Instructions for use

periPAP

Keep these instructions!

CE 0482

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Version 1.2

Content

1 Introduction

These instructions for use are intended to assist you in operating the DEHAS periPAP.

2 Intended Use

The periPAP is used to provide mixed oxygen / air during ventilation for resuscitation of infants using the T-piece occlusion method. The periPAP incorporates a variable PIP valve to set a positive inspiratory pressure of 1-18 mbar and facilitates the provision of safe and consistent breathing patterns for neonates; by providing a consistent PEEP of 2-20 mbar to assist in maintaining residual functional capacity.

The periPAP is intended for use with an O2/AIR mixer (QualityMIX DEHAS series) or, in exceptional cases, can be used for direct supply through an O2/AIR connection to a central gas supply.

3 Definition

PIP = Peak Inspiration Pressure

PEEP = Positive End Expiratory Pressure

mbar = Millibar

4 Technical Data

4.1 Safety features

Type of device: not electrically operated

Mode of operation: mechanical / pneumatic

Characteristics of the patient circuit:

- - Fixed safety release valve
- - Integrated pressure gauge
- - Variable orderable accessories
- - Variable PEEP - adjustment
- - Variable PIP - regulator

Technical data periPAP	Value
Available O_2 concentration	Up to 100% O_2
Safety valve	30 mbar
Fixed setting of the internal pressure relief valve	25 mbar
Adjustable PIP	1 – 18 mbar

Adjustable PEEP	2 - 20 mbar (with max. ALARM at approx. 25 mbar)
Manometer	0 – 60 mbar
Flowmeter	0 - 15 LPM with 9/16 " connection to mixer
Connection hose for alternative supply 9/16" to central gas supply	1.5 m ISO - colours 9/16" to DIN (AGA, BS, NF-Carba, UNI - also available)
Rail bracket 10 - 35 mm - if the supply is via a hose	10 - 35 mm rail bracket as accessory

4.2 Warehousing:

Technical data periPAP	Value
Storage temperature range	-20°C to +50°C / Up to 95% humidity
Operating temperature range	0°C to +50°C / Up to 95% humidity

5 Delivery / Variations and accessories

The periPAP is also available with an installed rail bracket. For connection to the central gas supply, we offer a wide range of gas hoses with different international standards

5.1 Available accessories and variations:

Art. No.	Description
D – periPAP	Main device without accessories
D-periPAP – Set	Main device wit accessories
D – periPAP -Z-0	Accessory set with mask (size 0)
D – periPAP -Z-1	Accessory set with mask (size 1)

6 Standards

The product complies with the essential requirements according to Annex I of Directive 93/42/EEC (Medical Devices Directive) as well as the applicable national regulations such as the Medical Devices Act.

Standard / Norm	Title
EN 62366-1	Medical devices - Part 1: Application of fitness for use to medical devices
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 15001	Anaesthesia and respiratory equipment - Compatibility with oxygen
EN ISO 15002	Flow measuring devices for connection to tapping points of piping systems for medical gases
EN ISO 15223-1	Medical devices - Symbols, marking and information to be used in the labelling of medical devices - Part 1: General requirements
EN ISO 5367:2014	Anaesthesia and respiratory equipment - Breathing sets and connectors

EN ISO 780	Packaging - Shipping packaging - Graphical symbols for handling and storage of packages
ISO 10651-5	Respiratory equipment for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas-operated emergency resuscitators
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
ISO 11195	Gas mixers for medical use – stand alone
ISO 20417	Medical devices - Requirements for information to be provided by the manufacturer

7 Safety information - Warning, caution and labelling information

Symbol	Description
CE 0482	The symbol indicates that the device complies with the requirements of Regulation 93/42/EEC concerning medical devices and all applicable international standards.
 WARNING	Indicates a potentially hazardous situation which, if not prevented, may result in death or serious injury.
 CAUTION	When this symbol is used, it indicates a potentially hazardous situation which, if not avoided, may result in property damage..
	Manufacturer
	Date of manufacture
	Store in a dry place / Protect from moisture / wetness
	Medical device

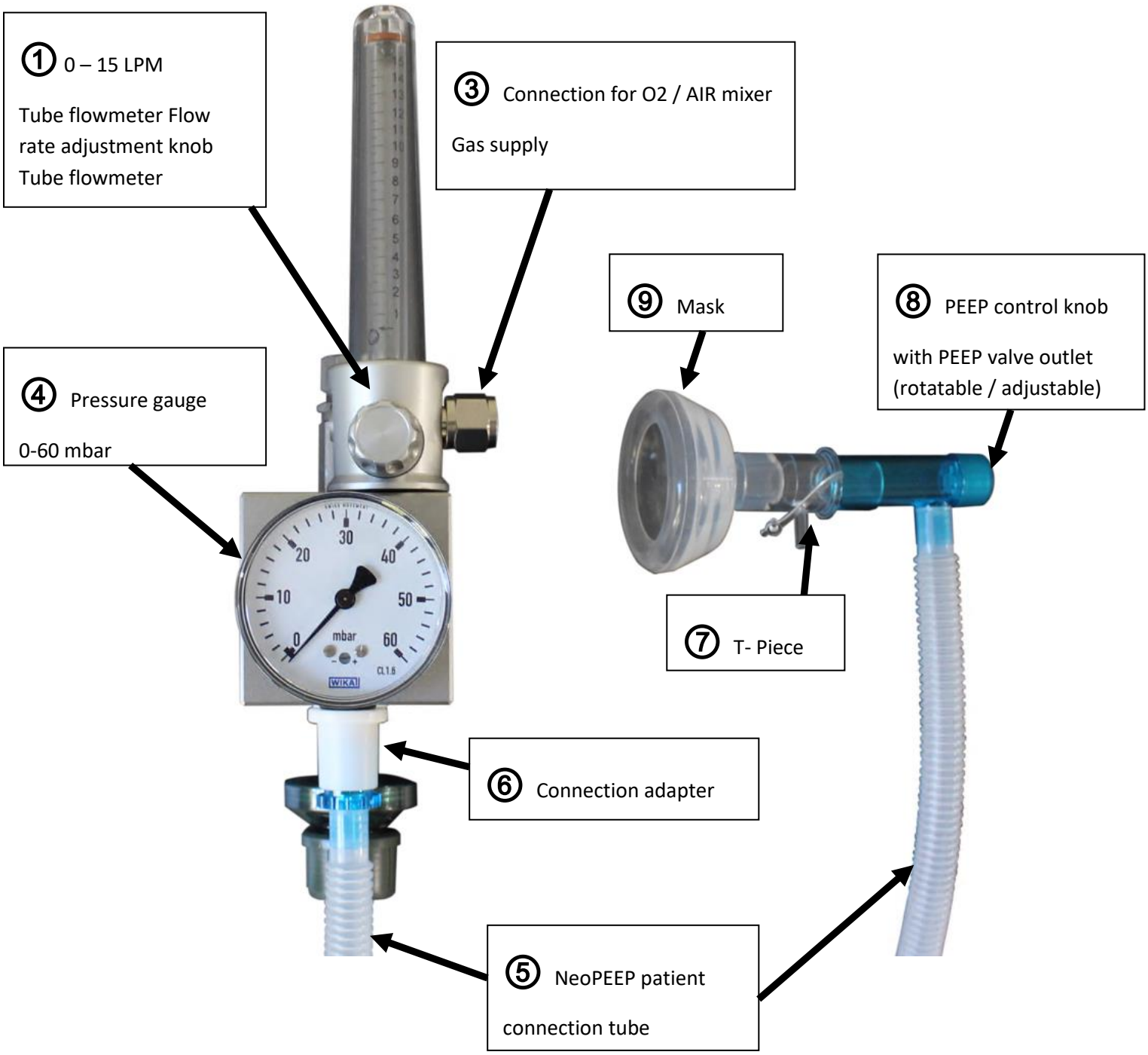
	LOT number
	Reference number / item number
	Unique device identifier
	Non sterile
 oder 	Refers to the need for the user to consult the instructions for use.
	Do not use if packaging is damaged
	Do not use oil

 **WARNING**

- **Only for use by trained, qualified personnel!**
- **The function of the periPAP DEHAS must be checked before use!**
- **Use with a gas inlet pressure of 4.3 bar recommended by the manufacturer!**
- **Only for use with a supply flow rate within the range specified by the flow meter!**
- **Not intended for use with a higher gas flow (flow) of 15 LPM!**
- **The outlet pressure must be adjusted after changing the flow rate on the flowmeter!**
- **Never attempt to adjust the safety valve!**
- **Only use the accessories intended by the manufacturer for this product!**
- **Do not use the unit in the presence of flammable materials and ensure that no ignition sources are present while the unit is in operation. Fire hazards are possible in oxygen-enriched environments!**
- **Do not use oil, grease or other incompatible substanceswith oxygen on any part of the product!**

- **Do not use the unit on unattended patients.**
- **Make sure you use a good mask seal and a mask of the correct size!**

8 Description Components



⑩ Safety valve fixed at 25 mbar

② Adjustable pressure valve for PIP adjustment (rotatable / adjustable)

9 Precautions

- Never wait to start resuscitation. If a Neo-Tee system is not immediately available, cannot be used effectively, or is flowing at an undesirable rate from the gas source, check your department manual or AHA guidelines for other recognised resuscitation procedures that could be performed.

- Use only by persons trained in infant and neonatal resuscitation!

- The device may only be used after a pre-use check has been completed to ensure that the correct ventilation pressure is delivered to the patient.

- The oxygen concentration should be monitored at all times with an oxygen analyser.

- The input flow setting affects the PIP and PEEP. The unit can achieve high PEEPs, these should always be checked with the pressure gauge.

10 Installation and testing prior to use

WARNING

- **Damage caused by dropping the periPAP unit or other similar forms of impact may cause damage resulting in incorrect operation of the unit.**
- **If you suspect damage or visible damage has occurred, do not use the unit and contact your supplier's service department.**

1. Set the flowmeter to the minimum by turning the setting knob on the flowmeter (**Fig.No. ① Tube flowmeter**) and the regulator to the minimum by turning the adjustable pressure valve (**Fig.No. ② Pressure valve PIP setting).**

2. Connect the periPAP to the oxygen/air supply to the O2/AIR mixer using the flow meter (**Fig.No. ① Tube flow meter)** with the help of the input connector (**Fig.No. ③ Input connector 9/16").**

3. Check whether the pressure gauge (**Fig. No. ④ Pressure gauge**) indicates zero (0) (within the black area). If not, the periPAP must be serviced by your DEHAS authorized dealer.

4. Connect the supply hose for the patient ventilation circuit (**Fig. No. ⑤ NeoPEEP patient connection hose**) to the periPAP block using the adapter (**Fig. No. ⑥ Connection adapter**). Do not yet connect the patient to the supply at this point!

5. Set the flow meter (**Fig.No. ① Tube flow meter**) to the desired flow rate using the adjustment head.

6. Close the patient opening of the T-piece (**Fig. No. ⑦ T-piece**) and the outlet of the PEEP* valve (**Fig. No. ⑧ PEEP valve outlet**) to achieve an airtight seal.

7. Turn the knob of the adjustable pressure valve (**Fig.No. ② Pressure valve PIP setting**) until the desired PIP* **(*Peak Inspiratory Pressure)** value is set as indicated by the pressure gauge (**Fig.No. ④Pressure gauge).** The setting of the inlet flow affects PIP.

8. Uncover the PEEP valve outlet (**Fig. No. ⑧ PEEP valve outlet**). Adjust the PEEP setting by turning the PEEP control cap (**Fig. No. ⑧ PEEP control cap)** on the NeoPEEP patient connection tube until the reading on the pressure gauge (**Fig.No. ④ Pressure gauge**) indicates that the correct PEEP has been reached. Adjusting the input flow rate influences the PEEP.

9. Connect the "T-piece" (**Fig. No. ⑥ T-piece**) to a suitable ventilation mask (**Fig. No. ⑨ Mask**) or to the patient's ventilation hose.

10. The safety valve (**Fig. No.⑩ Safety valve**) is fixed at 25 mbar.

11. The device is now ready for use.

11 Observance of the guidelines for use during resuscitation

1. Follow the pre-use set-up procedure and ensure the required flow rate and outlet pressures according to the hospital protocol for resuscitation.

2. Ensure that the pressures are checked before administering the gas to the patient.

3. Connect the patient circuit to the mask and place it over the patient's mouth and/or nose.

4. Resuscitate by placing and removing the thumb (or index finger) over the PEEP buttonhole to allow inspiration and expiration at the desired respiratory rate, according to hospital protocol.

12 Cleaning / Disinfection

Manufacturer DEHAS Medical Systems GmbH Wesloer Str. 107-109 23568 Lübeck	Sterilisation method: N/A The product is not intended for the sterilisation process.	

Described product:

Product: **periPAP**

Product category: **Accessories**

Article name: **D - periPAP**

D - periPAP - SET

Please note that optionally ordered accessories (e.g. mask, T-piece) are for single use only.

Please follow the cleaning instructions of the manufacturer of the NeoPEEP patient connection tube.

WARNINGS:	Do not use disinfectants containing alcohol or phenol. Do not use strong solvents or abrasive cleaners. Do not clean with aromatic hydrocarbons. Do not autoclave! Do not sterilise! Do not immerse in liquids!
The instructions listed have been validated as SUITABLE by the medical device manufacturer for the preparation of a medical device for reuse. It is the responsibility of the reprocessor to ensure that the actual reprocessing performed with the equipment, materials and personnel used in the reprocessing facility achieves the desired results.	

 CAUTION
• **Do not bring into contact with oil, grease or flammable liquids - There is an increased risk of fire.**

INSTRUCTIONS	
Preparation for decontamination:	The outside of the periPAP must be cleaned and disinfected at regular intervals or at the latest after each use in accordance with the applicable hygiene standard.
Cleaning: Manual	1. Disconnect the product from the connecting hoses and from the gas supply by turning it off. 2. Wipe the surface of the product with a cloth soaked in water and detergent and wrung out. 3. Do not allow any liquid to get inside the product. 4. Wipe with a dry cloth.
Disinfection: **Manual**	1. Wipe the surface of the product with a cloth moistened with a non-oxidizing disinfectant. 2. Observe the exposure time of the disinfectant manufacturer according to the required spectrum of activity. 3. After the exposure time specified by the disinfectant manufacturer, wipe dry with a dry cloth. 4. Ensure that the product is free of disinfectant residues.
Manufacturer's Recommendation:	The manufacturer recommends the use of the disinfectant Bacillol ® 30 Foam, Bacillol ® 30 Tissues, Bode Chemie GmbH & Co. The current product data sheet of the disinfectant manufacturer must be observed.
Storage:	Store in a dry place.

13 Maintenance / Service

The DEHAS periPAP should be serviced at least every 24 months; or if the pressure gauge does not read zero in the absence of flow or if the accuracy of the device is in question. DEHAS recommends that the gas hoses are checked before use or at each patient change and replaced at least every 10 years.

14 Return of goods

Please contact your dealer in this regard. They will coordinate the return for you. It is important that you provide a description of the fault so that the return can be processed in a targeted manner. All returns must be shipped in sealed containers to prevent damage. The specialist dealer is not responsible for equipment that is damaged during transport.

15 Disposal

- **The product or parts of it may be contaminated after use. Clean and disinfect the product before disposal.**

At the end of the usage phase: Have the unit disposed of properly in consultation with the respective disposal company. Observe the applicable legal regulations.

16 Warranty

The warranty period for the appliance is 12 months from the date of sale, subject to the following conditions

In the event of a defect in the unit within the applicable period, the dealer, upon written notice thereof and upon proof that the unit has been stored, installed, maintained and operated in accordance with instructions and standard industry practices and that no alterations, substitutions or modifications have been made to the product, will correct such defects by appropriate repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE A WARRANTY.

Dealer is not authorised to make any oral warranties about the Product described in this Agreement and such statements are not binding and are not part of the Purchase Agreement. Therefore, this 2nd statement is the final, complete and exclusive representation of the terms of the contract.

- Subject to technical changes!

Declaration of conformity

DEHAS Medical Systems GmbH
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CE 0482

REF periPAP / Accessories for QualityMix oxygen/air mixer
Klassifikation: IIb
Klassifikation Kriterien: Klausel 1.2 Regel 11 in Anhang IX des MDD

We hereby declare under our sole responsibility that the above mentioned products comply with the provisions of the following EC Council Directives and Standards. All supporting documents are kept at the premises of the manufacturer and the notified body.

Guidelines:	General Application Directives: Medical Device Directive (MDD), Council Directive 93/42/EEC of June 14, 1993 Annex II, 3 on Medical Devices of the European Parliament.	
Applied standards:	EN 62366-1 EN ISO 14971 EN ISO 780 ISO 10651-5 ISO 20417 ISO 5367	ISO 10993-1 ISO 11195 ISO 15001 ISO 15002 ISO 15223-1

Notified body:	DNV Medcert GmbH / CE 0482
Adress:	Pilatuspool 2, 20355 Hamburg; GERMANY
Certificate number:	4153DE410200327 / Expiration date: 2024-05-27
Traceability of already manufactured devices:	Traceability via LOT number / Serial number
Valid from/until:	2020-03-27 until expiration date
Manufacturing Representative:	Quality Manager
Position:	Quality Management
Date of issue:	20.12.2021

17 Manufacturer's information

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Sales	

Rev. 1.2 Version 17.08.2023