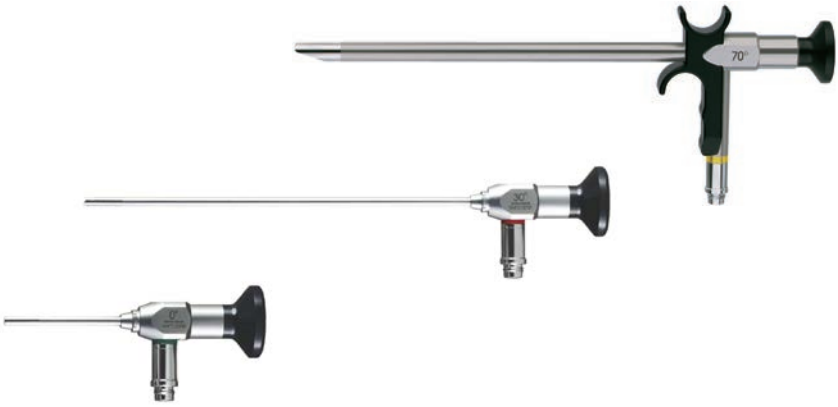
ATMOS MedizinTechnik

Operating Instructions

ATMOS® Rigid Endoscopes

English



CE

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1 Introduction

1.1 Notes on operating instructions

These operating instructions contain important instructions on how to operate your product safely, correctly and effectively.

These operating instructions are designed for training and instructing new operating personnel in the use of the system, and also for use as a reference manual. This document may only be reprinted, either in part or in whole, with written permission from ATMOS.

These operating instructions must always be kept to hand near the device.

Care, period tests, regular cleaning and proper application are essential. They ensure the operational safety and usability of the product.

Maintenance, repairs and period tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. The person in question must possess the necessary test devices and original spare parts required to carry out these measures.

Read chapter “2 Notices for your safety” on page 6 before using the product for the first time. This will help you to avoid potentially dangerous situations.

The product bears the CE marking CE in accordance with EC Directive 93/42/EEC of the Council concerning medical devices and meets the basic requirements of Appendix I of the directive.

The product complies with all the applicable requirements of Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).

The declaration of conformity and our general standard terms and conditions can be obtained on our website at www.atmosmed.com.

The quality management system at ATMOS has been certified according to international standard EN ISO 13485.

These operating instructions are valid for the following devices:

- Laryngoscope HD 70°, diameter 8 mm, L 190 mm 950.0254.0
- Laryngoscope HD 70°, diameter 10 mm, L 190 mm 950.0255.0
- Laryngoscope HD 90°, diameter 10 mm, L 190 mm 950.0256.0
- Otoscope HD 0°, diameter 4 mm, L 50 mm 950.0257.0
- Otoscope HD 30°, diameter 4 mm, L 50 mm 950.0258.0
- Otoscope HD 0°, diameter 2.7 mm, L 50 mm 950.0259.0
- Sinuscope HD 0°, diameter 4 mm, L 175 mm 950.0260.0
- Sinuscope HD 30°, diameter 4 mm, L 175 mm 950.0261.0

- Sinuscope HD 45°, diameter 4 mm, L 175 mm 950.0262.0
- Sinuscope HD 70°, diameter 4 mm, L 175 mm 950.0263.0
- Sinuscope HD 0°, diameter 2.7 mm, L 110 mm 950.0264.0
- Sinuscope HD 30°, diameter 2.7 mm, L 110 mm 950.0265.0

The following section lists all the product versions with ATMOS® rigid endoscopes.

1.2 Explanation of pictures and symbols

In the operating instructions

⚠ DANGER
Warning of a danger that results in immediate fatal or serious injury. Observe the necessary measures.

⚠ WARNING
Warning of a danger that can cause fatal or serious injury. Observe the necessary measures.

⚠ CAUTION
Warning of a danger that can cause minor injury. Observe the necessary measures.

ATTENTION
Notice of a danger that can damage the product or other objects. Observe the necessary measures.

⚠ Warning of a danger that can cause fatal or serious injury.

Notice of potential material damage.

Useful information on the handling of the device.

1. Action. Proceed step by step.

» Result of an action.

On device and type plate

	Observe the operating instructions	CE	This product complies with the relevant requirements of the EU Directives.
	Manufacturer	⚠	Warning; take extra care to observe
SN	Serial number	REF	Order number

	Not sterile		Autoclavable
	Fragile, handle with care		Store in a dry place
	Keep away from sunlight		

1.3 Intended use

Name:	Rigid endoscopes
Main function:	For short-term diagnostic application in the natural body orifices, for visualisation of the existing structures and, where applicable, with the aid of an endoscopic camera
Medical indications/ application:	For diagnostic endoscopy on humans
Specification of the main function:	Light transmission from the light conductor to the distal end, image transmission from the distal end to the eyepiece lens. Option for connecting an endoscopic camera for digital recording.
User profile:	Doctors and medically trained personnel
Patient groups:	Patients of all ages with no restrictions, where an endoscopic standard examination is indicated.
Application organ:	Ear, mouth and pharynx, nose
Application time:	< 60 minutes
Area of application:	Outpatient clinics
Contraindications:	The application of rigid endoscopes is contraindicated if endoscopic procedures are generally contraindicated.
The product is:	Not active
Sterility:	Not sterile
Single-use product/ re-sterilisation:	Not a single-use product. Re-sterilisation options provided in operating instructions

1.4 Function

ATMOS® rigid endoscopes are indicated for the visualisation of bodily orifices and body cavities. Each of the endoscopes is designed for a specific purpose in a particular field of medicine based on its cross-section and length.

1.5 Intended users

Endoscopic procedures may only be carried out by qualified professionals (e.g. doctors) who possess the corresponding training and are familiar with endoscopic procedures. As such, it is the responsibility of the user to stay up-to-date with the manufacturer's specification regarding the indication, contraindication, potential complications and risks, as well as with further developments in the endoscopic procedures.

1.6 Scope of delivery

- ATMOS® Rigid Endoscope
- Protective sleeve
- Operating Instructions

1.7 Transport and storage

Only transport the device in a shipping carton that is padded and offers sufficient protection.

If damage occurs during transport:

1. Document and report the transport damage.
2. Send the product in to ATMOS, see Chapter "6.3 Sending in the product" on page 15.

Ambient conditions for transport and storage:

- Temperature: -20...+70°C
- Relative humidity: 5...95% without condensation
- Air pressure: 70...106 kPa

Store the product in a dry place at room temperature, in its original packaging, a sieve or a container. Always keep the product in its protective sleeve during storage.

2 Notices for your safety

Please read and pay attention to the safety instructions prior to using the product.

2.1 General safety instructions

Never operate the device if it has any obvious safety defects. Check the device at regular intervals to ensure that it is safe and fully functional.

2.2 Danger for users, patients and third parties

Reduce the risk of infection for you and your patients!

Risk of deadly diseases being transmitted.

- Clean and disinfect the product after every use.
- Clean and disinfect the product according to the operating instructions.

Protect yourself from electric shocks.

Risk of burns, cardiac arrhythmias and even fatal injury.

- Never touch the endoscope and the metal housing of the light source at the same time.

Avoid misuse.

Risk of severe injury to your patient.

- A function check must be performed prior to each use.
- Always keep a replacement light source to hand, or use light sources that have a spare bulb.
- Always keep a spare operational endoscope to hand.

Hot surfaces at the light source and distal end of the endoscope.

Risk of burns.

- Make sure that the distal end of the endoscope does not touch the tissue. Safety clearance: min. 5 mm.
- Switch off the light source when not in use.
- Keep the level of illumination as low as possible for the task at hand.
- Where applicable, rinse the surgical area sufficiently.

The product will only meet the safety requirements of users, patients and third parties if fully functional. As such, observe the following additional instructions regarding the product.

2.3 Avoid damage to the device

Incorrect or careless handling of the product.

Risk of damage to the product.

- Ensure that the endoscope is not subjected to heavy impacts.
- Do not pull, bend or put pressure on the endoscope.
- Always allow the product to cool down to room temperature without any additional cooling measures.
- Observe the ambient conditions regarding transport, storage, and operation.

Improper cleaning, disinfection and sterilisation.

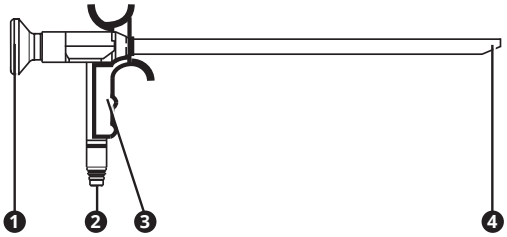
Risk of damage to the product.

- Observe the instructions for cleaning, disinfection and sterilisation provided in chapter “5 Cleaning and disinfection” on page 9.

3 Setting up and starting up

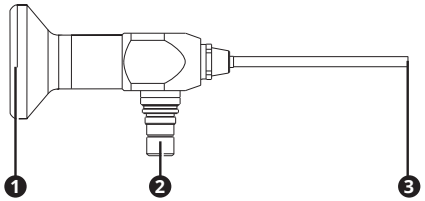
3.1 Device overview

3.1.1 Laryngoscopes



1. Eyepiece lens (camera connection possible via adapter)
2. ACMI fibre-optic connection
3. Hand piece
4. Objective lens

3.1.2 Otoscopes/sinuscopes



1. Eyepiece lens (camera connection possible via adapter)
2. ACMI fibre-optic connection
3. Objective lens

3.2 Preparing the device

The product is not sterile upon delivery.

1. Clean and disinfect the device prior to first use.
2. Sterilise the device if necessary for the medical indication.
3. Sterilise the accessories if necessary.

3.3 Using with other devices

Only qualified personnel are authorised to install electrical systems. The person who installs an electrical medical system is responsible for ensuring that the performance, safety, technical data and intended use are not affected.

- Refer to the specifications of IEC 60601-1 on medical electrical systems.
- Pay particular attention to the information on the patient environment, multi-outlet power strips and leakage currents.

Make sure that the devices used with the endoscope meet all the safety requirements.

When using the endoscope with an electrical medical device, ensure compliance with the terms and conditions for type BF application parts (insulated, floating application parts).

4 Operation

⚠ WARNING

Danger of infection due to secretion on the endoscope.

Risk of deadly diseases being transmitted.

- Used endoscopes must be stored separately from other re-sterilised instruments.
- Clean and disinfect the endoscope within 45 minutes after each use.

4.1 Prior to use

1. Connect the accessories and components.
2. Perform a function check.

☞ Check the functionality of accessories and components.

4.2 After use

1. Remove all used adapters from the fibre-optic connection.
2. Remove any visible residue immediately and as completely as possible under cold tap water (< 40°C), then place the product in distilled water.
3. Clean and disinfect the endoscope within 45 minutes after each use.

5 Cleaning and disinfection

We recommend that you always document all maintenance work and part replacements in writing.

It is the responsibility of the operator to ensure that the required results for cleaning and disinfection are adhered to. Validation and routine monitoring of the procedure will generally be necessary.

⚠ WARNING

Risk of infection due to secretion on the product and accessories.

Risk of deadly diseases being transmitted.

- Always wear your own personal protective equipment during all cleaning measures.
- Clean and disinfect the product after every use.
- Clean and disinfect the product according to the operating instructions.
- Always start by carrying out manual pre-cleaning/disinfection, followed by manual cleaning/disinfection.
- Make sure that the endoscope does not come into contact with other instruments or endoscopes. If a single canister contains multiple endoscopes or instruments, each one must be fixed in place separately.
- Observe the relevant national legal regulations and standards for cleaning, disinfection and sterilisation. This applies especially to patients with Creutzfeldt-Jacob-Disease (CJD), suspected CJD or possible variants.

ATTENTION

Dried residue after surgery due to incorrect cleaning.

Risk of corrosion difficulty in cleaning.

- Clean and disinfect the endoscope within 45 minutes after each use.
- Do not use pre-cleaning temperatures > 40°C.
- Do not use fixing cleaning agents containing aldehyde or alcohol.

Incorrect cleaning and disinfectants.

Damage to the surface, faded laser marking or chemical damage to the product.

- Observe the correct dosage for neutralising agents and basic cleaners.
- Do not use abrasives.
- Only use cleaning agents and disinfectants that are recommended by the manufacturer for endoscopes.
- Do not use cleaning agents or disinfectants that could cause stress cracks or corrosion in plastics.
- Make sure that the pH value of the application solution is < 8.

ATTENTION

Incorrect cleaning and disinfection.

Damage to the product.

- Never clean the product in an ultrasonic bath.
- Only use cleaning agents and disinfectants that are suitable for endoscopes.
- Only carry out thermal disinfection on products that are marked as autoclavable.
- Only autoclave products that are marked as autoclavable.
- Always allow the product to cool down to room temperature without any additional cooling measures.
- Only use the recommended disinfectants and sterilisation methods.

5.1 Manual pre-cleaning/disinfection

☞ The concentration of the cleaning agent depends on the contamination of the product. Observe the manufacturer's operating instructions for use of the disinfectant solution.

1. Remove all detachable parts.
2. Immerse the product in the cleaning solution completely, ensuring that all accessible surfaces are covered.
3. Thoroughly rinse areas that are difficult to access using a cleaning solution and a disposable syringe.

🛈 Damage to the product due to cleaning with a metal brush.

4. Clean the inside and outside of the product under running water using a soft cloth or a soft cleaning brush suited to this task (use distilled water where possible, or tap water as an alternative).
5. Clean areas which are difficult to access (e.g. concealed cracks, lumen, complex shapes) for at least one minute with a round brush suited to this task.
6. Rinse all the accessible surfaces and non-visible areas thoroughly.

» There is no more visible residue on the surface.

☞ If the product is not rinsed sufficiently, stubborn residue may form on the glass surfaces.

7. Dry the product using a lint-free cloth.

Removing stubborn residue from glass surfaces

☞ Stubborn residue develops when the device is not rinsed sufficiently.

1. Clean the glass surfaces using distilled water and a cotton bud.

5.2 Machine cleaning and disinfection

The following section describes the procedure for automatic alkaline cleaning and thermal disinfection in a cleaning and disinfection machine (Miele G 7735 CD).

1. Place the product in a perforated basket (Miele: OR instrument shelf).
2. Connect individual parts with channels and lumen to the special connections on the injector trolley.
3. Clean off any rinse residue.
4. Clean the product (Miele: Vario TD programme):
   - 1 min. pre-wash with cold water - allow to drain
   - 3 min. pre-wash with cold water - allow to drain
   - 5 min. wash at 55°C with 0.5% enzyme cleaner (neodisher® MediClean)
   - 3 min. neutralisation with cold water - allow to drain
   - 2 min. rinse with cold water - allow to drain
5. Check that all the visible surfaces are free of residue. If you find any residue, repeat the cleaning and disinfection process.
6. Carry out thermal disinfection.

☞ If stubborn residue cannot be removed by cleaning, the product must be sent to ATMOS or an authorised dealer.

5.3 Recommended disinfectants

The disinfectant recommendation refers exclusively to its compatibility with the product material. It is the responsibility of the user to ensure that the product is effective.

ATTENTION

Incorrect disinfectant.

Damage to the product.

- Only use the recommended disinfectants.
- Do not place the product in alcohol.
- Observe the disinfectant manufacturer's operating instructions. Pay particular attention to the information regarding the concentration and material compatibility.

5.3.1 Recommended endoscope disinfectants

Automatic disinfection of endoscopes

Disinfectant	Manufacturer
neodisher® MediClean	Dr. Weigert, Hamburg

5.4 Sterilisation

ATTENTION

Incorrect cleaning and disinfection.

Damage to the product.

- Only autoclave products that are marked as autoclavable.
- Once sterilisation is complete, leave the endoscope to cool down to room temperature without any additional cooling measures.
- Make sure that the endoscope does not come into contact with any hot metal parts.
- Avoid any shocks and jolts to the heated endoscopes.
- Always use the same sterilisation procedure on the product.
- Observe the manufacturer's operating instructions.

It is the responsibility of the user to ensure that the sterilisation is effective.

5.4.1 Preparing for sterilisation

The product must be cleaned, disinfected and checked prior to every sterilisation.

1. Check the fibre optics, see chapter "6.2.1 Checking the fibre optics" on page 14.
2. Check the glass surfaces and the surface, see chapter "6.2.2 Checking the glass surfaces and the surface" on page 15.
3. The product must not be sterilised if any damage or defects are found. Resolve the defect or send the product in to ATMOS or an authorised dealer.

5.4.2 Sterilisation

Observe the manufacturer's operating instructions.

1. Prepare for sterilisation, see chapter "5.4.1 Preparing for sterilisation" on page 13.
2. Ensure that the sterilising agent reaches all the surfaces.

Autoclaving

Only autoclave products that are marked as autoclavable.

Max. no. of re-sterilisation cycles: 250. Send the product in to ATMOS or an authorised dealer for testing.

Only use the following parameters:

- Pre-vacuum: 3 x
- Temperature: 132 - 134°C
- Exposure time: 3-18 min. (full cycle)
- Drying time: 10 min

1. Place the endoscope in a sterilisation box.

2. Autoclave the endoscope.
3. Allow the endoscope to cool down to room temperature without any additional cooling measures.

Low-temperature sterilisation: Plasma

- STERRAD® 50 (Short Cycle)
- STERRAD® 100S (Short Cycle)
- STERRAD® 200 (Short Cycle)
- STERRAD® NX (Standard Cycle)

6 Maintenance and service

Maintenance, repairs and period tests may only be carried out by persons who have the appropriate technical knowledge and are familiar with the product. The person in question must possess the necessary test devices and original spare parts required to carry out these measures.

ATMOS recommends: Work should be carried out by an authorised ATMOS service partner. This ensures that the repairs and testing are carried out professionally, that original spare parts are used and that warranty claims remain unaffected.

6.1 Function check

A function check must be performed prior to each use.

Do not use the product if you notice any damage. In this case, clean and disinfect the device and send it to ATMOS for repair.

Carrying out a function check

1. Check that the endoscope is not damaged:
   - The product is hygienically sound.
   - The surfaces are undamaged.
   - The endoscope has no sharp edges.
   - The distal and proximal glass surfaces are undamaged.
   - There are no abnormalities in terms of image quality.

6.2 Further tests

6.2.1 Checking the fibre optics

☞ Do not use a cold light source for this test.

1. Hold the distal end of the fibre optics towards a bright ceiling lamp or similar light source.
2. Hold the fibre-optic connection relatively close to your eye and examine it.

» The individual fibres appear to be bright.

3. Move the distal end back and forth.

» The brightness of the fibres now changes a little.

☞ If individual fibres remain dark, this is not an issue. However, working with the endoscope is severely hampered if the fracture rate reaches about 10% - 20% or higher.

4. Check that the surfaces of the light inlets and outlets are smooth and clean.
5. If there are deposits on the surfaces, or if individual fibres are rough fibres or withdrawn, send the product in to ATMOS or to an authorised dealer for inspection.

☞ An endoscope with damaged fibre optics can lead to inadequate illumination. Use or sterilisation in this condition may cause permanent damage to the endoscope.

6.2.2 Checking the glass surfaces and the surface

1. Check that the glass surfaces on both sides of the endoscope are undamaged, clean and free of deposits.
2. Check that the image is suitable sharp and clear at the working distance. If the image is dull or dusky, the product may be damaged.
3. Check that the surfaces are undamaged and have no sharp edges. Pay attention to dents, mechanical or thermal damage (e.g. due to high-frequency or laser surgical devices), and cracks or spalling in the probe tube and at the ocular funnel.
4. Do not use the product if there are any signs of damage to the glass surfaces, the image quality is impaired, or the surfaces are damaged or deformed. Send the product in to ATMOS or an authorised dealer.

6.3 Sending in the product

1. Remove all consumables and dispose of them properly.
2. Clean and disinfect the product and accessories in accordance with the operating instructions.
3. Place any used accessories with the product.
4. Fill in the QD 434 “Delivery complaint/return shipment” form and the corresponding **decontamination certificate**.

☞ This form is enclosed with each delivery and can be found at www.atmosmed.com.

5. The device must be well padded and packed in suitable packaging.
6. Place the QD 434 “Delivery complaint/return shipment” form and the corresponding **decontamination certificate** in an envelope.
7. Affix the envelope to the outside of the package.
8. Send the product in to ATMOS or your dealer.

7 Troubleshooting

The product has been subjected to a thorough quality control in the factory. If a fault should occur despite this care, you may be able to resolve it yourself.

Error symptom	Possible cause	Remedy
Image is dull, dusky	Glass surfaces dirty	1. Clean the glass surfaces, see chapter “5.1 Manual pre-cleaning/disinfection” on page 11.
	Stubborn residue, encrusting on the glass surfaces	1. Remove the residue, see “Removing stubborn residue from glass surfaces” on page 11. 2. Check the water quality.
	Leaky, defective lens system	1. Send the product in for repair.
Image is too dark; insufficient illumination	Glass surfaces dirty	1. Clean the glass surfaces, see chapter “5.1 Manual pre-cleaning/disinfection” on page 11.
	Stubborn residue, encrusting on the glass surfaces	1. Remove the residue, see “Removing stubborn residue from glass surfaces” on page 11. 2. Check the water quality.
	Fibre-optic cable connection incorrect	1. Check that the fibre-optic cable is fitted properly.
	Fibre optics defective	1. Check the fibre optics, see chapter “6.2.1 Checking the fibre optics” on page 14
	Fibre-optic cable defective, light source defective	1. Check the fibre-optic cable and light source.
Light has yellowish hue	Fibre optics dirty	1. Clean the glass surfaces, see chapter “5.1 Manual pre-cleaning/disinfection” on page 11. 2. Send the device in for repair.
	Fibre-optic cable dirty, defective	1. Check the fibre-optic cable, e.g. by shining it on a white surface.

Error symptom	Possible cause	Remedy
Spotting, discolouration	Inadequate cleaning (e.g. protein residue)	1. Clean the endoscope again, rubbing thoroughly if necessary.
	Inadequate rinsing of the endoscope between re-sterilisation steps (especially before actual sterilisation)	1. Ensure that the product is rinsed adequately between the individual re-sterilisation steps.
	Chloride concentration too high	1. Check the water quality.
	Heavy metal ions, silicate, elevated levels of iron, copper, manganese, minerals (lime) or organic substances	1. Check the water quality. 2. If necessary, always use purified water.
	Rust due to vapours containing rust or because device was sterilised together with other instruments	1. Check the supply system. 2. When sterilising the device together with other instruments, make sure that the materials are compatible and have suffered no prior damage; avoid contact between instruments.
	Cleaning and disinfecting solutions contaminated or used too frequently	1. Change the disinfection and cleaning solutions regularly.

8 Disposal

Packaging

1. Please recycle the packing.

Endoscope

Do not dispose of the product together with household waste.

The product does not contain any hazardous materials.

1. Clean and disinfect the product according to the operating instructions.
2. In Germany: Send the product back to ATMOS or your specialist dealer. They will dispose of the device professionally.
3. In other countries: Dispose of the product professionally and according to the country-specific laws and regulations.

9 Technical data

Ambient conditions for transport/storage	
• Temperature	-20...+70°C
• Relative humidity	5...95% without condensation
• Air pressure	70...106 kPa
Ambient conditions for operation	
• Temperature	+15 to +28 °C
• Relative humidity	5 to 95% without condensation
• Air pressure	70 to 106 kPa
Classification according to Annex IX, EC Directive 93/42/EEC	Class 1 acc. to rule 1
MD/MDS code	MDA 0310

Laryngoscopes

REF	950.0254.0	950.0255.0	950.0256.0
Dimensions Total length (mm)	281	270	271
Working length (mm) (+/-10 mm)	190	190	190
Diameter (mm)	8	10	10
Angle of view	70°	70°	90°
Opening angle	55°	50°	50°
Weight (g)	150	165	165

GMDN code	36648
UMDNS code	15-076

Otoscopes

REF	950.0257.0	950.0258.0	950.0259.0
Dimensions Total length (mm)	112	112	112
Working length (mm) (+/-10 mm)	50	50	50
Diameter (mm)	4	4	2.7
Angle of view	0°	30°	0°
Opening angle	70°	75°	70°
Weight (g)	70	70	70

GMDN code	12849
UMDNS code	12-849

Sinuscopes

REF	950.0260.0	950.0261.0	950.0262.0	950.0263.0	950.0264.0	950.0265.0
Dimensions Total length (mm)	237	237	236	237	172	172
Working length (mm) (+/-10 mm)	175	175	175	175	110	110
Diameter (mm)	4	4	4	4	2.7	2.7
Angle of view	0°	30°	45°	70°	0°	30°
Opening angle	83°	95°	80°	70°	60°	65°
Weight (g)	100	100	100	100	100	100

GMDN code	36948
UMDNS code	12-710

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