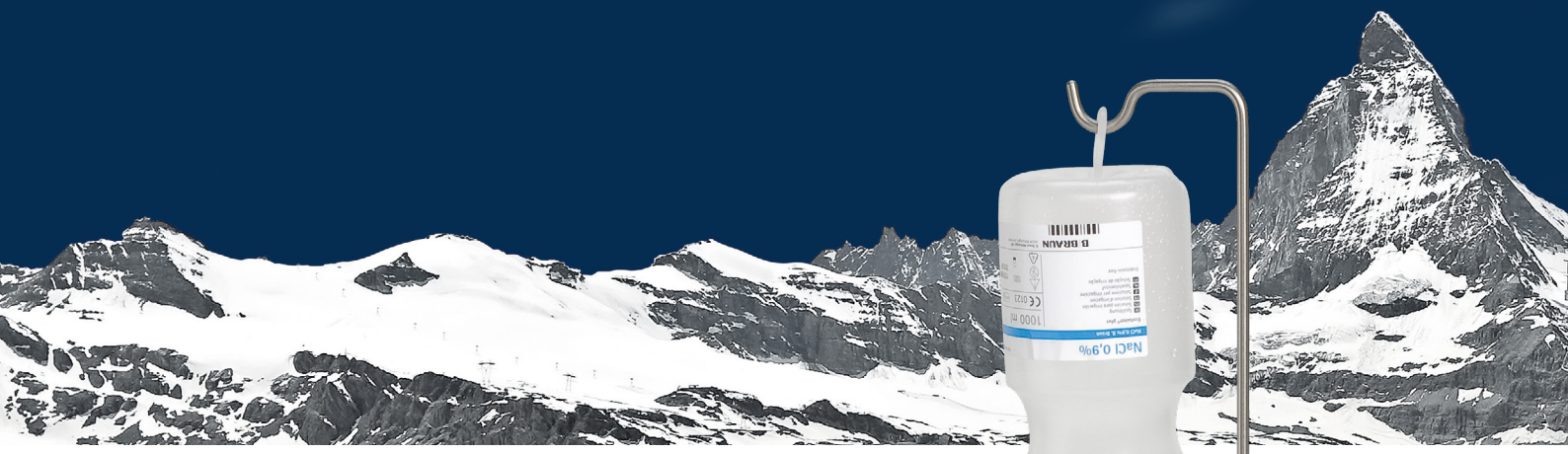
NOUVAG



EN Operation Manual

Dispenser DP 30

Infiltration Pump

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EN: Subject to change. Pictures and technical data may slightly differ due to consistent further development.
FR: Sous réserve de modifications techniques. En raison du développement constant de nos produits, les figures et les caractéristiques techniques peuvent différer légèrement.
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Vorwort

Herzlichen Glückwunsch zum Kauf eines Produktes der Firma NOUVAG AG. Wir freuen uns, dass Sie sich für ein NOUVAG Erzeugnis entschieden haben und danken Ihnen für Ihr entgegengebrachtes Vertrauen.
Diese Bedienungsanleitung wird Sie mit dem Gerät und seinen Eigenschaften vertraut machen, damit eine möglichst lange und problemlose Funktion gewährleistet werden kann.
Im Anhang finden Sie die Konformitätserklärung und unsere autorisierten Servicestellen.

- **Bitte lesen Sie diese Anleitung vor Inbetriebnahme aufmerksam durch!**

Foreword

Congratulations on your purchase of a NOUVAG AG product. Thank you for the confidence shown in our products.
Please consult the instruction manual for the use and maintenance of the device in order to ensure that it will function properly and efficiently for many years.
You will find the conformity statement and list of authorized service representatives attached.

- **Please read instructions carefully before operating!**

Préface

Félicitations vous venez d'acheter un produit NOUVAG AG. Merci de la confiance que vous montrez en nos produits.
Merci de consulter le mode d'emploi pour l'utilisation et l'entretien de cet appareil de manière à vous assurer qu'il fonctionnera correctement et efficacement pendant de nombreuses années.
Vous trouverez ci-joint les déclarations de conformité et la liste des agents agréés pour l'entretien.

- **Lire soigneusement les instructions avant utilisation!**

Prefazione

Ci congratuliamo con Lei per l'acquisto di un prodotto NOUVAG AG e le auguriamo un susseguirsi di successi professionali.
Questo manuale l'aiuterà a conoscere meglio l'apparecchiatura e le sue caratteristiche. Contiene indicazioni utili che le assicureranno un funzionamento efficiente ed una lunga durata.
Qui allegato troverete la dichiarazione di conformità e la lista dei rivenditori autorizzati.

- **Prego leggere attentamente le istruzioni per l'uso prima di mettere in funzionamento!**

Preposición

Muchas gracias por la compra de un producto NOUVAG AG.
Felicidades por la elección y la confianza depositada en nuestros productos.
Para garantizar una función duradera y eficiente del aparato, por favor consultar el manual de instrucciones.
El Certificado de Conformidad y la lista de Centros de Servicio se encuentran en el apéndice.

- **Por favor leer las instrucciones detenidamente antes de poner en marcha el aparato!**

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Table of contents

1 Product description

1.1 Intended use and operation

The Dispenser DP 30 is intended for the general surgical fluid irrigation and infiltration under the direct control of a physician.

The Dispenser DP 30 may only be operated by trained and qualified personnel.

1.2 Contraindications

a) Infectious wounds - liposuction may only be performed after the treatment of the infection and necrotic tissue.
b) In principle, generally poor health of the patient
c) liposuction shortly after a strict diet of the patient
d) Morbid obesity (obesity) - large suction volumes increase the risk of death due to fluid shifts.
e) Intravascular infusion of fluids

Relevant cases in the literature must be considered.

1.3 Technical data, Dispenser DP 30

Voltage: ---------- switchable: 100 V~/ 115 V~/ 230 V~, 50–60 Hz
Fuse, power supply: ---------- (2 fuses) T 1 AL 250 V AC
Power consumption: ---------- 40 VA
Volumetric displacement:---------- 0 – 12.5 l/h
Maximum pressure with closed tube set: ---------- 2.0 bar
Protection class:---------- Class II
Applied part (Applied part is the tube set with its attached instruments): ---------- Type BF
Dimensions (W x D x H): ---------- 260 x 250 x 110 mm
Net weight control unit: ---------- 2.4 kg
Maximum weight at the stand for the irrigation fluid bottle: ---------- 2.0 kg

The mentioned volumetric displacement is only valid for aqueous solutions without any instrument connected.

1.4 Ambient conditions

	Transport and storage:	**Operation:**
Relative humidity:	max. 90 %	max. 80 %
Temperature:	0 – 60°C, (32 – 140°F)	10 – 40°C, (50 – 104°F)
Atmospheric pressure:	700 – 1060 hPa	800 – 1060 hPa

1.5 Warranty coverage

Purchasing the Dispensers DP 30 entitles you to a 1-year warranty. If you return the warranty card for registration within four weeks of the date of purchase, warranty coverage will be extended for a further 6 months. Consumable parts are not covered by the warranty. Improper use or repair, or failure to observe these instructions, relieve us from any obligation arising from warranty provisions or other claims.

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2 Explanation of symbols

	Important information		Observe the instruction for use
	Do not use if the packaging is damaged	SN	Symbol indicating the serial number with the date of manufacture (year/month)
	Warning	CE 0197	CE symbol with notified body
	Manufacturer	STERILE EO	Sterilized using ethylene oxide
	Certified by the Canadian Standards Association (CSA) for Canada and the USA		Electrical and electronic devices that have reached the end of their service life comprise hazardous waste and may not be disposed of together with household waste. Prevailing local disposal regulations apply
	Do not reuse		Biohazard
	Pedal	REF	Symbol indicating the order number
	Indication of pump flow direction		Tube set with attached instrument is Type BF applied part
IPX8	Protected against permanent immersion.	LOT	Symbol indicating the lot number
	Manufacturing date		Tube set, REF 6022 is phthalate-based
	Date of expiry		Tube set is latex-free
	Protection class II		Potential equalization

3 Safety information

Your safety, the safety of your team and of course that of your patients is very important to us. It is therefore essential to bear the following information in mind.

Every use of the Dispenser DP 30 different to the product description defined in chapter “Intended use and operation”, causes risks for patients and trained personnel. If physical examinations and therapies are carried out without use of the devices then the device must be removed from the place of treatment. Avoid any connection or close adjacency to other devices.

3.1 EMC, Manufacturer's Declaration of Conformity

The use of (RF) Radio Frequency emitting devices and equipment as well as the occurrence of negative environmental factors in the close area of the Dispenser DP 30 may cause unexpected or adverse operation. The connection or the placing of other devices in close vicinity is not allowed.

The Product is suitable for use in establishments of the industrial sector and hospitals. When used in the domestic establishments, this unit may not provide adequate protection for radio services. The user must take remedial measures such as implementation or reorientation of the product.

Use only accessories and cables as specified in the product description. Further observe the EMC manufacturer declaration of conformity.

3.2 Integrated peristaltic pump

The integrated peristaltic pump is used for infiltration of watery solutions into the human connective tissue. The infiltration pump is not designed for intravascular infusion of liquids.

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3.3 Modification and misuse

Modifications/manipulations on the Dispenser DP 30 and its accessories are not permitted. For consequential complications, resulting from illicit modifications/manipulations the manufacturer assumes no responsibility and the guarantee is void.

3.4 Essential requirements

⚠	The Dispenser DP 30 may only be operated by qualified and trained personnel.	⚠	Improper use or repair of the device, or failure to observe these instructions, relieves Nouvag AG from any obligation arising from warranty provisions or other claims.
⚠	The use of third-party products is the responsibility of the operator. Functionality and patient safety cannot be guaranteed with third-party accessories.	⚠	Prior to using the device, before startup, and before operation, the user must always ensure that the device and accessories are in good working order and are clean, sterile and operational.
⚠	Repairs may only be performed by authorized NOUVAG service technicians.	⚠	Ensure that the operating voltage setting corresponds to the local mains voltage.
⚠	The Dispenser DP 30 may only be operated under constant supervision of medical personnel. The absence of a warning buzz to indicate malfunctions of the device requires the permanent control of the volumetric displacement of the pump.		

3.5 During use

⚠	The device is not sterile on delivery. Please observe the cleaning instructions on Chapter 8.	⚠	Do not use device in the vicinity of flammable mixtures!
⚠	At choice of the instrument the user has to make sure it confirms to EN ISO 10993, means that it's biocompatible.	⚠	The employment of the Dispenser DP 30 other than that for which it was designed (see chapter 1.1) is not permitted. The responsibility is solely carried by the operator.

4 Scope of delivery

	REF	Description	Quantity
	31678USA	Dispenser DP 30 Operation Instructions on CD-ROM	1
	4180	Dispenser DP 30 control unit	1
⊗	6022	Tubing set, sterile, 4 m, single-use	1
	1770	Stand for irrigation fluid bottle	1

Selectively

Set No. 4186, Dispenser DP 30 control unit with ON/OFF pedal

IPX8	1513	ON/OFF pedal, IPX8	1

Set No. 4187, Dispenser DP 30 control unit with VARIO pedal

IPX8	1501	VARIO pedal, IPX8	1

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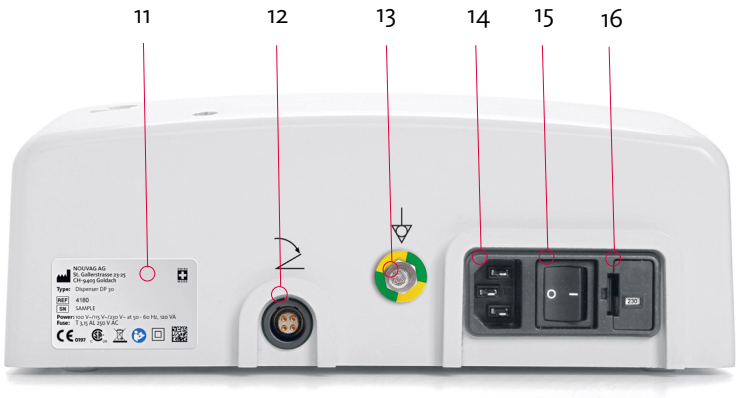
5 Device overview

Front view

1. Indicator light for Power On/Off
2. Operating panel with pump displacement scale
3. Control dial to set pump displacement volume
4. Release key for tubing set bracket
5. Peristaltic pump
6. Tubing set
7. Stand for irrigation fluid bottle
8. Roller clam
9. Venting valve
10. Irrigation fluid
11. Type plate with type designation, reference number, serial number, information on power supply and device fuse
12. Pedal socket, device rear
13. Potential equalization
14. Power entry module with power plug socket
15. Power entry module with power switch
16. Power entry module with national voltage setting

Rear view

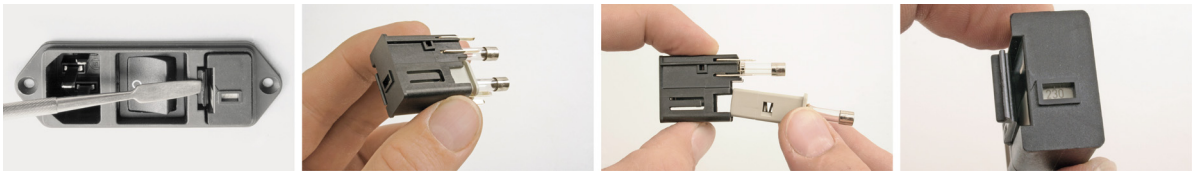


6 Startup

6.1 Connection to the power supply

In order to prevent the risk of electric shock, the device may only be connected to a power network with a PE protective earth conductor.

If the voltage shown does not correspond to the local mains voltage, the grey fuse holder must be set to the correct voltage:



A) Switch off device.

B) Unplug the power cable.

C) Use a screwdriver to open the fuse slot.

D) Remove the fuse holder.

E) Remove the grey fuse holder and reinsert it so that the local mains voltage setting is shown in the small window.

F) Slide the grey fuse holder back in and close the fuse slot.

G) Check the mains voltage shown on the fuse slot.

H) Plug the power cable back into the device.

6.2 Device preparation

1. Insert the stand for the irrigation fluid into the stand holder.
2. Plug the pedal plug into the pedal socket at the rear of the control unit.
3. Assemble the tubing set (see images).

Check the expiry date of the tubing set and ensure that the packaging is not damaged. Using non-sterile tubing sets can result in serious infection, and in extreme cases, can be fatal.

When inserting the tubing set, notice the arrow marked on the tubing set bracket. It indicates the direction of flow of the infiltration liquid.

Do not regulate the amount of irrigation fluid using the roller clamp on the tube set; with the Dispenser DP 30, this is regulated instead using the control dial and the foot pedal. For this reason, make sure to open the roller clamp as far as it will go.

Use only the Nouvag tube set, otherwise the function cannot be guaranteed.

The container of irrigation fluid may weigh a maximum of 2 kg. Heavier containers than allowed can cause the device to tip over.

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A) Press the release key for tubing set bracket (on top of the control unit) to open the pump.

B) The compartment with the integrated tubing bracket opens.

C) Place the tubing set into the tubing bracket provided in such a way that the end of the tubing set with the spike exits the pump to the rear of the control unit. Check that the tubing is secure.

D) With the tubing set inserted, press the compartment downwards until it clicks into place.

4. Insert the spike at the end of the tubing set into the irrigation fluid bottle and hang the bottle onto the stand.
5. Open the roller clamp on the tubing set as far as it will go.
6. Open the vent valve at the spike.
7. Connect the control unit to the power socket.

Ensure that the operating voltage setting corresponds to the local mains voltage.

The container of irrigation fluid may weigh a maximum of 2 kg. Heavier containers than allowed can cause the device to tip over.

6.3 Device setup

- Place the Dispenser DP 30 and all required accessories and instruments on an even, non-slip surface and make sure you have good access to all controls.
- Do not allow the operating range of the device (including the cable) to be compromised by limiting factors.
- The system operation panel and the infiltration liquid bottle must be fully visible at all times.
- It must be explicitly ensured that no objects can fall on the pedal.
- The power plug at the rear of the device must be accessible at all times.

7 Operation

7.1 Switching the device on and off

Use the power switch “I/O” at the rear of the control unit to switch the control unit on and off.
The device may be switched off at any time irrespective of any procedure for switching off the device.
The green indicator light up left on the operation panel is on, when the main switch is switched on and the device is ready for operation.

7.2 Regulation of the infiltration process

With ON/OFF pedal

With VARIO pedal

Control dial in conjunction with ON/OFF pedal

The desired volumetric displacement is set with the control dial. The pumping process is started by actuating the ON/OFF pedal. The volumetric displacement can be varied at any time using the control dial.

Control dial in conjunction with VARIO pedal

The maximum volumetric displacement can be varied at any time using the control dial, even while the pedal is being pressed. Control using the VARIO pedal regulates the volumetric displacement of the pump up to the set maximum value.

7.3 Flexible tube pump

Turn control dial clockwise from the OFF position. Pump starts, liquid emerges from the open tube end.
Turning the dial up to the maximum value controls the increase in volumetric displacement.
The pump stops immediately when the release button of the pump compartment is pressed.

7.4 Functional check

Prior to Dispenser DP 30 startup or use of accessory equipment, the user must always ensure that each individual component is in good working order, free of defects, clean, sterile and operational. The tube set has to correspond with the correct flow direction (6.2 Device Preparation) and the pump has to function.
The green LED is on after the device is switched on.

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8 Cleaning and disinfection

The following point is important with regard to caring for the material:

- Perform cleaning and disinfection after every treatment.

8.1 Control unit and pedal

Wipe the outside using tested surface disinfectant or 70 percent of isopropyl alcohol. The front plate of the control unit is sealed accordingly for this purpose and can be wiped clean.

8.2 Tube set, REF 6022

- Single-use tubing sets may not be reused.
- Tube sets must be disposed of properly after use.
- Don't use tube set when pack was open or damaged .
- Don't use tube set when expiry date is timed out.
- Use only Nouvag tubing sets with REF 6022!

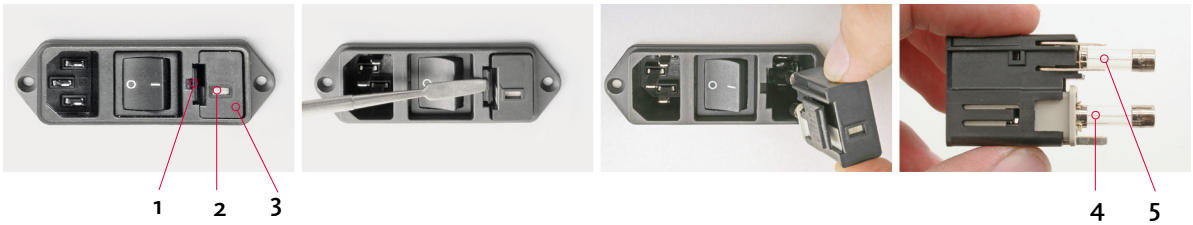
Sterility cannot be guaranteed by reusing and re-sterilization of tubing sets. The characteristics of the material change in a manner that can result in failure of the system. This may result in serious infections or even patient death worst-case.

9 Maintenance

9.1 Replacing the control unit fuse

Users can replace faulty control unit fuses themselves. These are located at the rear of the device in the fuse slot beside the power switch:

- Switch off device.
- Unplug the power plug.
- Open the fuse slot using a screwdriver.
- Replace the faulty fuse T 1 AL 250 V AC.
- Slide the fuse holder back in and close the fuse slot.
- Check the mains voltage shown on the fuse slot.
- Plug in the power plug again.



1. Fuse slot locking mechanism
2. Display window for voltage setting
3. Fuse slot
4. Fuse 1
5. Fuse 2

9.2 Safety inspections

The essential requirements have been defined and within the risk analysis assessed. The approved results have been filed in the risk management act with the manufacturer.

The performance of safety inspections on medical devices is required by law in several countries. The safety inspection is a regular safety check that is compulsory for those operating medical devices. The objective of this measure is to ensure that device defects and risks to patients, users or third parties are identified in time.
The STI (Safety Technical Inspection) for the Dispenser DP 30 shall be executed every 2 years by authorized experts. Results shall be documented.

The service manual, wiring diagrams, and descriptions are available upon request from the manufacturer.

NOUVAG AG offers a safety inspection service for its customers. Addresses can be found in the appendix of this operation manual under “Service centers”. For further information please contact our technical service department.

Further international service centers are listed on the Nouvag website:

www.nouvag.com › Service › Service providers

9.3 Information on disposal

When disposing of the device, device parts and accessories, the regulations prescribed by law must be observed. To ensure environmental protection, old devices can be returned to the dealer or manufacturer.

Contaminated single-use tubing sets are subject to specific disposal requirements. Please observe prevailing national disposal regulations.

When discarding the device components and accessories, please comply with the issued statutory regulations. With regard to the preservation of the environment old equipment may be returned to the distributor or manufacturer.

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10 Malfunctions and troubleshooting

Malfunction	Cause	Solution	Refer to the operating instructions
Device is not functional (Indicator light is not on)	Control unit not switched on	Set the power switch "I/O" to "I"	7.1 Switching the device on and off
	Power connection not established	Connect the control unit to the mains power supply	6.1. Connection to the power supply
	Incorrect operating voltage	Check the mains voltage	6.1. Connection to the power supply
	Faulty fuse	Replace the fuse	9.1 Replacing the control unit fuse
Pump doesn't work (Indicator light is on)	Control switch is on too low position or "Off"	Raise pump performance by turning control switch up	7.2 Regulation of infiltration process
	Tubing set incorrectly inserted	Insert tubing set correctly (note the direction)	6.2 Device preparation
	Incorrect operation	Check operating instructions	6.2 Device preparation
	Pedal was not pressed	Press pedal	7.2 Regulation of infiltration process
	Roller clamp is closed	Open Roller clamp all the way	6.2 Device preparation
Pedal doesn't work (Indicator light is on)	Pedal is not connected	Connect pedal with the socket on rear of device	5.0 Device overview 6.2 Device preparation
	Incorrect operation	Check operating instructions	7.2 Regulation of infiltration process 6.2 Device preparation

If the problem cannot be solved please contact your supplier or an authorized service center. The addresses are provided in the appendix of this operation manual under "Service center".

11 Spare parts list with order numbers

Accessories	**REF**
ON/OFF pedal, IPX8	1513
VARIO pedal, IPX8	1501
Stand for irrigation fluid bottle	1770
Tubing set with spike, roller clamp and Luer Lock, sterile, 4 m, single-use	6022
Operation manual for Dispenser DP 30 on CD-ROM	31678USA *

**A printed version of the operation manual is available at Nouvag AG, free of charge. At order please designate that you wish to receive a printed version.*

To order additional parts, please contact our customer service department.

Appendix EN

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE / DICHIARAZIONE DI CONFORMITA / DECLARACIÓN DE CONFORMIDAD

Wir, die Firma
We, of the company
Nous, la firme
Noi, della ditta
Nosotros, la empresa

NOUVAG AG
St.Gallerstrasse 23-25
CH-9403 Goldach
Switzerland

erklären in alleiniger Verantwortung, dass das Medizinprodukt
declare on our own responsibility that the medical device
déclarons sous notre propre responsablité que le dispositif médical
dichiariamo sotto propria responsabilità che il dispositivo medico
declaramos bajo nuestra propia responsabilidad que el dispositvo médico

Dispenser DP 30 SET (REF 4186 / 4187)

REF	*Bezeichnung / Description*	*Klassifizierung nach MDD / Classification acc. MDD*
4180	Steuergerät Dispenser DP 30 / Control unit Dispenser DP 30	IIa
6022	Schlauchset / Tubing set	IIa
1501nou	Vario-Fusspedal / Footpedal Vario	Ersatzteil
1513nou	Fussschalter On/Off / Foot switch On/Off	Ersatzteil

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht.
meets all the provisions of the medical directive 93/42/EEC which apply to him.
remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE qui le concernent.
addempie a tutte le exigenze della direttiva 93/42/CEE che lo riguardano.
cumple con todos los requistos establecidos en la Directiva Médica 93/42/CEE que le corresponden.

Angewandte harmonisierte Normen
Applied harmonized norms
Normes harmonisées appliquées
Norme armonizzate applicate
Normas acordes aplicadas

EN 60601-1:2006
EN 60601-1-2:2007
EN 62366:2008

Konformitätsbewertungsverfahren
Conformity assessment procedures
Procédure d'évaluation de la conformité
Procedimento d'evaluazione della conformita
Procedimineto de evaluación de la conformidad

93/42/EWG, Anhang II
93/42/EEC, Appendix II
93/42/CEE, Appendice II
93/42/CEE, Appendice II
93/42/CEE, Apéndice II

Gültigkeitsdauer Konformitätserklärung
Validity of declaration of confirmity
Durée de validità de la declaration de conformité
Tempo di validità della dichiarazione di conformita
Tiempo de validez de la declaración de conformidad

27.Januar 2021 (Gültigkeit QS-Zertifikat, Reg.-Nr. HD 60108201 0001)

Benannte Stelle / Notified body / Organisme notifié / Organismo notificato / Organismo notificado

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
DE-90431 Nürnberg

CE 0197

Goldach, 22.12.2017
Ort, Datum / place, date
lieu, date / luogo, data / lugar, fecha

B. Hutter, President

Electromagnetic compatibility (EMC)

Remark:
The **Product** subsequently referred to herein always denotes the Dispenser DP 30 / Nanotec Endo.

Changes or modifications to this product not expressly approved by the manufacturer may result in increased emissions or decreased immunity performance of the product and could cause EMC issues with this or other equipment. This product is designed and tested to comply with applicable regulations regarding EMC and shall be installed and put into service according to the EMC information stated as follows.

WARNING
Use of portable phones or other radio frequency (RF) emitting equipment near the product may cause unexpected or adverse operation.

WARNING
The product shall not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the product shall be tested to verify normal operation in the configuration in which it is being used.

Compliant Cables and Accessories
WARNING
The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the product.
The table below lists cables, transducers, and other applicable accessories for which the manufacturer claims EMC compliance.
NOTE: Any supplied accessories that do not affect EMC compliance are not listed.

Description	**Length max.**
On/Off Footswitch IPX8	2.9m
Footpedal Vario IPX8	2.9m

Guidance and manufacturer's declaration – electromagnetic emissions

The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.

Immunity tests	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines (+/- 1 kV for input/output lines)	+/- 2 kV for power supply lines (+/- 1 kV for input/output lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	> 100 % dip for 0,5 cycle 60 % dip in U_T for 5 cycles 30 % dip in U_T for 25 cycles < 5 % U_T > 100 % dip in U_T for 5 sec	> 100 % dip for 0,5 cycle 60 % dip in U_T for 5 cycles 30 % dip in U_T for 25 cycles < 5 % U_T > 100 % dip in U_T for 5 sec	Mains power quality should bet hat of a typical commercial or hospital environment. If the user of the Product requires continued operation during power mains interruptions, it is recommended that the Product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity for not life support equipment

The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.

Immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz outside ISM bands	3 V rms 150 kHz to 80 MHz outside ISM bands	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz
			where P is the maximum output power rating in the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Fixed strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Product is used exceeds the applicable RF compliance level above, the Product should b observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Product.

b over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the not life support equipment

The Product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Product can help prevent electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the higher frequency range applies.

Note 1: At 80 MHz and 800 MHz, the separation distance fort the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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