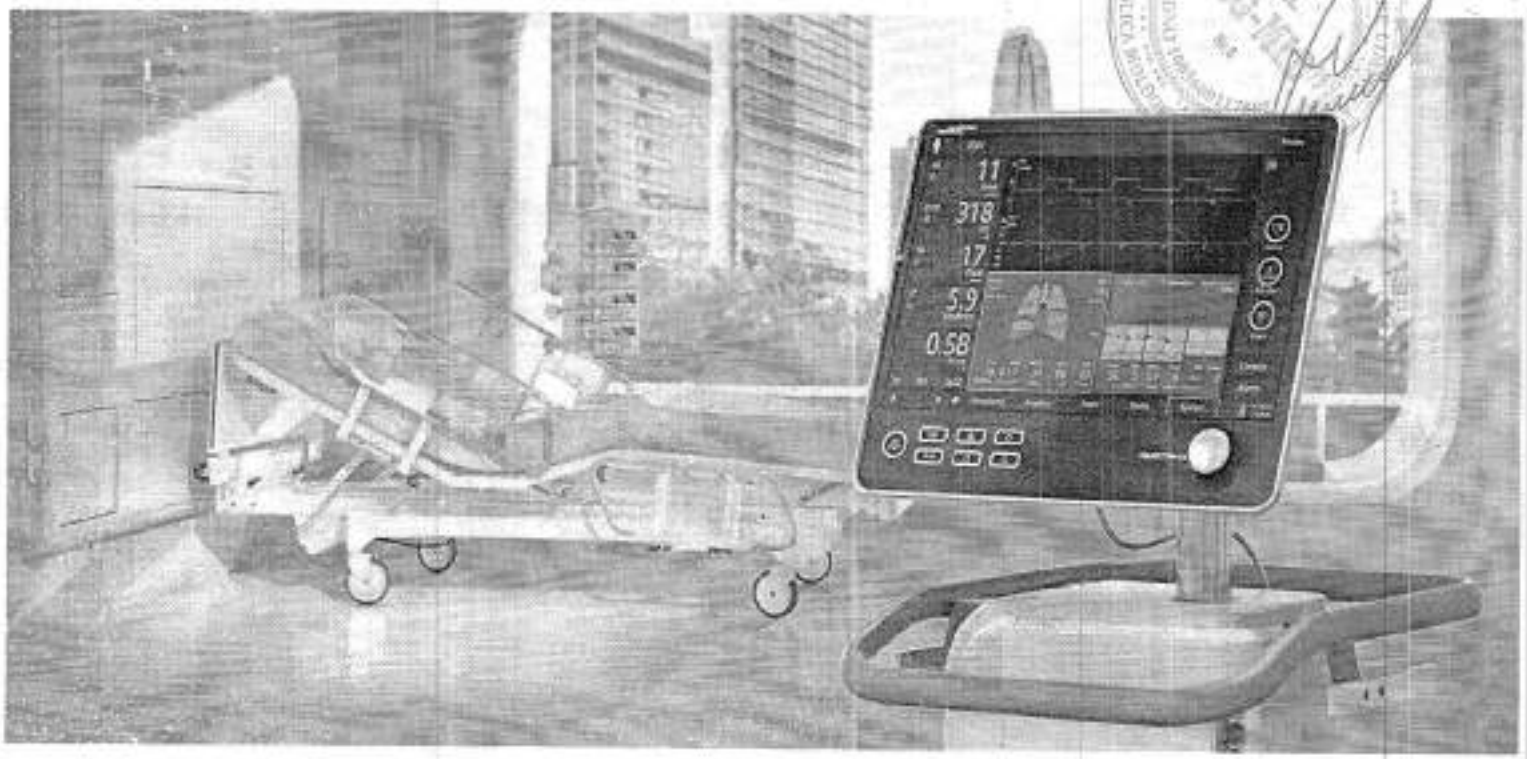
Jens Hallek
President

Bob Hamilton
Member of the board

Meet the HAMILTON-C6

The HAMILTON-C6 represents a new generation of high-end ventilators. The combination of modularity, ease of use, mobility, and advanced features allows you to individualize your patient's ventilation therapy:

- ✓ State-of-the-art ventilation modes for adult, pediatric, and neonatal patients
- ✓ Adaptive, lung-protective ventilation modes ASV® and INTELLIVENT®-ASV
- ✓ IntelliSync+ real-time patient synchronization
- ✓ High-performance noninvasive ventilation
- ✓ High flow oxygen therapy
- ✓ P/V Tool Pro for lung assessment and recruitment
- ✓ Transpulmonary pressure measurement
- ✓ Integrated IntelliCuff® pressure controller
- ✓ Integrated HAMILTON-H900 humidifier control

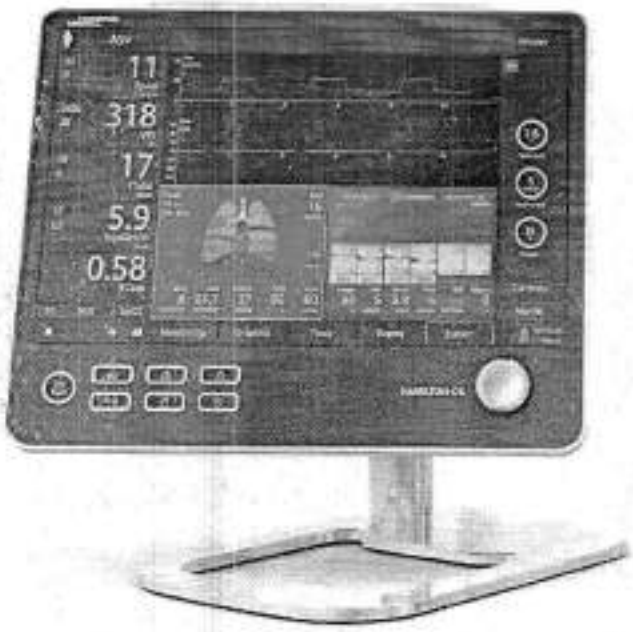


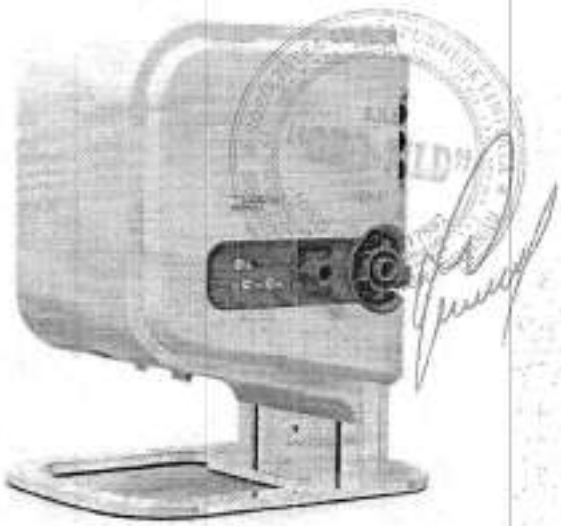
Slender, flexible, convenient

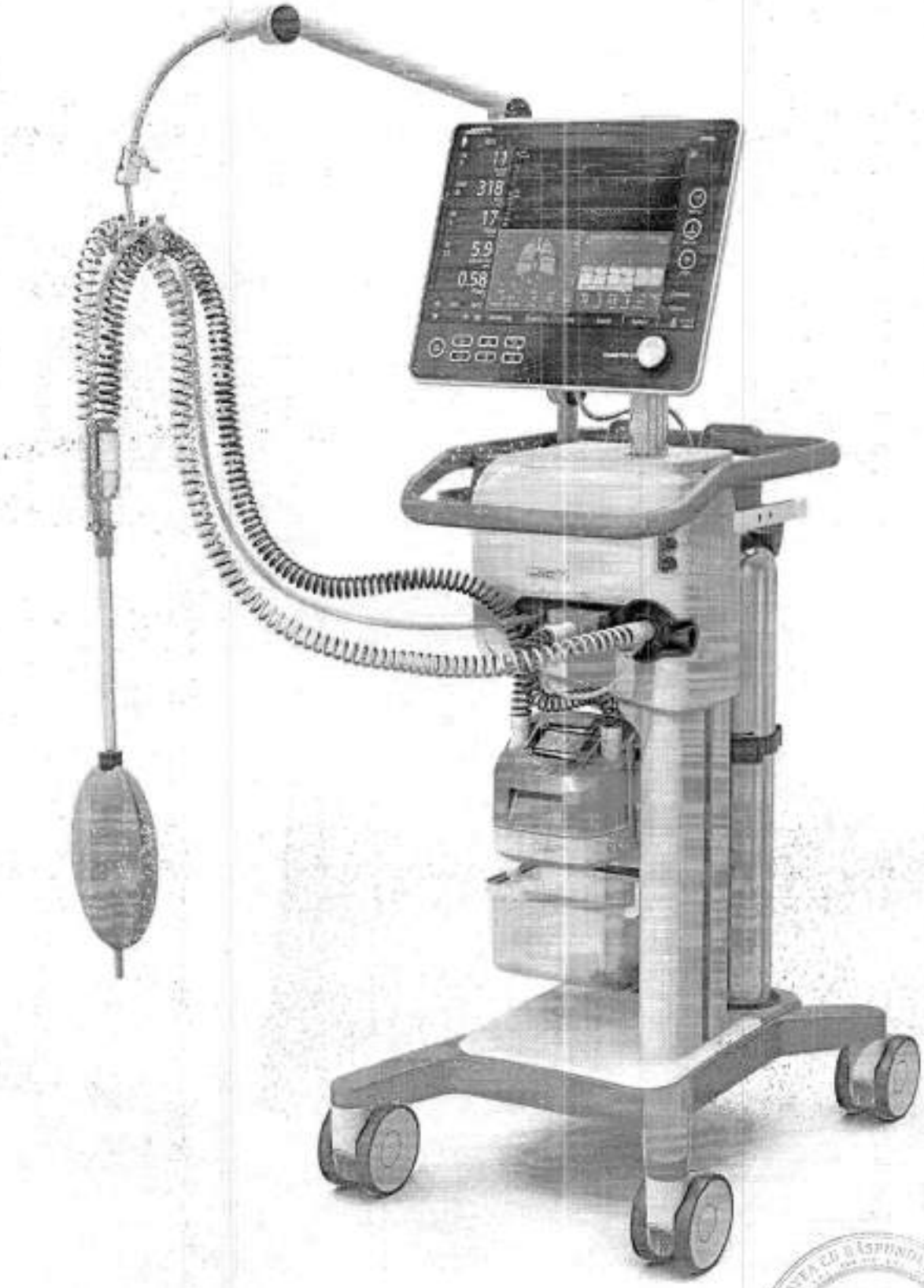
Flexible device configuration
The HAMILTON-C6 adapts to your individual user environment. Mount it on a trolley, with the interaction panel on top or in front, or use the shelf-mounted version with the interaction panel on the side or mounted on the pendant system.

For intrahospital transport
Thanks to the slender frame, an integrated O2 cylinder carrier, and the high-performance turbine, the HAMILTON-C6 can stay at your patient's side for intrahospital transports.

Ergonomic maneuverability
With a compact footprint and high-quality trolley wheels the HAMILTON-C6 is designed for easy handling and maneuverability.






11
318
17
5.9
0.58

Ease of use

In close cooperation with users and ventilation experts, our engineers have designed a user interface that is particularly intuitive. Switching between the HAMILTON-C6 and all other Hamilton Medical ventilators is easy because they are all operated according to the same principles.

The Ventilation Cockpit on the HAMILTON-C6 consolidates the monitoring data and displays it as intuitive graphics. They give a quick overview of the patient's current ventilation status and provide a reliable basis for therapy decisions.

The 17-inch, high-resolution monitor with capacitive touch screen was designed for smooth and fast operation.

“

In my experience the Dynamic Lung is very helpful, because not everybody can always understand the numbers, especially inexperienced therapists. They cannot always understand the data, but they can understand the picture.

Craig Jolly, Adult Clinical Education Coordinator
University Medical Center, Lubbock (TX), USA

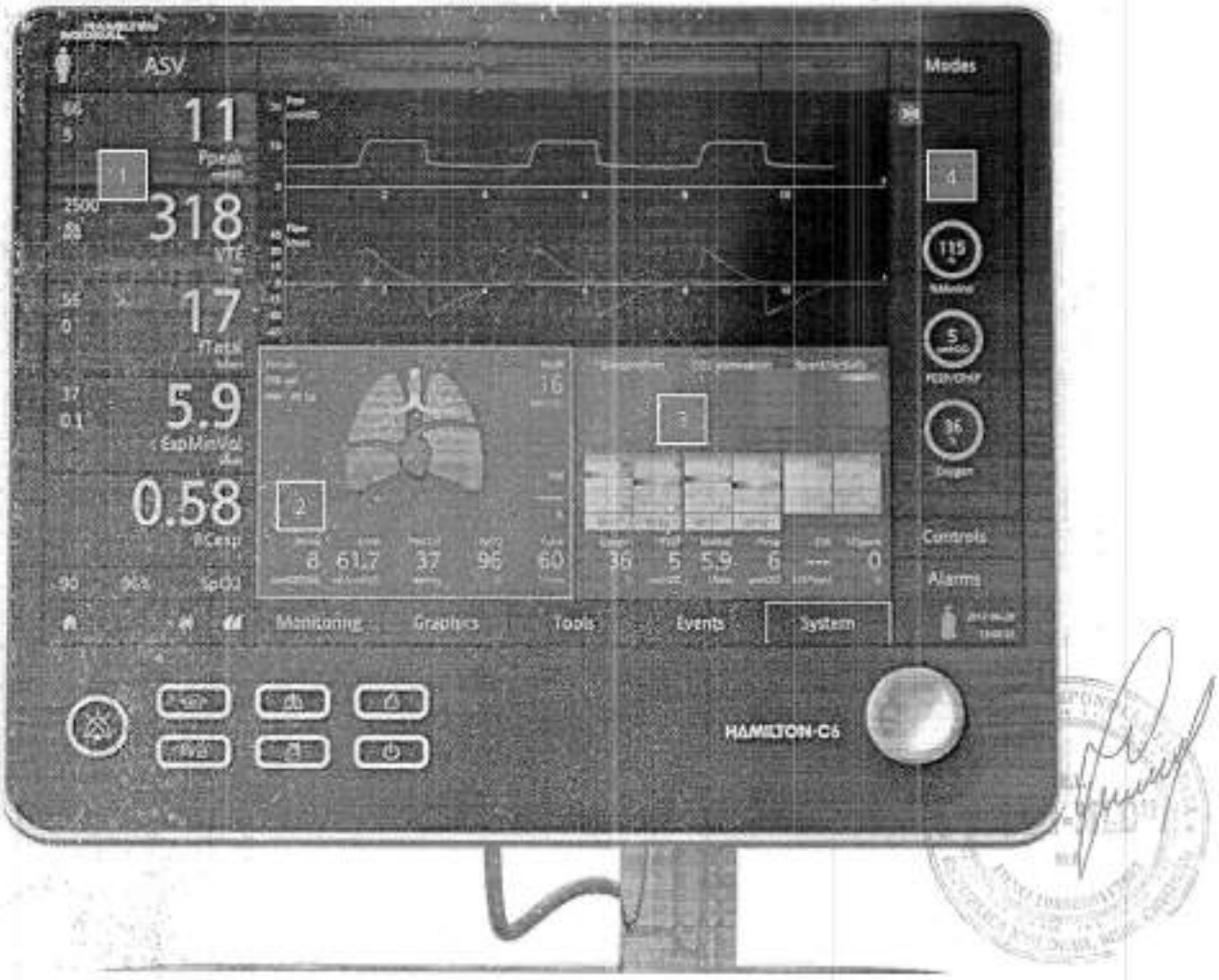
The Ventilation Cockpit

1 Main monitoring parameters
All of the main monitoring parameters at a glance. The large characters allow you to see them even from a distance.

2 Dynamic Lung
One quick look shows you tidal volume, lung compliance, patient triggering, resistance in real-time, cuff pressure, and pulse. The lungs expand and contract in synchrony with the actual breaths.

3 Vent Status
The Vent Status panel displays six parameters related to the patient's ventilator dependence. When all values are in the weaning zone, the panel is framed in green, indicating that spontaneous breathing trials or extubation can be considered.

4 Direct access to main controls
Access and adjust the most important controls for the current mode directly on the main display.



Individualized, lung-protective ventilation

The features available on the HAMILTON-C6 help you individualize your patient's ventilation and to implement a lung-protective ventilation strategy.

Adaptive, lung-protective ventilation with ASV

- ✓ Supports the earliest possible spontaneous breathing by the patient[1,2]
- ✓ Shortens the ventilation time in various patient groups[1,2]

Adaptive, lung-protective ventilation with INTELLiVENT-ASV

- ✓ Rated best among all evaluated modes in terms of capabilities relating to safety, comfort, and weaning[3]
- ✓ Follows the current recommendations for lung-protective ventilation in terms of tidal volumes and driving pressure[4]

Lung assessment and recruitment with the P/V Tool Pro

- ✓ Hysteresis of the pressure/volume curve can be used for assessing the recruitability of the lung at the bedside[5]
- ✓ Has been shown to open the lung in the majority of patients with early ARDS[6]

Synchronization based on waveform analysis with IntelliSync+

- ✓ Waveform analysis is a reliable, accurate, and reproducible method for assessing patient-ventilator interaction[7]
- ✓ In terms of cycling, IntelliSync+ performs at least as well as ETS optimized by clinicians[8]

Automatic cuff pressure control with IntelliCuff

- ✓ Continuous cuff pressure control can decrease microaspiration and VAP[9,10]

Transpulmonary pressure measurement

- ✓ PEEP set based on transpulmonary pressure can improve compliance and oxygenation in ARDS patients[11]
- ✓ Transpulmonary pressure measurement can avoid the use of ECMO in the most severe patients[12]

1 [illegible] | 2 [illegible] | 3 [illegible] | 4 [illegible] | 5 [illegible] | 6 [illegible] | 7 [illegible] | 8 [illegible] | 9 [illegible] | 10 [illegible] | 11 [illegible] | 12 [illegible]

Adaptive Support Ventilation (ASV)
continuously adjusts breath-by-breath, the respiratory rate, tidal volume, and inspiratory time depending on the patient's lung mechanics and effort, 24 hours a day, from intubation to extubation.

INTELLiVENT-ASV
continuously controls the ventilation and oxygenation of the patient. It sets the minute ventilation, PEEP, and Oxygen based on the targets set by the clinician, and on physiological input from the patient. INTELLiVENT-ASV also provides tools to promote early, automated weaning (Quick Wean).

P/V Tool Pro for lung assessment and recruitment
helps you assess recruitability and set PEEP based on respiratory mechanics. It also provides a repeatable method for quickly performing recruitment maneuvers.

IntelliSync+ keeps an eye on patient-ventilator synchrony
by continuously analyzing waveform shapes hundreds of times per second. This allows IntelliSync+ to detect patient efforts and cycling immediately, and initiate inspiration and expiration in real-time. IntelliSync+ applies to invasive and noninvasive ventilation, regardless of the ventilation mode.

IntelliCuff cuff pressure controller
continuously measures and automatically maintains the user-set cuff pressure of an endotracheal or tracheostomy tube in real-time.

Transpulmonary pressure measurement
allows optimization of PEEP, tidal volume, and inspiratory pressure. Use it in combination with P/V Tool Pro to assess lung recruitability more precisely and perform recruitment maneuvers.

Features and options

State-of-the-art ventilation modes

High-performance turbine with lifelong warranty

High flow oxygen therapy

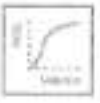
Integrated control for IntelliCuff pressure controller

Integrated pneumatic nebulizer, optional Aerogen® nebulizer

Integrated control for HAMILTON-H900 humidifier

Pulse oximetry (SpO2 and pulse measurement)

Serial interface for connection to electronic patient data records, and patient monitors



Mainstream (volumetric) and sidestream capnography

On-screen help for alarm troubleshooting

Continuous monitoring of driving pressure

From the ventilation specialist

E-learning
Hamilton Medical College provides free and open e-learning on mechanical ventilation and ventilators. Join at college.hamilton-medical.com

Universal ventilator consumables
Our accessories and consumables are specially developed for the highest possible patient safety and ease of use. Choose between reusable and disposable parts, according to your institutional policies.

Peripheral devices
Our ventilation portfolio includes an active humidifier, the HAMILTON-H900, as well as the automatic cuff pressure controller, IntelliCuff. Both devices may be used with all kinds of mechanical ventilators.

More information and free software simulation:
www.hamilton-C6.com

HAMILTON MEDICAL
Intelligent Ventilation since 1983

Manufacturer:
Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz, Switzerland
+41 (0)58 610 10 20
info@hamilton-medical.com
www.hamilton-medical.com

HAMILTON MEDICAL
Intelligent Ventilation since 1983

Declaration of Conformity

We, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland, confirm that the following products	Wir, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Schweiz, bestätigen, dass die folgenden Produkte	La société Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Suisse, confirme que les produits ci-dessous

CEDCL-HAM-C6, Attachment on page 2

meet the following EC directive (including all applicable amendments):	mit der folgenden EG-Richtlinie (einschliesslich aller zutreffenden Änderungen) übereinstimmt: EC Medical Device Directive: 93/42/EEC, Annex II, Art. 3 All listed products are classified as class IIb.	sont en conformité avec le directive CE suivant (y compris leurs amendements, le cas échéant):

CE 0197

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg
Germany

Registration No: HD 60137935 0001

Validity:	**Gültigkeit:**	**Validité:**
This declaration is valid for products manufactured in 2019. Lot numbers are traceable via manufacturing protocols. This declaration is valid in connection with the final inspection report.	Diese Konformitätserklärung gilt für Produkte, welche 2019 produziert werden. Die Losnummern sind über Fertigungsnachweise nachvollziehbar. Diese Konformitätserklärung ist gültig in Verbindung mit dem Endprüfprotokoll.	Cette déclaration est valable pour les produits fabriqués en 2019. Les numéros de lot peuvent être retracés par les preuves de production. Cette déclaration est valable associée au rapport d'inspection final.

Hamilton Medical AG

Jens Hallek
CEO

Bonaduz, 2019 -07- 08

HAMILTON MEDICAL
Intelligent Ventilation since 1983

CEDCL-HAM-C6 Attachment

Product name	P/N	Basis UDI-DI / GTIN
HAMILTON-C6	160021	07630002806590

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

has established and applies a quality management system for medical devices for the following scope:

Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems (see attachment for additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-03-06
Certificate Registration No.:	SX 60136805 0001
An audit was performed. Report No.:	21213508 012
This Certificate is valid until:	2020-07-08

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2019-03-06

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60136805 0001
Report No.: 21213508 012

Organization:
Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Scope:

Additional site:

Hamilton Medical AG
Parc Industrial Vial 10
7013 Domat/Ems
Switzerland

Activities: Manufacturing and Service

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2019-03-06

Dipl.-Ing. I. Munkler

Certificate

Standard	**ISO 9001:2015**
Certificate Registr. No.	**01 100 1710001**

Certificate Holder:	**Hamilton Medical AG** Via Crusch 8 7402 Bonaduz Switzerland including the locations according to annex
Scope:	Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems
	Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.
Validity:	The certificate is valid from 2017-07-09 until 2020-07-08.

2019-05-07 (Change)

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

IAF

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1710001**

No.	Location	Scope
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	Design and development and distribution of ventilators and ventilator systems
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland	Manufacturing and servicing of ventilators and ventilator systems

2019-05-07

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

TÜVRheinland®
Precisely Right.

Anexa Lot Nr. 15 Dispozitiv fizioterapeutic de frecventa ultrainalta (unde scurte), UVC-60, Medteko, Rusia

Specificatia tehnica solicitata	Specificatia tehnica ofertata
Dispozitiv fizioterapeutic cu unde scurte Tensiunea rețelei electrice: 220V, 50 Hz Frecvența: 50 Hz Frecvența de funcționare: max 27 MHz Puterea : max 60 VA Ecran LED cu indicarea puterii și timpului Timpul de funcționare max 20 min, pauză max 10 min Electrozii înlocuiți: 3 perechi de diferite diametre Clasa de securitate: I, BF	Dispozitiv fizioterapeutic cu unde scurte Tensiunea rețelei electrice: 220V, 50 Hz Frecvența: 50 Hz Frecvența de funcționare: max 27,12 MHz Puterea : max 60 VA Ecran LED cu indicarea puterii și timpului Timpul de funcționare max 20 min, pauză max 10 min Electrozii înlocuiți: 3 perechi de diferite diameter (ø36mm; ø80mm; ø120mm) Clasa de securitate: I, BF

Аппарат УВЧ-терапии «**УВЧ - 60 - Мед ТеКо**» предназначен для местного лечебного воздействия электромагнитным полем высокой частоты.

Принцип действия

Аппарат предназначен для применения в клиниках терапевтического, неврологического, хирургического, психиатрического, акушерско-гинекологического профиля и в других лечебных учреждениях.

Показания к применению:

- острые воспалительные процессы
- травма спинного мозга и периферических нервов
- радикулит
- невралгия
- полиомиелит
- энцефалит

- миелит в периоды подострого и хронического течения
- болезнь Рейно
- облитерирующий эндартериит
- острые и подострые воспаления матки и придатков.

Противопоказания:

- злокачественные новообразования
- системные заболевания крови
- сердечная недостаточность II-III степени
- аневризм аорты; гипотония
- склонность к кровотечениям
- инфаркт миокарда
- туберкулез легких в активной фазе.

Отличительные особенности

- Современная элементная база
- Автоматическая настройка резонанса
- Гибкие электродержатели, совмещённые с проводящими фидерами
- Современный дизайн
- Сравнительно малый вес и габариты аппарата

Основные технические параметры

Режимы работы

Номинальное сопротивление нагрузки, Ом

Оптимальный зазор электродов, мм	15
Время выхода аппарата на рабочий режим, мин	не более 1
Время работы аппарата в повторно-кратковременном режиме, ч	6
время работы, мин	20
время паузы, мин	10
Диапазон установки таймера, мин	(0...99)±5%;

Характеристики воздействия

Рабочая частота аппарата, МГц	27,12 ± 0,163
Выходная мощность, регулируемая ступенчато, Вт	(10 / 15 / 20 / 30 / 40 / 50 / 60) ±20%

Питание

Напряжение питания, В	220
Частота питающей сети, Гц	50
Потребляемая мощность, ВА	не более 250

Габариты

Габариты без упаковки, мм	не более 421 x 285 x 170
Габариты в упаковке, мм	не более 520 x 320 x 210
Масса, кг	не более 7,5

Дополнительно

Класс защиты от поражения электрическим током	I, тип BF по ГОСТ Р

	50267.0
Срок службы	5 лет

Комплект поставки

В комплект поставки аппарата входит:

Электронный блок	1
Фидер-электрододержатель	2
Сменные электроды:	
Ø36±5мм	2
Ø80±5мм	2
Ø120±5мм	2
Индикатор наличия магнитного поля	1
Паспорт	1

ДЕКЛАРАЦИЯ О СООТВЕТСТВИИ

Общество с ограниченной ответственностью "Мед ТеКо"
(ООО "Мед ТеКо")
наименование организации или фамилия, имя, отчество индивидуального предпринимателя, принявших декларацию о соответствии

Зарегистрировано Инспекцией Федеральной налоговой службы по г. Мытищи Московской области 20.04.2011 г. ОГРН 1025003519716
сведения о регистрации организации или индивидуального предпринимателя (наименование регистрирующего органа, дата регистрации, регистрационный номер)

Россия, 141006, Московская область, г. Мытищи, Олимпийский проспект, д.16, корп.2
телефон/ факс: (495) 586-73-00
адрес, телефон

в лице Генерального директора Бенькова Александра Васильевича
должность, фамилия, имя, отчество руководителя организации от имени которой принимается декларация

заявляет, что Аппарат для УВЧ - терапии со ступенчатой регулировкой мощности
наименование, тип, марка продукции, на которую распространяется

УВЧ-60 - «Мед ТеКо» по ТУ 9444-002-56812193-2002 в составе:
(см. приложение на 1 листе)
Серийный выпуск.
ОКПД2 26.60.13.130 (ОКП 94 4420) ТН ВЭД 9018 90 840 9
декларация, коды ОКПД2, ТН ВЭД, сведения о серийном выпуске или партии (номер партии, номера изделий, реквизиты договора (контракта),

Изготовитель - Общество с ограниченной ответственностью "Мед ТеКо"
(ООО "Мед ТеКо")
Россия,141006, Московская область, г. Мытищи, Олимпийский проспект, д.16, корп.2
наименование, наименование изготовителя, страны)

соответствует требованиям ГОСТ Р МЭК 60601-1-2010,
обозначение нормативных документов, соответствие которым подтверждено

ГОСТ Р 50444-92, ГОСТ Р 50267.3 -92, ГОСТ 28603-90,
ГОСТ Р МЭК 60601-1-2-2014
данной декларацией, с указанием пунктов этих нормативных документов, содержащих требования для данной продукции

Декларация принята на основании протоколов испытаний № 061/ЭБ -18
информация о документах, являющихся основанием для принятия декларации
от 22.08.2018 г., № 061/ЭМС-18 от 22.08.2018 г. ИЛ МИ ФГБУ ФНКЦ ФХМ ФМБА России (№ RA.RU.21МИ25).
Регистрационное удостоверение № ФСР 2012/13524 от 02.07.2018 г.
Федеральной службы по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР)

Дата принятия декларации 24 августа 2018 г.

Декларация соответствия действительна до 24 августа 2021 г.

подпись А.В. Беньков
инициалы, фамилия

М.П.

Сведения о регистрации декларации о соответствии Декларация зарегистрирована Органом по сертификации медицинских изделий АНО «ВНИИИМТ» (ОС МИ АНО «ВНИИИМТ») № RA.RU.11ИМ02, 129301, Москва, ул. Касаткина, д. 3 тел.(495) 683-97-42, факс (499) 187-89-54, e-mail: im02@bk.ru
наименование и адрес органа по сертификации, зарегистрировавшего декларацию

24 августа 2018 г. № РОСС RU.ИМ02.Д01516
дата регистрации и регистрационный номер декларации

М.П.

Подпись, инициалы, фамилия руководителя Органа по сертификации Е.И. Полянская

ПРИЛОЖЕНИЕ К ДЕКЛАРАЦИИ О СООТВЕТСТВИИ

Аппарат для УВЧ - терапии со ступенчатой регулировкой мощности УВЧ-60 - «Мед ТеКо» по ТУ 9444-002-56812193-2002:

в составе:

1. Электронный блок – 1 шт.
2. Сменные электроды:

диаметр – 36 мм – 2 шт,

диаметр – 80 мм – 2 шт,

диаметр – 120 мм – 2 шт.

3. Электрододержатель в сборе – 2 шт.
4. Индикатор наличия ВЧ-поля – 1 шт.
5. Паспорт – 1 шт.
6. Руководство по эксплуатации – 1 шт.

подпись А.В. Беньков
инициалы, фамилия

М.П.

Сведения о регистрации декларации о соответствии Декларация зарегистрирована Органом по сертификации медицинских изделий АНО «ВНИИИМТ» (ОС МИ АНО «ВНИИИМТ») № RA.RU.11ИМ02, 129301, Москва, ул. Касаткина, д. 3 тел. (495) 683-97-92, факс (499) 187-89-54, e-mail: im02@bk.ru

наименование и адрес органа по сертификации, зарегистрировавшего декларацию

24 августа 2018 г. № РОСС RU.ИМ02.Д01516

дата регистрации и регистрационный номер декларации

М.П. Для сертификатов и деклараций

подпись, инициалы, фамилия руководителя Органа по сертификации Е.И. Полянская

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2012/13524

от 07 июня 2012 года

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "Мед ТеКо"
(ООО "Мед ТеКо"), Россия,
141006, Московская область, г. Мытищи, Олимпийский проспект, д. 16, корп. 2
и подтверждает, что медицинское изделие
Аппарат для УВЧ-терапии со ступенчатой регулировкой мощности УВЧ-60-"Мед ТеКо" по ТУ 9444-002-56812193-2002
производства
Общество с ограниченной ответственностью "Мед ТеКо"
(ООО "Мед ТеКо"), Россия,
141006, Московская область, г. Мытищи, Олимпийский проспект, д. 16, корп. 2
место производства:
141006, Московская область, г. Мытищи, Олимпийский проспект, д. 16, корп. 2
класс потенциального риска **2а** ОКП **94 4420**

вид медицинского изделия -

соответствующее регистрационному досье № 14686 от 03.05.2012

приказом Росздравнадзора от 07 июня 2012 года № 2788-Пр/12

и приказом от 28 августа 2013 года № 4402-Пр/13 о замене
допущено к обращению на территории Российской Федерации

Приложение: на 1 листе

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

0002878

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

Лист 1

№ ФСР 2012/13524

1. Электронный блок - 1 шт.;
2. Сменные электроды:
диаметр - 36 мм - 2 шт.;
диаметр - 80 мм - 2 шт.;
диаметр - 120 мм - 2 шт.;
3. Фидер-электрододержатель - 2 шт.;
4. Индикатор наличия ВЧ-поля - 1 шт.

Приказом от 28 августа 2013 года № 4402-Пр/13 о замене допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

07 июня 2012 года

0002589

Anexa Lot Nr. 16 Dispozitiv fizioterapeutic pentru amplipuls terapie, Etius, Astar, Polonia

Specificatia tehnica solicitata	Specificatia tehnica ofertata
Dispozitiv de fizioterapie cu curenți de joasă și medie frecvență Forme de curenti: galvanici, diadinamici, sinusoidali modulați Ecran LED Taimer încorporat Control automat al curentului pacientului Tensiunea rețelei electrice: 220V Frecvența: 50 Hz Puterea: max 40 VA Clasa de electrosecuritate: II	Dispozitiv de fizioterapie cu curenți de joasă și medie frecvență Forme de curenti: galvanici, diadinamici, sinusoidali modulați Ecran LED Taimer încorporat Control automat al curentului pacientului Tensiunea rețelei electrice: 230V Frecvența: 50 Hz Puterea: max 70 VA Clasa de electrosecuritate: II

Electrotherapy

Etius

Etius – it is a modern and ergonomic unit intended to use in electrotherapy and electrodiagnostics of nervous-muscle system.

The unit is distinguished by the fact that has got two completely independent treatment channels. Thanks to this solution it is possible to perform simultaneous treatments with different parameters on one or two patients.

Basic area of its functionality is electrotherapy, in which the unit provides the availability of all typical and commonly used currents. Additionally, the Etius offers completely new possibilities: application of microcurrents, unipolar sine surge and specially designed TENS currents used in spastic paralysis therapy.

SPECIFICATION

ELECTROTHERAPY – CURRENTS

- interferential (isoplanar, dynamic, static, one-channel AMF)
- TENS (symmetric, asymmetric, alternating, Burst)
- TENS to spastic paralysis therapy
- Kotz / Russian stimulation
- tonolysis
- diadynamic (MF,DF,CP,CP-ISO, LP)
- Trabert pulse, Leduc, faradic
- pulse – rectangular, triangular
- unipolar sine surge
- galvanic
- microcurrents

ELECTRODIAGNOSTICS

- electrodiagnostics with graphic presentation of I/t curve
- automatic calculation of rheobase, chronaxie as well as threshold, coefficient and quotient of accommodation

MANUAL MODE

complete control over parameters for advanced users

TREATMENT PROGRAMS

- simplification of the unit operation
- treatment programs chosen by name
- 89 preset treatment procedures
- 50 user-defined programs
- 20 favourite programs
- naming individual user programs

Etius

Technical specification

ERGONOMICS
- two independent treatment channels
- operation mode: program/manual
- easy-to-read display
- operation in graphic mode
- preset treatment program base
- treatment programs chosen by name
- treatment timer
- electrodes test
- statistics – the number of performed treatments
- buzzer volume setting

STRUCTURE
- graphic LCD display
- heavy-duty and reliable keyboard
- modern design
- operation in CC (stabilized output current) and CV (stabilized output voltage) modes
- complete galvanic isolation between channels in each mode
- generation of unidirectional (unipolar) currents in interrupted mode
- self-test – systematic control of the unit

TECHNICAL SPECIFICATIONS

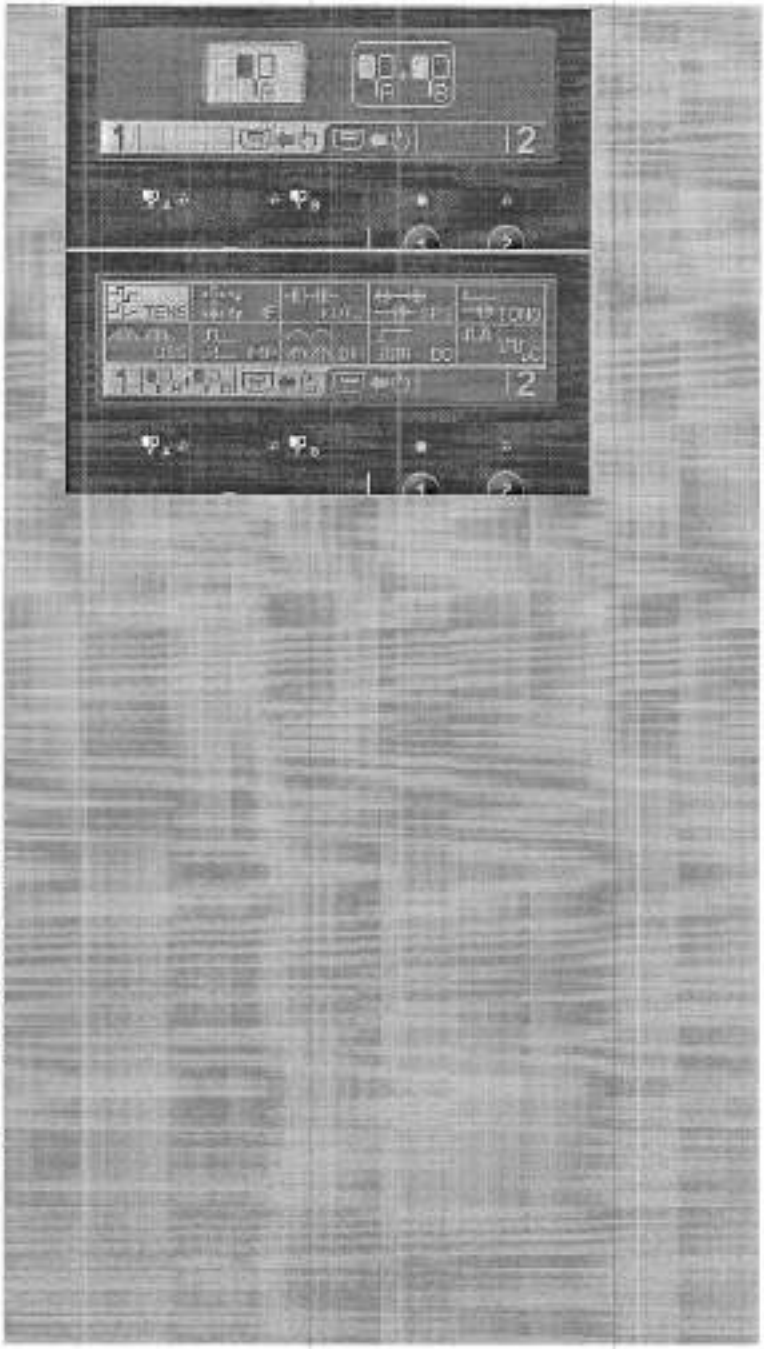
controller – maximum constant current in patient's circuit (CC mode)	
galvanic	40 mA
diadynamic, pulse	60 mA
interferencial, Kotz', unipolar sine surge	100 mA
TENS	140 mA
tonolysis	100 mA
microcurrents	1 000 µA
maximum voltage in patient's circuit (CV mode)	140 V
mains supply	230 V, 50 Hz, 50 W, 70 VA
weight	max 6 kg

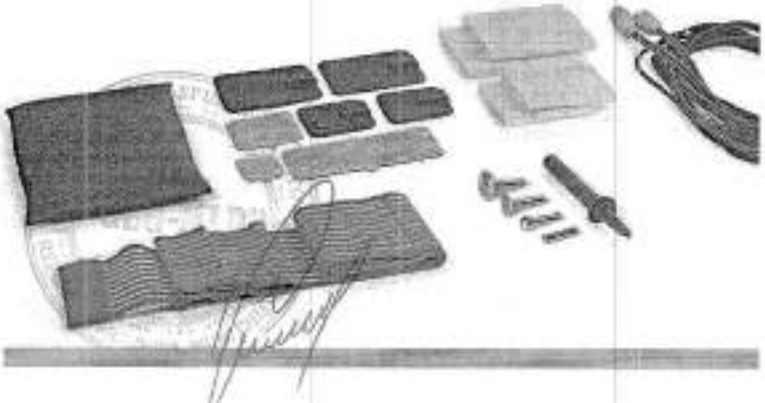
WARRANTY

Etius	2 years

STANDARD ACCESSORIES
- mains cable
- patient lead (2 pcs)
- electrotherapy electrode 6x6 cm (4 pcs); 7,5x9 cm (2 pcs)
- viscose electrode cover 6x6 cm (8 pcs); 7,5x9 cm (4 pcs)
- velcro fixing belt 40x10 cm (2 pcs); 100x10 cm (2 pcs)
- spare fuse T1 AL250 V (2 pcs)
- user guide

OPTIONAL ACCESSORIES
- disposable self-adhesive electrodes 3x4 cm; 5,5x5,5 cm; 5,5x12,5 cm
- point electrodes 5 mm, 10 mm, 15 mm, 20 mm
- crocodile clip
- sand-filled bag 21x14 cm, 21x28 cm
- bag for the unit and accessories
- Versa trolley
- patient's switch





TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

"Astar ABR"
Aleksander Jedrzejowski,
Robert Dziendziel Spolka Jawna
ul. Swit 33
43-382 Bielsko-Biala
Poland

has established and applies a quality management system for medical devices for the following scope:

(see attachments for scope included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-01-12
Certificate Registration No.:	SX 60125636 0001
An audit was performed. Report No.:	26300254 005
This Certificate is valid until:	2020-12-11

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-01-12

Maciej Sciera

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate
Registration No.: SX 60125636 0001
Report No.: 26300254 005

Organization:
"Astar ABR"
Aleksander Jedrzejowski,
Robert Dziendziel Spolka Jawna
ul. Swit 33
43-382 Bielsko-Biala
Poland

Scope:

Design and development, manufacture, distribution, installation and servicing of active medical devices for electrotherapy, laser therapy, light therapy, ultrasound therapy, magnetic field therapy, vacuum therapy and shock wave physical therapy

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-01-12

Maciej Sciera

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

TÜVRheinland®

APPROVAL

EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60027842 0001

Report No.: 26300062 002

Manufacturer:

Astar ABR
A. Jedrzejowski, R. Dziendziel S.J.
ul. Strazacka 81
43-382 Bielsko-Biala
Poland

Scope:

Design/development and production of
active medical therapy devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60010720 0001

Date of Expiry: 14.12.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Cologne, 21.12.2009

Dipl.-Ing. I. Munkler

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜVRheinland

Doc. 1/1, Rev. 0

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: HD 60027842 0001
Report No.: 26300062 002

Manufacturer:
Astar ABR
A. Jedrzejowski, R. Dziendziel S.J.
ul. Strazacka 81
43-382 Bielsko-Biala
Poland

Scope:

Products:

- Electrotherapy devices
- Laser therapy devices
- Light therapy devices
- Magnetic field therapy devices
- Ultrasound therapy devices
- Ultrasound therapy combined with electrotherapy devices

Certification Body

Dipl.-Ing. I. Munkler

TÜV Rheinland Product Safety GmbH

Cologne, 21.12.2009

Anexa 20 Pompa de infuzie (perfuzor) cu seringa

Pompă de infuzie (perfuzor) cu seringă - 15 unități				
Descriere	Acest grup de produse include pompe pentru seringi cu cerințe de bază, au rata reglabilă de flux, prevăzute pentru anestezie, folosirea de durată la patul bolnavului, pentru transportarea pacienților gravi, pot fi instalate seringi pînă 60 ml.			
Parametrul			Specificația	Specificatia tehnica ofertata **S300 (Medima/Polonia)**
Display	Date afișate	Doza	da	da
		Concentrația	da	da
		Viteza de infuzie	da	da
		Volumul de infuzie	da	da
		Timpul de infuzie	da	da
		Timpul pînă la final de infuzie	da	da
		Mărimea seringei	da	da
		Nivelul de ocluzie	da	da
		Rata KVO	da	da
		Data, ora	da	da
		Nivelul de încărcare a baterii	da	da
		Evenimente	da	da
		Alarme	da	da
Proprietățile pompei	Rata fluxului	diapazonul	0.1 - 1,200 ml/h	0.01 - 2000 ml/h
		Pasul de incrementare	0.1 mL/h	0.01 - 99.99 ml/h
	Dozarea bolusului	Incrementarea	0.1-25 ml	0.1-25 ml
	Rata KVO		0.1 - 3 ml/h	0.1 - 3 ml/h

	Eroarea		≤2%	2%
	Compatibil cu seringi produse de diferiți producători		min. 8 producători	da
	Seringi acceptate		5, 10, 20, 30, 50, 60	5, 10, 20, 30, 50, 60
	Detector de mărime a seringei		da	da
	Nivelul presiunei de ocluzie		≥ 8 nivele	1-12 nivele
	Protecție la pătrunderea lichidelor în dispozitiv		IP 22 - 24	IP 22 - 24
	Chemare asistentă		da	da
Caracteristici de siguranță	Protecție la curgere liberă din sistem		da	da
	Intervalul de timp de blocare, min		≤ 5-100	5-100
	Limita dozei acumulate		da	DA
	Limitarea de acces prin buton de blocare sau parolă		da	DA
Alarme și indicatori	Ocluzie sus/jos		da	DA
	Eroare de flux		da	DA
	Eroare de sistem		da	DA
	Seringă goală		da	DA
	Perfuzia pe sfîrșite		da	DA
	Baterie descărcată		da	DA
Alarmă sonoră	Volum reglabil		Da	DA
	Buton mod silențios		da	DA
Jurnalul de evidență	Numărul de evenimente memorate		≥ 1000	1000
	Evenimente stocate	Butoane apăsate	da	da
		Coduri de eroare	da	da
		Alarme	da	da
		Medicamente injectate	da	da

		Cantitatea infuzată	da	da
		Setări	da	da
		Bolus solicitat	da	da
Alimentarea	Rețea electrică	220 V, 50 Hz	da	da
	Baterie internă	Reîncărcabilă	da	da
		Timp de operare	≥ 7 h la 5 mL/h	7 h la 5 mL/h
Acesorii				
Suport	sistem de fixare a pompei de stativul de infuzie		da	da
Seringi	5 ml		50 buc.	50 buc.
	10 ml		50 buc.	50 buc.
	20 ml		50 buc.	50 buc.
	30 ml		50 buc.	50 buc.
	50 ml		50 buc.	50 buc.
	60 ml		50 buc.	50 buc.
Circuite	circuit de interconectare		300 buc.	300 buc.

QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-439-135-1611

The **Directorate of Device Testing and Clinical Engineering (EMKI)**

as a Certification Body with ID No. NAH-4-0096/2016
accredited by the National Accreditation Authority for management system certification

certifies that the quality management system applied by

MEDIMA Sp. z o.o.
Al. Jerozolimskie 200
02-486 Warsaw
Poland

meets the requirements of standard

EN ISO 13485:2016

in the field:

Developing, manufacturing, marketing and service of syringe infusion pumps, volumetric infusion pumps, docking stations, medical software and infusion sets

Registry number of the related audit report: **43-131-2007**

This certificate is valid until **2019-11-22** supposed that the results of the regular yearly surveillance audits are satisfactory.

The Company has been certified by EMKI since 2004-11-22.

Issue: 3 First issued: 2016-11-23

Budapest, 2018-12-20

Head of EMKI

EMKI 2148

The authenticity and validity of the certificate are verifiable at EMKI.

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering
H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33
E-mail: cert@emki.hu, Web: www.emki.hu
H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-768-200-1411

The **Directorate of Device Testing and Clinical Engineering (EMKI)**

certifies that the manufacturer:

MEDIMA Sp. z o. o.
Al. Jerozolimskie 200
02-486 Warsaw
Poland

for the products / product categories:

Syringe infusion pumps
Volumetric infusion pumps
Docking stations for infusion pumps
Infusion sets
Medical software

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **42-131-2007**

This certificate is valid until **2019-11-19** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by EMKI as a Notified Body with identification number **1011.**

This certificate is valid only with the attachment.

Issue: 3 First issued: 2014-11-20

Budapest, 2018-02-26

Head of EMKI

EMKI 1840

The authenticity and validity of the certificate are verifiable at EMKI.

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering
H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33
E-mail: cert@emki.hu, Web: www.emki.hu
H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

ATTACHMENT TO EC CERTIFICATE

Additional information for Certificate 5-768-200-1411

The certificate is valid for the following manufacturing site:

MEDIMA Sp. z o. o.
Al. Jerozolimskie 200
02-486 Warsaw
Poland

The certificate is valid for the following models:

Syringe infusion pumps:
S100, S200, S300, S300 PCA

Volumetric infusion pumps:
P, P1, P2, P100, P200, P300

Docking stations for infusion pumps:
DS302, DS304, DS306, DS308

Infusion sets:
Medima Line S
Medima Line L
Medima Line B
Medima Line

Medical software:
Medima User ToolBox
Medima Service ToolBox
MedimaNet

The detailed description of the products is kept by EMKI under No. 42-131-2007.

Issue: 3 Date: 2018-02-26 First issued: 2014-11-20

Head of EMKI

EMKI

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering
H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33
E-mail: cert@emki.hu, Web: www.emki.hu
H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

MedimaNet
network software

medima

MedimaNet provides information about infusions out across the Care Unit or even by individual pumps and automatically transfers it to PDMS/HIS.

Centralized alarm system indicates pumps currently in active operation requiring intervention. Remaining infusion time bar indicates incoming events.

Patient's infusion screen shows all the details of the actual therapy.

Configurable drill-down reports allow statistical analysis of completed infusions and audit with implementation of new DERS technologies.

medima

Medima Sp. z o.o.
Al. Jerozolimskie 200, 02-486 Warsaw, Poland
tel. +48 (22) 313 22 66 fax. +48 (22) 313 22 69
email: medima@medima.pl
www.medima.pl

Technical specifications

Syringe pumps

Flow rates	0.01 – 2000 ml/h
Syringe types	2 - 50/60 ml of all world known brands, automatic type recognition, other syringes may be calibrated according to customer needs
Flow rate accuracy	±2% in accordance with EN 60601-2-24
Operation modes	ml/min, ml/h, ml/24h
	[illegible]
	continuous, intermittent and profile (24 cycles) infusion
	TPN mode
	PCA/PCEA mode
	TCI/TIVA mode *
Occlusion pressure detection	12 levels, 50 mmHg - 900 mmHg, automatic reduction of occlusion bolus
Drug library (ESDS only)	6000 drug protocols, 40 Care Units, 40 categories
	Soft and hard limits, advisory notes, alarm priority, security level, max syringe size,
	additional pump configuration parameters for each drug and care unit
Additional functions	Colour display, touch screen
	Automatic syringe fixation, improper syringe fixation alarm
	Infusion parameters protected by password with two levels of protection
	Fast keypad lock
	History log with minimum 2000 entries, each containing event date and time
	Night mode
	Connectivity to hospital information system (HIS) via MedimaNet software
	Automatic configuration by Medima Toolbox or MedimaNet software
Power supply	100 – 230 V AC, 12-15 V DC, internal battery NiMH, [illegible], 4.5 hour to full charge
Weight	Less than 2.2 kg
Classification	Protective Class II, type CF, defibrillation proof, IP 22
Compliance	EN 60601-1, EN 60601-1-2, EN 60601-2-24, EN 1789, MDD 93/42/EEC - IIb

Volumetric pumps

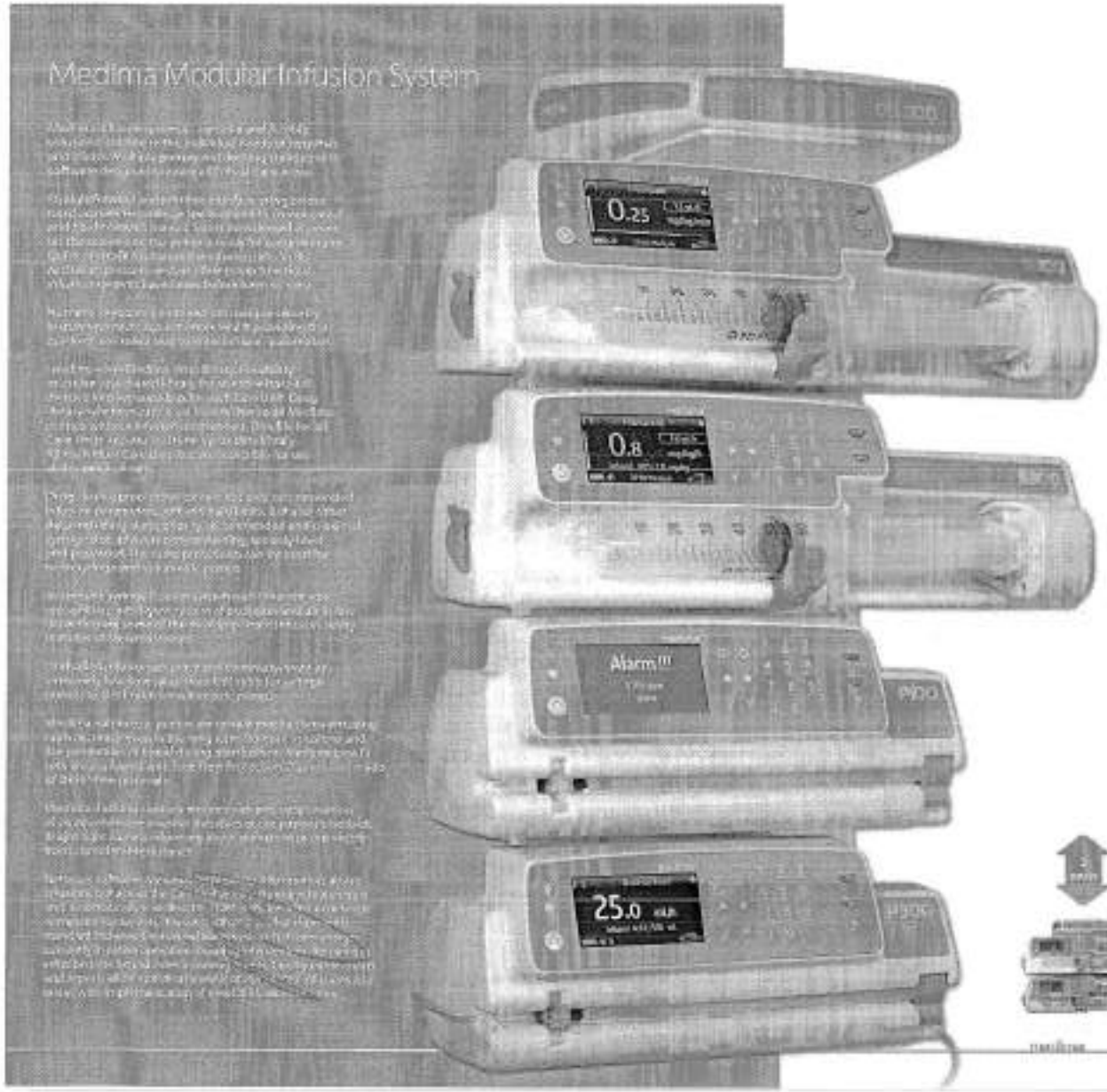
Flow rates	0.1 – 1200 ml/h
IV set	PVC/DEHP free, with automatic free flow protection
Flow rate accuracy	±5% in accordance with EN 60601-2-24 (with Medima Line IV sets)
Operation modes	ml/min, ml/h, ml/24h
	[illegible]
	continuous, intermittent and profile (16 cycles) infusion
	TPN mode
	PCA mode
	TCI/TIVA mode *
Occlusion pressure detection	12 levels, 50 mmHg - 900 mmHg, automatic reduction of occlusion bolus
Drug library (PSDS only)	6000 drug protocols, 40 Care Units, 40 categories
	Soft and hard limits, advisory notes, alarm priority, security level, additional pump configuration parameters for each drug and care unit
Additional functions	Colour display, touch screen
	Infusion parameters protected by password with two levels of protection
	Fast keypad lock
	History log with minimum 2000 entries, each containing event date and time
	Night mode
	Connectivity to hospital information system (HIS) via MedimaNet software
	Automatic configuration by Medima Toolbox or MedimaNet software
Power supply	100 – 230 V AC, 12-15 V DC, internal battery NiMH, [illegible], 4.5 hour to full charge
Weight	Less than 2.1 kg
Classification	Protective Class II, type CF, defibrillation proof, IP 22
Compliance	EN 60601-1, EN 60601-1-2, EN 60601-2-24, EN 1789, MDD 93/42/EEC - IIb

medima

Medima Modular Infusion System

Infusion systems have never been so easy
Simple and intuitive operation
Colour display with touch screen
State-of-the-art precision infusions

Medima Modular Infusion System



medima

Syringe pumps

S100
- Infusion in ml/h
- Flow rates 0.01 – 2000 ml/h
- Min. syringe size 2 ml

S200
- S100 capabilities
- Infusion in all popular units
- Continuous infusion, Intermittent infusion, Profile infusion

S300
- S200 capabilities
- Drug library (DERS)

S300PCA
- S300 capabilities
- PCA infusion

S300TCI
- S300 capabilities
- TCI infusion

Volumetric pumps

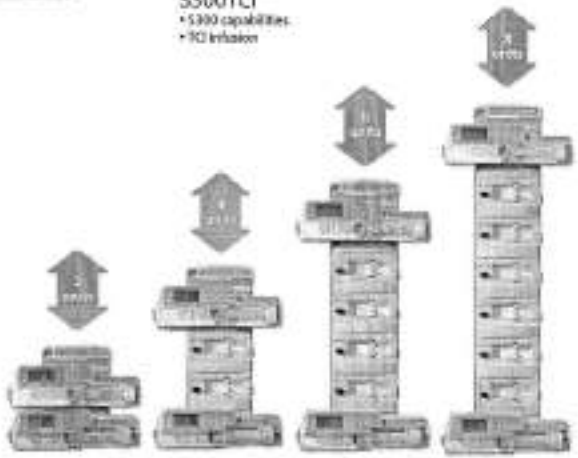
P100
- Infusion in ml/h
- Flow rates 0.1 – 1200 ml/h
- DEHP - free sets with Free Flow Protection Clamps

P200
- P100 capabilities
- Infusion in all popular units
- Continuous infusion, Intermittent infusion, Profile infusion

P300
- P200 capabilities
- Drug library (DERS)

P300PCA
- P300 capabilities
- PCA infusion

P300TCI
- P300 capabilities
- TCI infusion



Docking Stations

DS100
- Available models for 2/4/6/8 pumps
- Automatic Power supply
- DS102A/DS102AC - docking stations for two pumps installation in ambulances

DS200
- DS100 capabilities
- Light signals informing about pump status

DS300
- DS200 capabilities
- Ethernet, WiFi, USB

Light status signals:
- INFUSION
- STOP
- ALARM LOW PRIORITY
- ALARM HIGH PRIORITY