Lot 28 Pompa de infuzie (perfuzor), volum mare (caracteristici de baza), model P300 (Medima, Polonia)

Pompă de infuzie (perfuzor), volum mare (caracteristici de bază)
Cod 130500
Descriere Acest grup de produse include pompe de infuzie pentru volume mari cu cerințe de bază; pot avea 2 sau mai multe canale. Fluxul este calibrat în ml/oră. Au posibilitatea de a efectua calcule a raportului medicament/doză, ce permite programarea fluxului reeşind direct din indicaţiile medicului.
Parametrul Specificația
Display Date afișate LCD
posibilitatea de ajustare a luminozitatii
Alarme
Rata
Volum infuzat
Timpul infuzat
Rata KVO
Nivelul de încărcare a beteriei
Nielul de ocluzie
Evenimente 10000
Istoria
Data, ora
Capacitatea pompei Diapazonul volumului infuzat 0.1 - 9999 ml
Rata fluxului 0.1 - 1,200 ml/h
Setarea prin incrementare incepind cu 0.1 ml Increment de 0.01 de la 0.1 la 99.99 mL; increment de 0.1 mL de la 100 la 999.9 mL; increment de 1 mL de la 1000 mL la 20000 mL
Regim de lucru KVO - menţinerea venei deschise 0.1 - 20ml/h
Acurateţia infuziei 5 %
Funcţia bolus Da
Funcția de reglare a vitezei de infuzie în bolus 0.1 - 1200 ml/h
Selectarea volumului infuzat Da
Selectarea ratei de infuzie Da
Calcularea dozei/medicament Da
Regim de lucru în flux (setarea fluxului) Da
Carcasa ermetizată pentru a preveni scurgerea de lichide în interiorul dispozitivului IP22
Nivelul presiunei de ocluzie maxime 75 - 900 mmHg
12 nivele
Funcția de evacuare a bulei de aer din sistema IV Da
Blocarea panoului de control Da
Alarmă sonoră Da
Alarmă vizuală Da
Fixarea perfuzorului pe rampă verticală Da
Alarme și indicatori Ocluzie da
Nivelul presiunei de ocluzie da
Afișarea ocluziei în timp real da
Bula de aer da
Eroare de sistem da
Set decuplat da
Rezervor gol da
Uşă deschisă da
Senzor de picături Da
Infuzia completă da
Baterie descărcată da
Alimentarea electrică Rețea electrică 220 V, 50 Hz da
Baterie încorporată da
Durata de operare autonomă ≥ 4 h la fluxul de 5ml/h
Acesorii
Suport Sistem de fixare a pompei de stativul de infuzie da
Circuite ≥ 200 buc. pentru fiectare pompă procurată da

Lot 29 Pompa de infuzie (perfuzor), volum mare (caracteristici avansate) model P300 (Medima, Polonia).

Pompă de infuzie (perfuzor), volum mare (caracteristici avansate)
Cod 130510
Descriere Acest grup de produse include pompe de infuzie pentru volume mari cu cerințe avansate; pot avea 2 sau mai multe canale. Fluxul este calibrat în ml/oră. Au posibilitatea de a efectua calcule a raportului medicament/doză, ce permite programarea fluxului reeşind direct din indicaţiile medicului.

Parametrul Specificația
Display Date afișate LCD
posibilitatea de ajustare a luminozitatii
Alarme
Rata
Volum infuzat
Timpul infuzat
Rata KVO
Nivelul de încărcare a beteriei
Nielul de ocluzie
Evenimente 10000
Istoria
Data, ora
Capacitatea pompei Diapazonul volumului infuzat 0.1 - 20000 ml
Rata fluxului 0.1-1,200 ml/h
Setarea prin incrementare incepind cu 0.01 ml in diapazonul 0.1 to 99.99 mL.
Regim de lucru KVO - mentinerea venei deschise 0.1 - 20 ml/h
Acuratetia infuziei 5 %
Functia bolus Da
Funcția de reglare a vitezei de infuzie în bolus 0.1 - 1000 ml/h
Selectarea volumului infuzat Da
Selectarea ratei de infuzie Da
Calcularea dozei/medicament Da
Regim de lucru in flux (setarea fluxului) Da
Trecerea automată în regim de așteptare da
Carcasa ermetizata pentru a preveni scurgerea de lichide in interiorul dispozitivului minim IP22
Nivelul presiunei de ocluzie maxime 75 - 900 mmHg
12 nivele
Funcția de evacuare a bulei de aer din sistema IV Da
Funcție de chemare asistentă Da
Blocarea panoului de control Da
Alarma sonora Da
Alarma vizuala Da
Fixarea perfuzorului pe rampă verticală Da
Setări IV Protecție la flux liber Da
Capacitatea de captare aer Da
Conectare IV a acului Da
Alarmă acustică și vizuală Ocluzie Da
Nivelul de ocluzie Da
Afișarea ocluziei în timp real Da
Alarmă de flux Da
Bula de aer Da
Eroare de sistem Da
Set decuplat Da
Rezervor gol Da
Ușă deschisă Da
Senzor de picaturi Da
Infuzia completă Da
Baterie descărcată Da
Posibilitatea de setare a volumului Da
Mod silence a alarmei Da
Sistem de reducere a erorii (tehnologie inteligentă) Setarea parametrilor impliciți dați de sistemul de reducere a erorii de dozare la pornirea pompei Da
Programe de analiză presetate Da
Alimentarea electrică Rețea electrică 220 V, 50 Hz Da
Baterie incorporata Da
Durata de operare autonoma Da
Accesorii
Suport sistem de fixare a pompei de stativul de infuzie da
Circuite ≥ 200 buc. pentru fiectare pompă procurată da

EC CERTIFICATE

Full Quality Assurance System

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

No. 5-871-200-1911

The **NEOEMKI National Medical Device Conformity Assessment and Certification LLC.** 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: **NE/1038/2020**

This certificate is valid until **2024-05-26** supposed that the results of the regular yearly surveillance audits are satisfactory.

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

This certificate is valid only with the attachment.

Issue: 2

First issued by the Directorate of Device Testing and Clinical Engineering (EMKI) on 20 November 2019.

Budapest, 2020-08-05

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI 2528

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

ATTACHMENT TO EC CERTIFICATE

Additional information for Certificate 5-871-200-1911

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

Issue: 2 Date: 2020-08-05 First issued: 2019-11-20

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI

medima

EC Declaration of Conformity

MANUFACTURER:	MEDIMA Sp. z o.o. Al. Jerozolimskie 200 02-486 Warsaw, Poland
MEDICAL PRODUCTS:	Syringe Infusion Pumps Models: S100, S200, S300, S300 PCA
CLASSIFICATION:	Class IIb, Active Devices - Rule 11, according to Annex IX MDD 93/42/EEC Non-sterile device

We hereby declare that the above mentioned devices comply with the Essential Requirements and provisions of the Medical Devices Directive 93/42/EEC with subsequent changes.

Product marked with the CE mark. Conformity assessment procedure has been carried out according to Annex II to mentioned above Directive under surveillance by Notified Body No. 1011: neoEMKI National Medical Device Conformity Assessment and Certification LLC.

EC certificate according to Annex II section 3 of Council Directive 93/42/EEC with subsequent changes: No. 5-871-200-1911.

Referenced standards that have been applied:

1) EN 60601-1:2006
2) EN 60601-1-2:2015
3) EN 60601-2-24:2015
4) EN 60601-1-8:2007
5) EN 60601-1-8:2007/A11:2017
6) EN 62304:2006+AC:2008
7) EN 62366:2008
8) EN 1789:2007+A1:2010
9) EN 1041:2008+A1:2013
10) EN ISO 14971:2012
11) EN ISO 15223-1:2016

Certificate of Quality Management System compliance with the requirements of standard EN ISO 13485:2016: No. 4-510-135-1911.

Warsaw August 31, 2020

Maciej Grabowski

President of Managing Board
of Medima Sp. z o.o.

DZCE 214

MEDIMA Sp. z o.o.
Al. Jerozolimskie 200, 02-486 Warsaw, Poland
Tel. +48 22 313 22 66, Fax. +48 22 313 22 69
E-mail: medima@medima.pl, www.medima.pl
VAT Registration No: PL 5222709842, Local Court in Warsaw Registered No: 0000201189

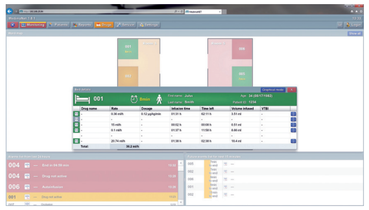
MedimaNet
network software

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

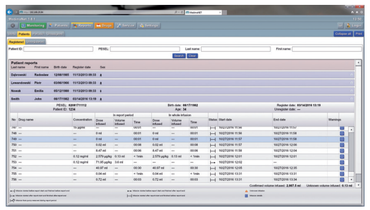
Medima Modular Infusion System

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 list indicates incoming events.

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



Configurable charts and reports allow statistical analysis of completed infusions and assist with implementation of new DERS technologies.

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 ng, µg, mg, g, µEg, mEg, Eg, mIU, IU, kIU, mIE, IE, kIE, mmol, mol, cal, kcal, J, kJ Units/kg, lb, in2, m2/ min, h, 24h 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 (S300 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, 30h - 5ml/h, 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 - II b

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 ng, µg, mg, g, µEg, mEg, Eg, mIU, IU, kIU, mIE, IE, kIE, mmol, mol, cal, kcal, J, kJ Units/kg, lb, in2, m2/ min, h, 24h continuous, intermittent and profile (24 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 (P300 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, 15h - 25ml/h, 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 - II b

DH-MedSys-01-EN-02_2016.11.03

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 infusion systems – versatile and flexible solutions, tailored to the individual needs of hospitals and clinics. Multiple pumps and docking stations with software designed to cover all Critical Care Areas.

Straightforward and intuitive interface using colour touch screen technology spells an end to complicated and hard-to-reach menus. Touch the selected element on the screen and the pump is ready for programming. Quick and safe to change the infusion rate, VTBI, occlusion pressure or start other pump functions. Infusion systems have never before been so easy.

Numeric keyboard combined with unique security features protects against errors whilst providing the quickest and safest way to enter infusion parameters.

Leading edge Medima drug library. Possibility to create one shared library for an entire hospital divided into separate lists for each Care Unit. Drug library synchronization via MedimaNet to all Medima pumps without infusion interruption. One file for all Care Units ensures real time up-to-date library. All individual Care Unit lists are accessible for use at the point of care.

Drug dosing procedures contain not only recommended infusion parameters, soft and hard limits, but also other data including alarm priority, recommended and maximal syringe size, advisory notice/warning, security level and password. The same procedures can be used for both syringe and volumetric pumps.

Automatic syringe fixation system with inherent size recognition, intelligent system of occlusion and air in line detection are some of the most important infusion safety features of Medima pumps.

Unrivalled infusion accuracy and continuity, even at extremely low flow rates, from 0.01 ml/h for syringe pumps and 0.1 ml/h for volumetric pumps.

Medima volumetric pumps are unique mechanisms ensuring high accuracy even in the long term, 96-hour infusions and the protection of blood during transfusions. Medima Line IV sets are equipped with Free Flow Protection Clamps and made of DEHP-free materials.

Medima docking stations ensure quick and easy creation of comprehensive infusion therapies at the patient's bedside. Bright light signals informing about pump status are visible from considerable distance.

Network software MedimaNet provides information about infusions out across the Care Unit or even by individual pumps and automatically transfers it to PDMS/HIS. Installed on a single computer (or server), it works with any workstation with standard browser. Centralized alarm system indicates pumps currently in active operation requiring intervention. Remaining infusion time list indicates incoming events. Configurable charts and reports allow statistical analysis of completed infusions and assist with implementation of new DERS technologies.

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 capabililities
- Light signals informing about pump status

DS300
- DS200 capabilities
- Ethernet, WiFi, USB

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