

irrimed_{Stoma}

battery-operated irrigation pump for bowel irrigation

instruction manual



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Thank you for choosing *irrimed classic Stoma*.



Read these instructions for use carefully and follow the directions before using the *irrimed classic stoma*. Always consult these instructions for use if you have any questions about the operation and troubleshooting of your *irrimed classic stoma*. If you have any further questions, please contact the specialist staff at your specialist dealer.

1. intended use of the *irrimed classic Stoma*

General precautions:

Your *irrimed classic Stoma* is a medical device and has been developed exclusively for intestinal irrigation (colostomy or rectal irrigation). Before you start using the device, have the medical safety of the bowel irrigation confirmed. Your doctor or nurse trained in stoma therapy will be happy to advise you. It is essential that irrigation is learned and taught under expert supervision, if possible by stoma therapists.

Intended patient group (patient is intended user):

- Age: Children from 3 years up to geriatric patients.
- Gender: No restriction
- Weight range: for children 3 years and older from normal range, otherwise no restrictions
- Patient condition: alert, sane

Irrimed classic Stoma (set) is supplied with the following accessories:

- Accessories: tubing system consisting of transfer tube (1.30 m) with non-return valve, irrigation cone for stomas - not suitable for Combifix bags.
- Accessories: Quick charger
- Irrigation cone size 1 (narrow stomas) for Combifix bags
- Irrigation cone size 2 (normal to large stomas) for Combifix bags



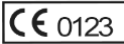










Indications: All indications leading to the creation of a colostoma such as:

- Removal of the anal sphincter (sphincter ani).
- Rectal carcinoma/ rectal cancer (distal)
- Faecal incontinence (inability to hold back wind or stool voluntarily)

Contraindications:

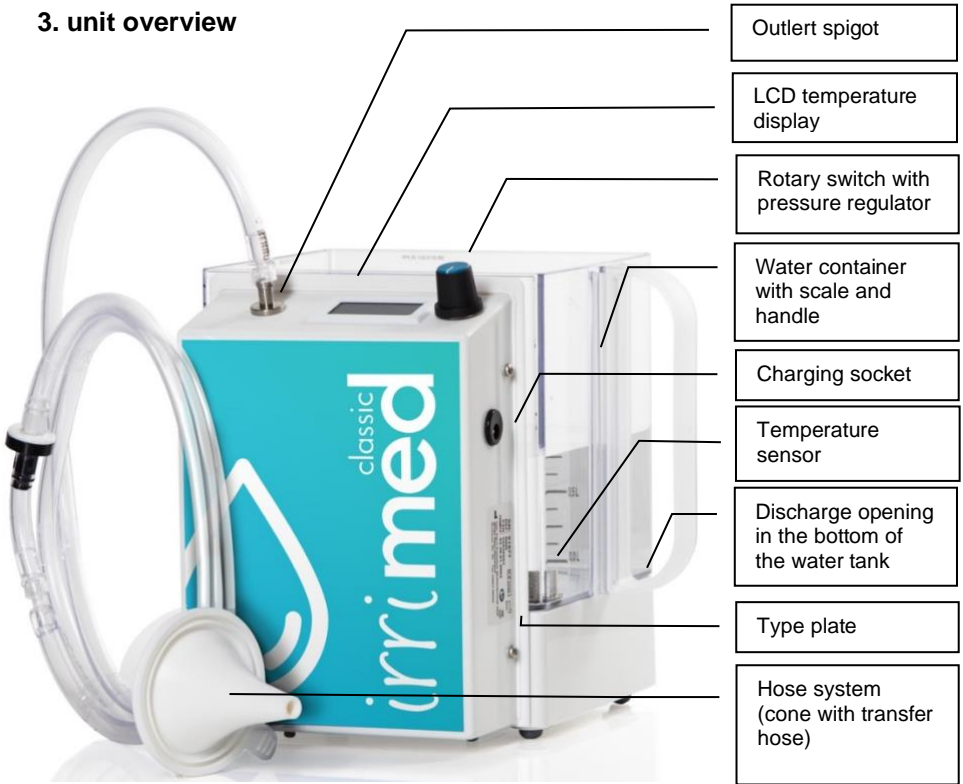
- Siphon formation
- ileostoma
- prolapse
- parastomal hernia
- stenosis
- chronic intestinal inflammation

2. safety instructions, explanation of symbols

	Follow operating instructions		Disposal - hand in the old appliance at a municipal disposal point!
	Conformity marking according to the European Directive for medical devices 93/42/EEC with the number of the notified body.		One-way valve. The transfer hose contains a non-return valve that allows water to flow in one direction only
	Caution		
	Manufacturer		Date of manufacture
	Protect from light		Protect from moisture
	Temperature limit		Caution fragile
	Classification BF according to standard EN 60601-1		Protection class II according to standard EN 60601-1

- Only the supplied quick charger may be used to charge the battery (see 8.3). For safety reasons, the pump function is automatically interrupted during the charging process.
- Do not use any external heat sources to heat the water, e.g. immersion heaters.
- Only fill with clear tap water.
- Never place the *irrimed classic stoma* in a bowl or in a wash basin with a closed drainage opening, as this can cause water to enter the operating housing and the pump chamber. Penetrated water destroys the electrical components.

3. unit overview



Quick charger



LED display:
charging / charging
completed

Backstop, never connect
to the outlet spigot.

Transfer hose



4. Functional description

irrimed classic Stoma is an irrigation pump for intestinal irrigation that automatically builds up the required irrigation pressure irrespective of the installation height, as the built-in centrifugal pump is supplied with energy by a built-in rechargeable battery.

The flushing pressure can be adjusted continuously from 0 to 0.5 bar using the rotary switch. The adjustable pressure values are medically safe.

The battery is dimensioned in such a way that even extensive or multiple rinses can be carried out. After each use, the battery must be recharged with the corresponding quick charger. The trolley lamp on the quick charger indicates when the charging process is finished. During the charging process, the pump function is automatically interrupted for safety reasons.



If the battery is not re-charged after each use, the deep discharge protection may switch off the pumping process without warning. The unit cannot be switched on again until the battery is recharged.

The digital LCD temperature display, which is switched on with the rotary switch, shows the water temperature in the water tank. **For the colonic irrigation, only tap water that is body-warm and in the temperature range of 35°C to 38°C should be filled into the water container. Always check the water temperature with a commercially available thermometer.**

**The device is not capable of heating water.
Do not use an immersion heater to heat water.**

5 Initial start-up and charging of the battery

5.1 Please check the packaging and contents for any visible transport damage or defects of any kind. If so, please contact us and do not put the unit into operation. The unit has not been tested according to IEC 60068-2-27 and 60068-2-64.



Furthermore, check that all the parts stated on the packaging are included.

5.2 The battery is not fully charged when delivered. You must therefore charge the battery before use. Only the supplied quick charger may be used for this purpose. The charging process lasts less than 8 hours.

To charge, first insert the charging plug into the charging socket on the unit and then plug the quick charger into the power socket. The charging indicator lamp on the quick charger indicates the charging status.

Indicator lamp red: Charging in progress

Indicator lamp green: Charging process completed or sufficient capacity available.

During the charging process, the rotary switch must be in the 0 position. The pump function is automatically interrupted during the charging process. When charging is complete, disconnect the quick charger from the power supply and remove the charging plug from the charging socket. The unit can be used again.

5.3 After switching on and increasing the flushing pressure, the running noise of the centrifugal pump is well perceptible. The noise corresponds to a low room volume and depends on the resonance conditions of the surroundings (approx. 50 to 55 dBA).

6. Carrying out irrigation

6.1 Irrigation must be learned and taught under expert guidance, preferably by a stomatherapist, in order to achieve an optimal effect. If you are already performing and mastering irrigation, you can now proceed.



6.2 Fill the water tank with approx. 1.5 litres of clear, body-warm tap water. The water temperature should be 35°C to 38°C at the beginning. Always check the water temperature with a commercially available thermometer. After you have switched on the rotary switch, the digital temperature display shows you the water temperature.

6.3 Place the appliance on a flat, dry surface, e.g. bath stool or floor, never in a bowl, wash basin or on a radiator.

6.4 The following photos show you the irrigation procedure:

6.5 The irrigation cone is clicked into the snap ring of the Combifix irrigation tube bag. Make sure that the snap ring is properly locked in place all around.



6.6 Remove the old supply and put it in the waste.



6.7 Snap the belt into the opening provided for this purpose on one side.



6.8 Place the bag on the stoma and snap the belt into the opening provided on the other side



6.9 To establish the connection to the *irrimed classic stoma* attach the 1.30m long transfer hose of the hose system to the outlet connection of the irrigation device. If you have separated the cone and the transfer hose, make sure that the return lock is connected to the cone and the other side of the transfer hose is connected to the outlet connection of the *irrimed classic stoma*. The connection is made by a $\frac{1}{4}$ turn to the right.



6.10 The lower end of the hose bag hangs open directly in the toilet. The water inflow is initiated by setting the rotary switch to 9 to 10 o'clock. Before the cone is inserted into the stoma, the water should run through the tubular bag into the toilet for a few seconds until no air bubbles are visible. This also ensures that the remaining water from the previous session has run out of the *irrimed classic stoma*. Now, the cone is inserted into the stoma and irrigation can be carried out.

Important note!



Make sure that the opening of the cone is above the water level of the device to prevent water from leaking out of the water container even if *irrimed classic stoma* is not switched on (physical: siphon principle).

6.11 After the water has run in, disconnect the hose and remove the cone from the bag. Make sure that the opening which has now been created points upwards to ensure that nothing gets out in the event of spontaneous emptying. Close the new opening with the sealing cap and wait for the remaining water to drain.



When the excretion is finished, remove the bag, take off the lid and put the bag, as it is a single-use product, into the non-recyclable waste. The cone and the lid can be cleaned and used again.

6.12 Clean the stoma and the area around it and cover the stoma with a stoma cap.

Always choose a one-piece system for stoma care, as it is not necessary to change it during the day.

7. care, maintenance and durability



Do not carry out service and maintenance acts when the device is in use, otherwise the functionality will be impaired.

7.1 After irrigation, remove the remaining water from the water tank and wipe it dry with a lint-free cloth (microfiber cloth).

Any contamination of the housing should only be wiped off with a damp cloth, do not use any solvents or disinfectants. Make sure that no moisture gets into the interior of the unit, the charging socket or the housing while cleaning. Furthermore, make sure not to push the temperature sensor to the side while cleaning, since this would cause leakage.

7.2 *irrimed classic stoma* does not need to be maintained at certain intervals.

The tube system (transfer tube and cone) should be cleaned with water after using and changed monthly for hygienic reasons, but at the latest when a dark, blotchy biofilm forms inside the tube, see point 9.

7.3 Durability

The service life of the *irrimed classic Stoma* is approx. 150 to 180 operating hours, which corresponds to approx. 2.5 to 3 years at a daily use of 10 minutes.

A repair after the expiration of the service life is usually hardly justifiable from an economic point of view.

8. Troubleshooting

8.1 Before sending in the *irrimed classic stoma* for repair, please note the following, as it is often unnecessary to send in the device.

The following malfunctions are due to wear and tear or incorrect operation, but do not necessarily require repair.

Before reading the section on remedying malfunctions, answer the following questions:

1. Does the quick charger light up when the quick charger is connected (charging plug in the charging socket and quick charger in the mains socket)? 2. Is the device removed from the charging socket on the *irrimed classic stoma* before use?
2. Has the charging plug been removed from the charging socket on the *irrimed classic stoma* before using the device?
3. Does the pure pumping time per application not exceed 15 minutes?
4. Is the battery charged after each use until the green control lamp on the quick charger lights up?
5. Has the transfer hose been connected correctly (non-return valve on the cone)?
6. Is the transfer hose permeable? This can be checked by blowing air through the end that is connected to your *irrimed classic stoma*.
7. Is the hose system screwed on after the water container has been filled?
8. Has at least 1 litre of water been filled into the device?
9. Does the temperature indicator light up after switching the unit on?
10. Can you hear a clear cracking sound when switching the unit on?

If you have answered all questions with Yes, this means You can now proceed to the point of *eliminating malfunctions*.

8.2 Troubleshooting and elimination of malfunctions

Error description	Possible cause	Troubleshooting
After both plug connections of the quick charger are properly plugged in, the LED does not light up.	1. Quick charger faulty	1. Renew quick charger.
Flow rate or flushing pressure decreases.	1. Air bubble in the centrifugal pump 2. The battery is not properly charged. 3. Battery capacity exhausted.	1. Bleed the centrifugal pump, see 8.4 Bleeding instructions. 2 The battery must be charged after each use until the green LED on the quick charger lights up. 3. Send in the unit and have the battery replaced
Battery is very quickly exhausted.	1. Battery insufficiently charged 2. Battery capacity exhausted.	1. The battery must be charged after each use until the green LED on the quick charger lights up 2. Send in the unit and have the battery replaced
Pump does not transport water, although the pump is pumping.	1. Transfer hose of the hose system incorrectly connected. 2. Backstop stuck	1. The crystal-clear fitting must be connected to the unit and the backstop (connection with union nut) to the cone or catheter. 2. Test the backstop by trying to blow through the tube from the crystal-clear fitting. If you cannot do this, a

Error description	Possible cause	Troubleshooting
	<p>3. Was the hose system screwed onto the outlet connection before filling the water tank?</p> <p>4. Is at least 1 litre of water in the water container?</p>	<p>new hose system must be ordered.</p> <p>3. First fill the water tank with more than 1 litre of water, then unscrew the hose system.</p> <p>4. Fill with more than 1 litre of water</p>

8.3 Battery replacement

Rechargeable, cylindrical Li-Ion cells are installed in this device. The battery of the *irrimed classic stoma* is not suited for replacement by the customer. If necessary, the battery can only be replaced in our service workshop.

8.4 Bleeding instruction

If the device has been completely emptied, i.e. *irrimed classic stoma* has been held upside down or turned upside down so that all water has drained from the device (also from the inner centrifugal pump and the inner hose system), it may happen that an air bubble forms in the inner centrifugal pump during the next filling. This air bubble reduces the pressure so that the pressure regulator must be set higher and higher. This can also happen with tap water that is heavily saturated with air.

Bleeding is to be carried out as follows:

Fill the unit with approx. 1.5 litres of water. Then screw the transfer hose onto the outlet connection. Close the opening of the backstop on the transfer hose tightly with your thumb. Now quickly turn the pressure regulator up and back again. If air bubbles appear from the outlet opening in the bottom of the water tank (see 3. Unit overview), the procedure should be repeated until no more air appears. Then, no more disturbing air is in the system.

9. Notes on use

Only use clear tap water.

Cation!



Do not use water with additives or medicine.

The hose system is an expendable item and becomes unappealing after prolonged use due to a biofilm. The germs are not toxic, but the normal bacteria that are present in all drinking water. This effect is usually first seen in the transfer tube at the attachment to the *irrimed classic stoma*. For hygienic reasons, the transfer tube and cone should therefore be changed monthly, but at the latest when the biofilm begins to develop (for ordering data, see 13 Spare parts - Accessories).

The tubing system is exclusively intended for use on one patient only.

To prevent a defect in the unit, make sure that the charging plug and the charging socket **never** get into touch with water.

The wire of the quick charger should not be wound too tightly, as this will cause the wire to break and the unit can no longer be used. A broken wire is not covered by the warranty.

Whether the flow rate or the flushing pressure are still sufficient can be tested by filling the water tank with 1 litre of water, screwing on the hose system and pumping out the contents of the water tank. The pressure regulator must be at the highest pressure. If the water is pumped out in approx. 1 minute or less, the flow rate is still satisfactory.

Important note!

Repairs and spare parts can be prescribed. The costs are usually covered by public health insurances or your provider.

Important notice! All serious incidents related to the product must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is registered.

10. Warranty

10.1 Should *irrimed classic Stoma* be faulty during the first 24 months following the date of purchase from the dealer due to proven manufacturing or material faults, we will repair this defect without charge in accordance to the following conditions.

10.2 We decide whether the defect is to be eliminated by repair or replacement.

10.3 If the unit is shipped for the purpose of troubleshooting, this is done at the risk of the sender. The sender bears the costs for the shipments to us.

10.4 Excluded from free troubleshooting are:

- Parts subject to wear such as batteries, transfer hose and cone.
- Defects due to water penetration, e.g. due to improper filling of the water tank.
- Electrical components such as the centrifugal pump, control electronics and accessories that have been damaged by water.
- Breakage of the wire of the quick charger.
- Devices on which the manufacturing number has been removed or destroyed.
- Devices with mechanically destroyed housing parts.
- Failure of the built-in centrifugal pump due to penetrated foreign bodies (fluff from cleaning cloths, hair and dust flakes).
- Error indication: *irrimed classic Stoma* too loud (see 5.3).

The proof of purchase must be presented in order to be eligible for free troubleshooting.

11. Repair and maintenance

Should repair or maintenance become necessary in the course of time, return your *irrimed classic stoma* to your dealer with the request that everything else be arranged.

Address for sending in a repair unit

In Hand Werkstatt
Industriestr. 4
D-46342 Velen

If you are insured by a public health insurance, the repair can be prescribed.

12. Technical data

12.1 Irrigator *irrimed classic Stoma*

Device type:	<i>irrimed classic Stoma</i>
Protection class:	II
Protection type:	IP 21
Classification:	BF
Internal power supply:	7,4 Volt Block Li-Ion 2600 mAh
Operating mode:	Continuous operation until the battery is exhausted.
Durability:	< 8 hours
Flushing pressure:	0 to 0,5 bar, infinitely variable
Dimensions, weight:	height = 180 mm, width = 180 mm, depth = 180 mm, 900 g
Operating conditions:	
Ambient temperature:	+ 10° C to + 40° C
Relative humidity:	30% to 80%

Transport and storage conditions under normal ambient conditions:

12.2 Quick charger

Manufacturer:	Mascot N-1601 Fredrikstad, Norway
Device type:	Plug-in charger with type G plug
Protection class:	II
Protection type:	IP 21
Supply voltage:	100 V to 240 V AC, 50 – 60 Hz
Output voltage:	8,4 V DC
Charging current:	max. 1,3 A
Control-LED	Charging orange; charging finished green;
Charging wire	175 cm long
	NV-Plug 5,5 x 2,1 x 11 mm
Dimensions, weight:	height=103,5 mm width=46,8 mm depth=38,7 mm, 170 g
Operating conditions:	
Ambient temperature:	+ 10° C to + 40° C
Relative humidity:	30% to 80%

Transport and storage conditions under normal ambient conditions:

12.3 LCD-thermometer

Accuracy	+/- 1°C
Measuring interval	< 3sek.

Temperature range -50 °C to +70°C

13. Order information

irrimed classic Stoma for intestinal irrigation via a colostoma (set)

Order no.: 444000

Every *irrimed classic Stoma* is supplied as a set with:

- Quick charger
- Cone size 1 for narrow stomas
- Cone size 2 for normal to large stomas
- Tube system consisting of a transfer tube (1.30 m) with non-return valve, irrigation cone for stomas - not suitable for Com-bifix bags
- Universal belt
- Combifix Irrigation Tube Bag (3 pieces)
- Sealing cap
- Bag clip
- Instruction manual

Spare parts - Accessories	Order no.:
Transfer tube 1.30 m long with non-return valve and Luer Lock connection on both sides	442003
Tube system consisting of transfer tube (1.30 m) with non-return valve, irrigation cone size 1 for Combifix bags and narrow stomas.	443100
Tubing system consisting of transfer tubing (1.30 m) with non-return valve, irrigation cone size 2 for Combifix bags and normal to large stomas.	443200
Tube system consisting of transfer tube (1.30 m) with non-return valve, irrigation cone for stomas - not suitable for Combifix bags.	443300
1 pack (30 pieces) Combifix Irrigation tube bag	443000
1 pack (3 pieces) Bag clip	443002
1 pack (3 pieces) Sealing cap	443004
Universal belt	443010
Quick charger	444003


Important note! *irrimed classic stoma* may only be used with the accessories intended for this purpose.

14. EMV-information for *irrimed classic Stoma*

Medical electrical equipment is subject to special precautions regarding EMC and must be installed and commissioned in accordance with the guidelines given below. Portable and mobile RF devices (e.g. mobile phones) can affect medical electrical equipment. The use of third-party accessories may result in increased emissions or reduced immunity of the device.

Guidelines and manufacturer's declaration- Electromagnetic emission			
The <i>irrimed classic Stoma</i> irrigator is intended for use in the electromagnetic environment specified below. The customer or the user of <i>irrimed classic Stoma</i> should ensure that it is used in such an environment.			
Emission measurements	Compliance	Electromagnetic environment guidelines	
HF-Emission according to CISPR 11	group 1	<i>irrimed classic stoma</i> uses RF energy exclusively for its internal function. Therefore, its RF emission is very low and it is unlikely to interfere with neighbouring electronic devices..	
HF-Emission according to CISPR 11	class B	<i>irrimed classic Stoma</i> is suitable for use under all conditions, including public low-voltage power supply networks. Harmonic emissions, voltage fluctuations and flicker emissions have no influence because <i>irrimed classic Stoma</i> is powered by batteries.	
Harmonic Emissions ICE61000 3-2	No specifications		
Voltage fluctuations/ flicker emissions ICE 61000-3-3	No specifications		

Interference immunity	Test	Adherence	Electromagnetic Conditions Directives
Electrostatic Discharge (ESD) IEC 61000-4-2	8 kV contact 16 kV air	8 kV contact 16 kV air	The floor should be made of wood, concrete or ceramic tiles. If the floor is covered with a synthetic material, the relative humidity should be at least 30%.

Interference immunity	Test	Adherence	Electromagnetic Conditions Directives
radiated HF disturbance quantities according to IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	The field strength of static radio transmitters is lower than the compliance level at all frequencies according to an on-site investigation. Interference is possible in the presence of equipment bearing these symbols.. 
Fast transient electrical disturbances/burst IEC 61000-4-4		No specifications	Not applicable because <i>irrimed classic stoma</i> is battery operated and has no external wires.
Overvoltage IEC 61000-4-5		No specifications	Not applicable because <i>irrimed classic stoma</i> is battery operated and has no external wires.
Voltage dips, short interruptions and voltage fluctuations in supply lines IEC 61000-4-11		No specifications	Not applicable, because <i>irrimed classic Stoma</i> is battery operated.
Mains frequency (50/60 Hz.) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Network frequency magnetic fields should match the characteristics of a typical exhibition site in a commercial or clinical environment.