Klinikbedarf
Heimtherapie

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Beratung
Service

Certified to DIN EN ISO 13485

Operating Instructions

Quality Mix

Air-Oxygen Mixer

Quality Mix HF (High Flow)
Quality Mix LF (Low Flow, as pictured)

Save these instructions!

CE
0482

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1. Contents of delivery; Inspection upon receipt

Contents of the delivery: One main device along with any additional components specified for your order
One operating instructions document

Inspection: Take the mixer out of its packaging and inspect it for damages. Do NOT use the mixer if you detect any damage. Contact your supplier.

2. Intended usage

The Quality Mix air-oxygen mixer from DEHAS Medical is used to administer a continuous, precise mix of medical air and medical oxygen through its outlet ports to infants, children and adults. The exact fractional inspired oxygen concentration (FIO_2) corresponds to the selected FIO_2 setting on the control knob (dial).

Indication: This device should be used for patients who find it difficult to get sufficient oxygen from the ambient air.

Contraindications: This device should not be used for patients who cannot breathe on their own. Do not use for life support or lifesaving procedures.

3. Before initial usage

Read all instructions before use!

These operating instructions are intended to show trained professionals how to install and operate the Quality Mix. They promote safety and protect your device from damage. If you do not understand information or instructions in this document, do not use the device and contact your supplier.

DANGER

This product is not intended for use as a life-sustaining or life-supporting device.

4. Explanation of the key abbreviations

FIO_2	Fractional concentration of inspired oxygen
DISS	Diameter Indexed Safety System
NIST	Non-Interchangeable Screw Thread Europe
Bar	Measurement unit for pressure
l/min	Litre per minute

5. Safety information – warnings and cautions

DANGER	Indicates an imminently hazardous situation, which if not avoided, will result in death or serious injury.
WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
CAUTION	When this key word is used without the safety alert symbol, it is meant to draw attention to a potentially hazardous situation which, if not avoided, may result in property damage.
or	REFER TO THE ACCOMPANYING DOCUMENTS
	Symbol indicating "DO NOT USE OIL"
0482	This symbol indicates that the device complies with the regulation 93/42/EEC concerning medical devices and all applicable international standards.

WARNING

- The air-oxygen mixer should only be operated by trained medical personnel under the direct supervision of a licensed physician.
- Use this air-oxygen mixer only for the purpose described in these instructions.
- Check the prescribed dose before administering to patients. Monitor the flow frequently.
- The air-oxygen mixer may only be serviced by a qualified service technician.
- Always follow the EN and DIN standards pertaining to medical gas products, flow meters and oxygen handling.
- The oxygen concentrations must be confirmed using an oxygen analyser and monitor.
- The accuracy of the oxygen concentration can be affected if the bleed **flow** is not activated at flow settings below 15 l/min for high-flow mixers, and at 3 l/min for low-flow mixers.
- Do not interfere with or disable the alarm.
- Do not use the mixer when the alarm sounds.
- Do not use oil in or near the mixer.
- Do NOT obstruct or block the bleed port at the auxiliary outlet of the mixer.
- Do NOT use the mixer near flames, flammable/explosive substances, vapours or gases.
- The rotary dial for the oxygen concentration cannot be rotated 360 degrees. The mixer can be damaged if the dial is turned to less than 21% or more than 100% oxygen.

CAUTION

- Close the gas supply line whenever the air-oxygen mixer is not being used.
- Store the air-oxygen mixer in a clean, dry place when it is not in use.
- The air-oxygen mixer contains NO magnetic, ferrous materials; it can be used with MRIs at a 2-metre distance with up to 3 Tesla.

CAUTION

- Make sure that all connections are secure and tight.
- Avoid excessive pressure surges of more than 6.5 bar whenever the mixer's inlets are pressurized.
- Do NOT sterilise in a steam autoclave.
- Do NOT immerse in liquids.
- Do NOT sterilise with Ethylene Oxide (EtO).
- Do NOT use if dirt or contaminants are found on or near the mixer or its connectors.
- NEVER smoke in an area where oxygen is being used.
- Do NOT clean with aromatic hydrocarbons.
- The supply's inlet pressure must correspond to the value specified on the mixer.
- When using bottled gas or a high-pressure gas source, always use a pressure reducer to maintain the pressure range between 3.5 and 5.5 bar.

6. Technical specifications

Technical specifications are subject to change without notice.

	High Flow with high flow capacity	**Low Flow** with low flow capacity
Main outlet of flow	15 – 120 l/min	3 – 30 l/min
	Pressure on both supply lines is 4.2 bar **<u>without</u>** bleed flow	
Auxiliary outlet flow	2 – 100 l/min	0 – 30 l/min
	Pressure on both supply lines is 4.2 bar **<u>with</u>** bleed flow	
Bleed flow	≤ 13 l/min at 3.4 bar	≤ 3 l/min at 3.4 bar
Maximum combined flow (of all outlets)	≥ 120 l/min	≥ 30 l/min
Emergency flow (malfunction of air or oxygen supply)	> 85 l/min	> 15 l/min

		High Flow with high flow capacity		**Low Flow** with low flow capacity	
Alarm sounds when supply pressure drops	Without pressure regulator modul	On	Off	On	Off
		3,3 bar	4,2 bar	3,3 bar	4,2 bar
	With pressure regulator modul	On	Off	On	Off
		2,3 bar	3,2 bar	2,3 bar	3,2 bar
Alarm volume		≥ 80 dB at a distance of 30 cm			
Setting range for the oxygen concentration		21 – 100%			
Gas inlet pressure		4,5± 0,5 bar: air and oxygen pressure differential should be within 0.7 bar			
Accuracy of the mixed gas (FIO_2)*		± 3 % oxygen			
Connection types		DISS inlets and outlets for oxygen and/or NIST inlets for air and oxygen			
Dimensions (LxWxH)		13 x 16.5 x 12.2 cm			
Weight		1600 g			
Operating temperature		+5°C to +40°C			

** The accuracy of the oxygen concentration can be affected if the bleed is not activated in accordance with the specifications.*

The air-oxygen mixer has been degreased before it was delivered to prepare it for use with oxygen. The reverse gas flow of the air-oxygen mixer corresponds to clause 6 of ISO 11195. The oxygen-analysis device being used must comply with the ISO 7767 standard and the CE regulations.

7. Pressure drop

Low Flow	≤ 0.14 bar at inlet pressures from 3.1 to 5.2 bar, with a flow rate of 10 l/min at 60% F_{IO_2}
High Flow	≤ 0.21 bar at inlet pressures from 3.1 to 5.2 bar, with a flow rate of 30 l/min at 60% F_{IO_2}

8. Transportation and storage conditions

Temperature range	-20 °C to 60 °C
Humidity	Max. 95% non-condensing humidity

9. Dryness and composition of the supply gases

Air:

The medical air supply must meet the requirements of the national standards.

Oxygen:

The oxygen being used must meet all requirements for medical oxygen according to the European Pharmacopoeia.

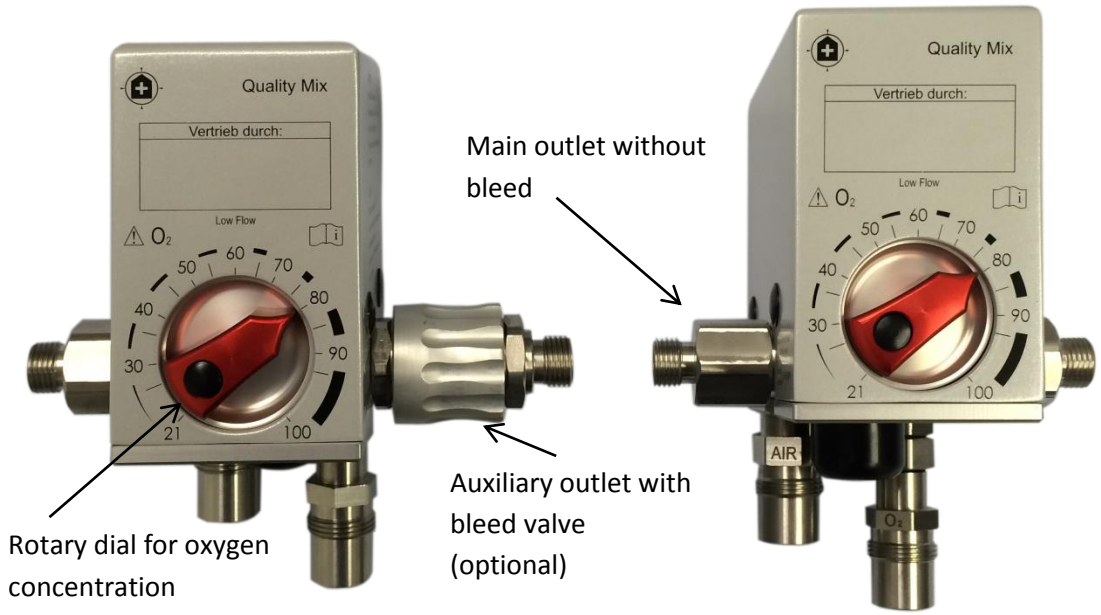
Condensation point of the gases:

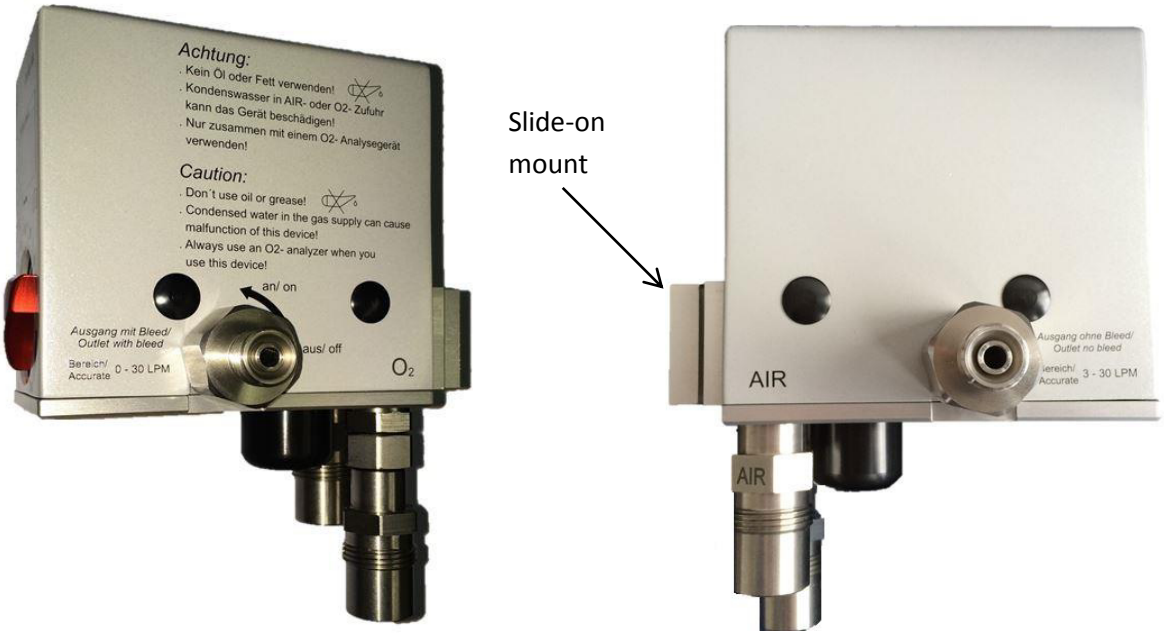
Both inlets must remain at least 5 °C below the lowest temperature to which the air distribution system is exposed.

10. Illustrations and identification of components

CAUTION
The labelling on the device will not come off if you follow the sterilisation instructions properly. Contact DEHAS or your local representative if the labelling becomes unreadable.

These photos show the Quality Mix LF:

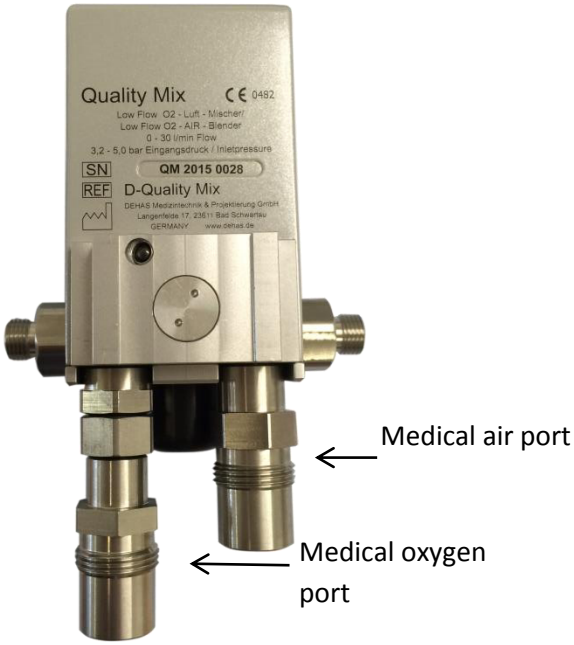




Right side, without bleed valve

Left side

Bottom view



Rear view

Components	Description
Rotary dial for oxygen concentration	A rotary dial for setting oxygen concentration levels between 21% – 100%. The FIO_2 scale is used for reference purposes only. This dial cannot be turned 360 degrees. It starts at 21% and can turn to 100%.
Main outlet without bleed	A DISS oxygen fitting with external (male) thread and a check valve. This provides the gas flow when connected to a control mechanism such as a flow meter.
Auxiliary outlet with bleed valve (optional)	A DISS oxygen fitting with external (male) thread and a check valve. This provides the gas flow when connected to a control mechanism such as a flow meter. The outlet can be fitted with a bleed valve that allows the user to activate (an/on) or deactivate (aus/off) the bleed function. If the bleed is activated (an/on), this outlet ensures an accurate oxygen concentration at the following flow rates: Model Flow range High Flow 2 – 100 l/min Low Flow 0 – 30 l/min
Adjustment collar on the bleed valve	This collar is used to activate or deactivate the bleed (vent) function. This bleeding ventilation is necessary to maintain an accurate FIO_2 concentration at flows below 15 l/min (for the HF mixer) or below 3 l/min (for the LF mixer). To activate the bleed function, turn the knurled collar ring until the ON position is reached.
Medical oxygen port	A DISS or NIST oxygen connection with internal thread and one-way valve. This is for connecting an oxygen supply hose.
Medical air port	A DISS or NIST oxygen connection with external thread and one-way valve. This is for connecting an air supply hose.
Alarm	An audible alarm that sounds when an excessive pressure drop or stoppage is detected on the air or oxygen supply lines.
Slide-on mount	Rail mount on the back of the mixer.

11. Installation

WARNING
• Read the operating instructions carefully before you install or use this device. • Use an oxygen analyser and monitoring device to monitor the air-oxygen concentrations.
CAUTION
Check the Quality Mix air-oxygen mixer for visible damages before use. **Do not** use it if it is damaged.

Note: Carry out the following tests before you use the device for the first time:

- **Alarm test**
- **Test of the reverse gas flow**

1. Mount the air-oxygen mixer on a wall or support rod in an upright position.
2. We recommend installing a water trap in the air supply line.
3. Connect the air and oxygen supply lines to the appropriate inlet ports on the bottom of the mixer.
4. Connect a flow meter or other metering device to one of the outlet ports.

   Flow capacity of the main outlets:

   - HF mixers: 15 – 120 l/min
   - LF mixer: 3 – 30 l/min

   Bleed outlet:

   Some of the air-oxygen mixture is vented at this outlet to maintain an accurate concentration at a low flow setting.

   - HF mixer: 15 l/min or less
   - LF mixer: 3 l/min or less
5. Connect a supply line to the outlet port of the flow meter.

12. Alarm test

1. Connect the air-oxygen mixer to the air and oxygen sources. Put the mixer under pressure and set the flow meter to "ON".

2. Set the oxygen concentration dial to 60% ($FIO_{2)}$.

3. Disconnect or turn off (set to "OFF") the air supply to the air-oxygen mixer. A loud whistling noise should be emitted from the mixer as an alarm. This whistling noise indicates that the alarm is working properly.

4. Re-connect the air supply to the mixer and activate; the whistling should stop.

5. Disconnect or turn off (set to "OFF") the oxygen supply to the mixer. This whistling noise indicates that the alarm is working properly.

6. Re-connect the air supply to the mixer and activate; the whistling should stop.

7. DO NOT USE the device when the alarm is not functioning properly.

13. Operating manual

CAUTION
Check the Quality Mix air-oxygen mixer for visible damages before use. **Do not** use if it is damaged.

1. Mount the mixer to the wall or to a stand holder.

2. Connect the air and oxygen supply lines from the mixer to the wall connections.

3. Connect the flow meter at the outlet of the mixer.

4. Set the oxygen concentration dial to the prescribed concentration.

   PLEASE NOTE: The dial for the oxygen concentration cannot be rotated 360 degrees. DO NOT forcefully turn the dial to a setting less than 21% or over 100% oxygen. This would damage the mixer.

5. Check the flow of the air/oxygen mixture to the patient.

6. Use an oxygen analyser/monitor to check the air-oxygen concentration. Activate the bleed valve, when necessary, to maintain the proper F_{IO_2} accuracy (only possible when using the optional bleed valve).

7. Turn the collar ring to the ON position to activate the bleed function.

8. Turn the adjustment collar to the OFF position to deactivate the bleed function.

9. Close the gas supply line ("OFF") whenever you are not using the air-oxygen mixer.

14. Cleaning

CAUTION
• Do **NOT** sterilise in a steam autoclave. • **NEVER** immerse the air-oxygen mixer in liquids. • Do **NOT** use strong solvents or abrasives. • Do **NOT** sterilise with Ethylene Oxide (EtO). • Do **NOT** clean with aromatic hydrocarbons.

1. Disconnect all gas connections and equipment before cleaning.

2. Wipe down the outer surfaces using a cloth moistened with mild detergent and water.

3. Wipe dry with a dry cloth.

15. Maintenance

The following maintenance and inspection tasks must be carried out:

- The user must test the alarm once per month.
- The safety technical inspection must be carried out each year by a trained operator or a medical technician.
- The **Quality Mix HF** or **Quality Mix LF** should be serviced by an authorized workshop at least once every two years.

16. Product returns

Contact DEHAS or your local dealer for more information about returning your product. They will help to coordinate the return. It is important that you provide a description of the error or malfunction so that the return can be processed effectively. All returns must be shipped in sealed containers to prevent damage. DEHAS is not responsible for any devices that are damaged during transport. The detailed terms for the return of our products are listed in the Terms and Conditions on our website at www.dehas.de.

17. Disposal

This device and its packaging contain no hazardous materials. No special precautions are required when disposing of the device and its packaging.

Please recycle.

18. Troubleshooting

Consult the following section in the event that the air-oxygen mixer malfunctions. If this information does not help to solve the problem, please contact DEHAS or your local dealer.

Problem	**Possible cause**	**Remedy**
Discrepancy between the oxygen concentration setting for the mixer and for the analyser/monitor (more than 3%)	1. Flow requirements for high-flow model: less than 15 l/min. Flow requirements for low-flow model: less than 3 l/min.	1. Use the bleed outlet and activate the vent (bleed) function.
	2. The analyser/monitor is not registering precisely.	2. Re-calibrate the monitor or check using another analyser/monitor.
	3. The bleed outlet is blocked at low flow.	3. Remove the blockage.
	4. The gas supply line is contaminated.	4. Check the gas supply using a calibrated oxygen analyser/monitor to ensure that the oxygen content is 100% and the air content is 21%.
	5. Downstream device causing back flow or restricted flow.	5. Disconnect the mixer. Check the oxygen concentration at the outlets of the mixer.
No flow at the mixer's outlets	1. The gas supply is switched off.	1. The gas supply is not connected.
	2. The gas supply is not connected.	2. Connect the gas supply.

Problem	Possible cause	Remedy
The alarm sounds	1. The difference between the oxygen pressure and air supply pressure is greater than specified.	1. Adjust this pressure differential until the air/oxygen pressures meet the specifications

19. Warranty conditions

DEHAS Medical ensures that the mixer will be free of material defects or workmanship errors for the following period:

Two (2) years from delivery.

If, within the applicable period, a device defect should occur, then DEHAS shall – after written notification thereof and substantiation that the device has been stored, installed, maintained and operated in accordance with the instructions of DEHAS and in accordance with standard industry practice, and that no modifications, substitutions or changes were made to the product – correct such a defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE A WARRANTY.

The representatives of DEHAS or any retailers are not authorized to make oral warranties about the merchandise described in this contract. Any such statements are not binding and not part of the sales contract. Thus, this written statement is a final, complete and exclusive statement of the contractual terms.

The current version of the DEHAS Terms and Conditions and German law are valid.

DECLARATION OF CONFORMITY

DEHAS Medizintechnik GmbH
Langenfelde 17
23611 Bad Schwartau
GERMANY

CE
0482

REF

Quality Mix HF, Quality Mix LF
and accessories

Classification: IIb

Classification criteria: Clause 3.2, Rule 11 of Annex IX of the MDD

We hereby declare that the above products comply with the following guidelines and standards of the EC Council. All supporting documents are kept on the premises of the manufacturer and the notified authority.

Directives: General Application Directives: Medical Device Directive (MDD), Council Directive 93/42/EEC of 14 June 1993 Annex II, 3 on medical devices of the European Parliament.

Applied standards:

EN 980:2008
EN 1041:2008
ISO 11195:1995
EN ISO 14971:2013
ISO 15001:2011
ISO 15223-1:2012
BS EN ISO 15614-1:2004

Notified authority:	Medcert GmbH / CE 0482
Address:	Pilatuspool 2, 20355 Hamburg, GERMANY
Certificate number:	4153GB43411109 Expiration date: 12/2021
Devices already manufactured:	Traceable by serial number
Valid from/to:	12/2016 to expiration date
Manufacturer representative:	Quality manager
Position:	Quality systems
Date of issue:	17/December/2016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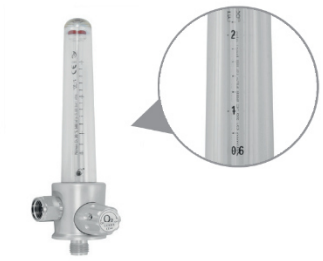
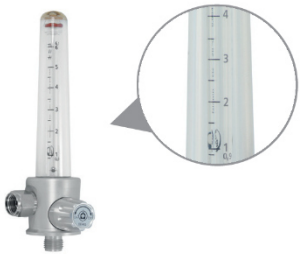
Durchflussmesser
Flowmeter



Durchflussmesser
Flowmeter
Quality Mix 0-3 LPM

Bestellnummer / Order Number: ***QM-FL-03***



Durchflussmesser
Flowmeter
Quality Mix 0-6 LPM

Bestellnummer / Order Number: ***QM-FL-06***

Durchflussmesser
Flowmeter
Quality Mix 0-15 LPM

Bestellnummer / Order Number: ***QM-FL-15***

Durchflussmesser
Flowmeter
Quality Mix 0-32 LPM

Bestellnummer / Order Number: ***QM-FL-32***

Durchflussmesser
Flowmeter
Quality Mix 0-85 LPM

Bestellnummer / Order Number: ***QM-FL-85***

Zertifiziert nach DIN EN ISO 13485
Zertifiziert nach DIN EN ISO 9001
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Medizintechnik
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Kundendienst & Vertrieb von
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Precision Medical-Sauerstoffmischern

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» Ein Ansprechpartner vor Ort
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» Entlastung des medizinischen Personals sowie der technischen Abteilung Ihrer Einrichtung
» Kein aufwendiger Versand der Geräte
» Bereitstellung eines Überbrückungsgerätes während der Durchführung der Servicearbeiten - Dadurch wird eine unterbrechungsfreie Versorgung in Ihrer Einrichtung sichergestellt
» Kostentransparenz durch unsere preiswerten Servicepauschalen

Sie benötigen eine Sonderlösung? – Sprechen Sie uns an. Wir helfen Ihnen gerne weiter!

Service and Maintenance works

The company HVS Hörnla offers a comprehensive on-site service in Germany, Austria and Switzerland for repair, maintenance and service works.

On-Site Service

The advantages are:

» No higher costs for the customer
» One contact person on-site
» On request instruction according to German medical regulations
» Relieve the medical staff and the technical department of your facility
» No expensive shipping of devices
» Provision of a bridging device during the service work execution to ensure an uninterrupted supply in your facility
» Cost transparency through our low-cost service flat rate

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Zertifiziert nach DIN EN ISO 13485

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