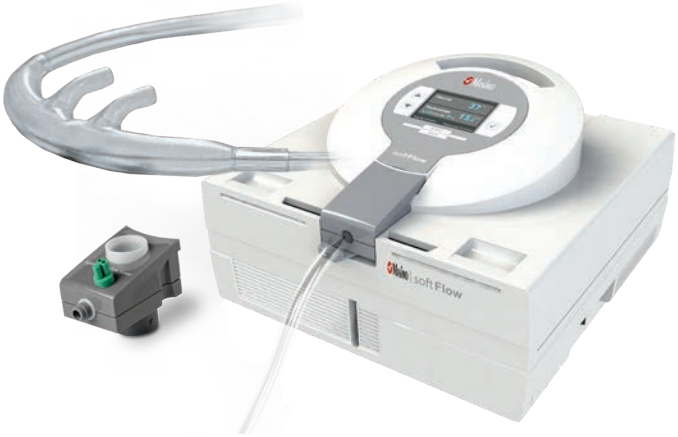
Operator's Manual

Masimo softFlow™



Masimo

First Notes

- These instructions for use are intended for healthcare professionals, adult third persons and patients using a Masimo softFlow™ system.
- These instructions for use apply to Masimo softFlow™ systems.
- To reduce the risk of injury and obtain the best possible benefit from the therapy, please follow these instructions and warnings carefully and adhere to the requirements of the product specifications.
- Keep these instructions for use ready at hand for future reference.
- Before first use, the Masimo softFlow™ system must undergo a setup and configuration process. The device must be cleaned regularly and particularly between patients.
- For additional information and support, please contact your local Masimo representative. See *7 Service/User Assistance Information* on page 65.

Model: TNI softFlow 2-60L/min | Part Number: 40610250

Manufacturer:
TNI medical AG
Tiefe Gasse 11-13
97084 Wuerzburg, Germany
Tel.: +49 931 20 79 29 02
Fax.: +49 931 20 79 29 18
info@tni-medical.de
www.tni-medical.de

CE 0297

WEEE-No: DE 92934592

Distributed by:
Masimo Corporation
52 Discovery
Irvine, CA 92618, USA
Tel.: 949-297-7000
Fax.: 949-297-7001
www.masimo.com

For patent information see www.tni-medical.com

Contents

1 Overview

During therapy with the Masimo softFlow™ system, the patient is supplied with an air flow of warmed, almost completely moisture-saturated air. Technically, the Masimo softFlow™ device consists of a ventilation and a humidifier unit. The flow generator draws in ambient air and then compresses it. In the humidifier unit, water is heated until it evaporates, thus moistening the therapy air.

If the patient additionally requires supplemental oxygen, an external oxygen source can be connected to the Masimo softFlow™ system. Using an applicator (comprising a respiratory circuit and a soft nasal cannula as patient interface), the warmed, humidified air or air-oxygen mixture is led into the nose of the patient and from here to the rest of the respiratory tract. If the patient's upper airways are bypassed a special applicator connected to an open tracheal interface can be used.

1.1 Intended Use

The Masimo softFlow™ system is used to treat spontaneously breathing patients of all ages who would benefit from a supply of warmed and moistened respiratory gases with high flow. The Masimo softFlow™ system is suitable for patients in hospitals, long-term care facilities and for homecare use. The Masimo softFlow™ system is not intended for life-sustaining measures.

The intended operators are healthcare professionals, adult patients, or adult third persons. Although no special education or skills are required to operate the Masimo softFlow™, training on the device is necessary. For information on training contact your Masimo representative. See *7 Service/User Assistance Information* on page 65.

1.2 Safety Notes

CAUTION: Masimo softFlow is to be operated by, or under the supervision of, qualified personnel only. Read the manual, accessories directions for use, all precautionary information, and specifications before use.

Risks

- Nasal application of high-flow therapy may cause positive airway pressure (PAP). The treating physician has to consider this possibility when deciding whether high-flow therapy with the Masimo softFlow system is appropriate for the patient.
- Thanks to humidification of the applied air and a thin and soft nasal silicone applicator, irritations of the nasal mucosa, bleeding and nasal obstruction are very unlikely when using the Masimo softFlow system. In the rare case when such symptoms occur, the humidity should be increased (see *3.2.2 Humidity* on page 39).
- The applicator tracheal interface is equipped with a hose heater up to its end. However, the tracheostomy interface usually does not have any integrated heating. Under adverse conditions, condensate may form. There is a risk of aspiration.

Precautions

- Read and follow the instructions for use carefully.
- Use the Masimo softFlow system within the product specifications and for the intended use only to allow the system to operate within given tolerances. See *5 Product Specifications* on page 53.

- The system may only be used by prescription by a physician as per his/her instructions.
- The Masimo softFlow system may only be operated by a mentally alert person, possibly a qualified third person. This must be taken into account especially when the appliance is used in children.
- In case of abnormalities, switch off the device and disconnect it from the power supply to reduce the risk of injury or damage. When in doubt, please contact your Masimo representative. See *7 Service/User Assistance Information* on page 65.
- Alarms and notes on the display indicate deviations from the tolerance limit.
- During therapy, the patient should be in a sitting or lying position and should not move excessively.
- Position the device on a horizontal surface. In homecare applications, keep the device stationary.
- Position the device where free ventilation is guaranteed. Do not block the air supply nor the air flow.
- Ensure that a sufficient amount of water is available in the humidification chamber at all times during use.
- Humidity performance can be compromised when used outside the recommended ambient temperature and humidity range.
- Use authorized, originally packed and unexpired components only.
- Follow the hygiene rules in order to gain the best potential benefits from the therapy. See *7 Service/User Assistance Information* on page 65.
- Check the connection between the applicator tube connector and the patient interface for strong hold.
- Disconnect the patient from the device before performing any service or maintenance.
- Keep pets away from the device to prevent damage.

Warnings

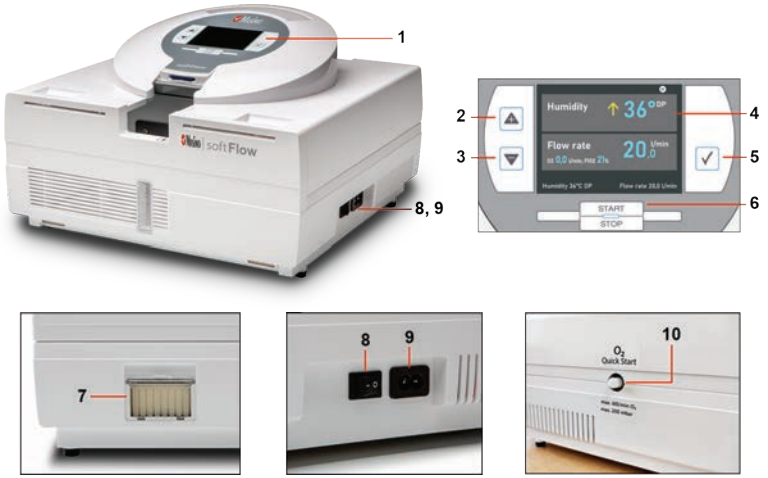
- Do not operate the device if you are cognitively or physically unable to follow the instructions in this manual.
- Do not use the device in a potentially explosive or easily flammable environment!
- Do not smoke or use open fire if a supplemental oxygen source is in use!
- Keep a min. distance of 1m to other electrical devices when using oxygen!
- Do not let children play with the hoses or cables to prevent injuries such as strangulation or swallowing of small parts!
- Do not reach into the housing directly after use since inner parts such as the heating plate and the bottom of the humidifier might be hot!
- Do not cover the device nor the applicator during use!
- Position the device where it cannot fall into water!
- Disconnect the power supply and discontinue use if water enters the housing or escapes from the humidification chamber!
- Disconnect the power supply and discontinue use if the device has been dropped or damaged!
- If the power cord or plug is damaged, disconnect the power supply and discontinue use!
- Do not use damaged applicators!

- As with all medical equipment, carefully route applicators to reduce the possibility of patient entanglement or strangulation.
- Do not connect unauthorized components to the power socket!
- Ensure that the characteristics of the local power supply correspond to the requirements of the Masimo softFlow system. See *5 Product Specifications* on page 53.
- Do not supply any gases other than oxygen via the lateral oxygen inlet port!
- Do not use the Masimo softFlow system in MRI environments, near HF surgical equipment or in other environments where the intensity of the EM disturbances is high!
- Do not use the Masimo softFlow at an altitude above 3000 m AMSL as the therapy quality might be affected due to low ambient pressure.
- If existing, do not remove the protective caps from the accesses below the carrying handle! The accesses are intended exclusively for maintenance purposes. Before commissioning, ensure that the connections are tightly closed by the protective caps!

Contraindications

- Do not use the Masimo softFlow applicators if you are allergic to silicone.
- The Masimo softFlow system is not intended as a life-supporting measure.
- The Masimo softFlow system may not be used for invasive ventilation.
- The nasal application of high flow by means of Masimo softFlow must not be used if the patient's upper airway is compromised due to a sustained (unrelievable) anatomical obstruction or injury induced blockage.
- The nasal application of high flow by means of Masimo softFlow must not be used if the patient's upper respiratory tract has been bypassed using a bypass.
- Masimo softFlow system must not be used in patients who have a history of anamnestic seizures.
- If the patient's upper respiratory tract is bypassed, only use the tracheal interface applicator with an open tracheal interface.
- Do not use the applicator headgear if you have significant pressure marks from it or in the event of material incompatibility of the stretch band or applicator headgear.

1.3 System Components



Item	Description	Item	Description
1	Masimo softFlow Control Panel	6	Mode Button
2	Up Button	7	Dust Filter
3	Down Button	8	On/Off Switch
4	Display Panel	9	Power Cord Connector
5	Enter Button	10	Oxygen Cap

General Description

The Masimo softFlow system includes the following:

- Masimo softFlow
- Power Cord
- Humidifier Rack Clinic (when delivered to healthcare institutions)
- Humidifier Clinic Hygiene Set (when delivered to healthcare institutions)
- Humidifier Homecare (when delivered to homecare patients)
- Dust Filters Reserves, 5 pieces
- Protection Cap for Oxygen Inlet, 5 pieces
- Operator's Manual, Masimo softFlow

softFlow Mode

When in softFlow mode, the nasal or tracheal applicators are used:

Nasal

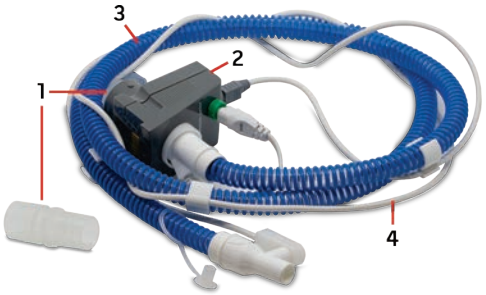
Item	Description	Item	Description
1	Applicator Plug	2	Patient Nasal Interface

Tracheal

Item	Description	Item	Description
3	Applicator Plug	4	Tracheal Applicator Connector

junior Mode

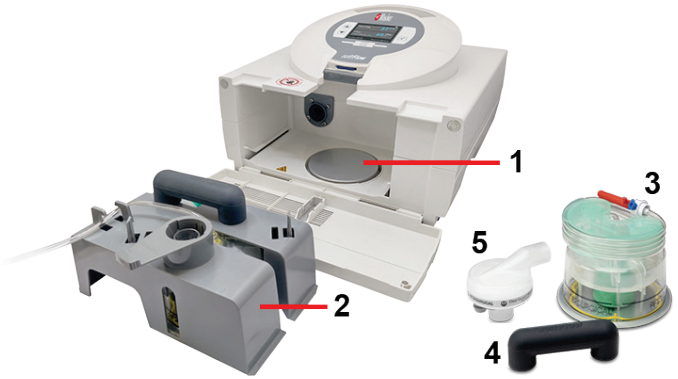
When in junior mode, the junior applicator is used. The junior applicator is the portion of the system that delivers the gas from the generator and mixing chamber to the patient. The junior applicator is made up of 4 components assembled together.



Item	Description	Item	Description
1	Connection Plug *	3	InnoTube
2	ApplicatorModule	4	Temperature Measuring Element

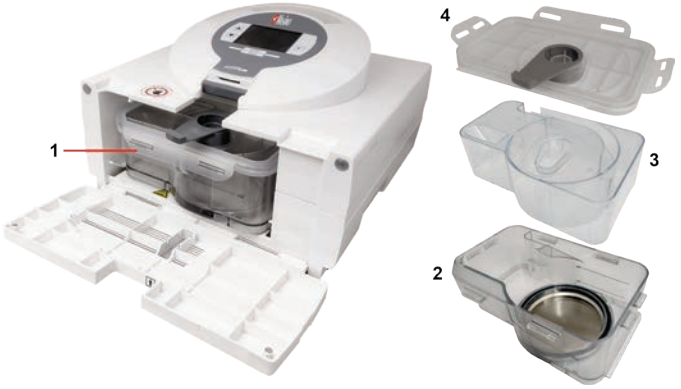
* The Connection Plug attaches to the InnoTube and passes through the ApplicatorModule and plugs into the Humidifier.

Clinical Use



Item	Description
1	Heating Plate
2	Humidifier, Clinic
3	Humidification Chamber Auto-Fill
4	Air Bridge
5	Breathing Filter

Home Use



Item	Description	Item	Description
1	Humidifier Homecare	3	Cyclone
2	Water Tank, Humidifier Homecare	4	Lid, Humidifier Homecare

2 Setup

- For highest efficiency, use the Masimo softFlow system within the given product specifications only.
- If the ambient conditions are out of the required range, keep the device switched off for safety reasons.
- When the device is brought into the therapeutic environment from outside, a significant temperature difference (transition from storage conditions to usage conditions) can develop, sometimes over 50°C. If that has occurred, allow up to 24 hours of adaptation to the ambient conditions (room temperature, e.g.) before startup.
- Place the Masimo softFlow device horizontally on a flat surface below the patient's head height.
- Place the device at a minimum height of 40 cm from the floor and keep a minimum distance of 40 cm from the wall and 1 m from any other electrical device.
- Place the device so that the power plug can be connected and disconnected without difficulty.
- Use the provided power cable to connect the power socket on the right side of the device to a power outlet.
- Switch on the device by pressing the rocker switch next to the power socket.

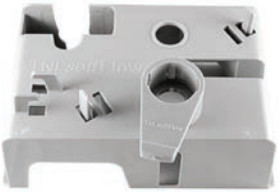
Note: The device performs an internal test during startup: An alarm sound must be audible.

WARNING: Ensure that the interior of the Masimo softFlow unit is dry before connecting it to the power supply.

2.1 Humidifier

2.1.1 Components of Humidifier Clinic

The humidifier clinic complete consists of the following components which need to be assembled before use:



Humidifier Rack Clinic

Breathing Filter

Humidification Chamber Auto Fill

Air Bridge Masimo softFlow

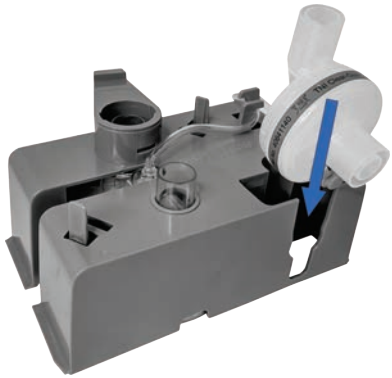
2.1.2 Assembly of Humidifier Clinic

Assemble the humidifier according to the following descriptive picture sequence:

1 Slide the humidification chamber auto fill from below into the dedicated socket of the rack.

2 Route the *Humidification Chamber* supply line through the opening in the *Humidifier Rack* and through the retainers as shown.

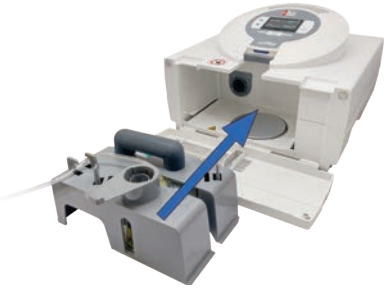
3 Push the breathing filter from above into the dedicated socket of the rack.



4 Place the air bridge from above onto the dedicated openings of the rack to connect the filter and the humidification chamber.

5 The applicator locking lever on the humidifier rack must face away from the device. Push the humidifier rack fully into the device. Make sure the rack slides beneath the rails.

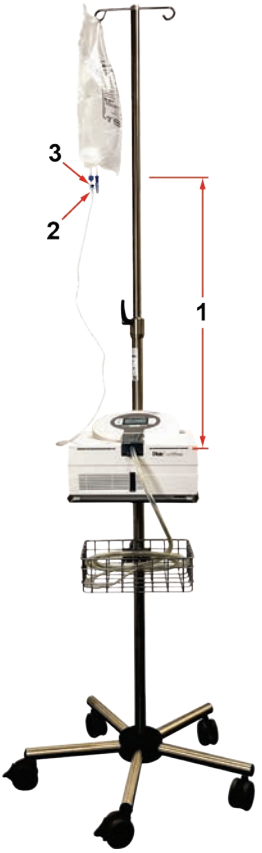
Route the humidifier supply line through the opening in the top of the humidifier door so it does not get pinched and close the door.



2.1.3 Water Bag Installation

When installing or changing the bag with sterile water ensure therapy has been paused by pressing the start/stop button.

1. Place the water bag so that the opening is 1 m above the upper edge of the device (see figure as example).
2. Push the spike of the chamber hose into the dedicated opening at the bottom of the water bag.
3. Open the vent cap on the side of the bag spike. The humidification chamber will now automatically and constantly be filled up to the mark line until the water bag is empty.



Note: Ensure that the Humidification Chamber and the water bag always contain sufficient amounts of water.

Note: Switch off the Masimo softFlow system if not in use.

WARNING: Ensure that the water level is always between the black marking lines (see Image)!

WARNING: Use sterile water only. Do not use any additives!

WARNING: Keep device horizontal during intra-hospital transport. The humidifier chamber should be emptied when packaging and shipping the product.

WARNING: Do not use the humidification chamber if it shows visible damage!

Note: The humidifier chamber should be emptied and removed from the device when packaging and shipping the product.

2.1.4 Components of Humidifier Homecare

The homecare humidifier consists of three parts:

1. Humidifier Lid
2. Humidifier Cyclone Element
3. Humidifier Water Chamber

2.1.5 Assembly of Humidifier Homecare

Assemble the humidifier according to following descriptive picture sequence:

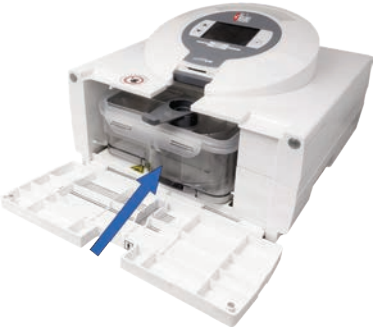
1 Fill the water chamber with purified, distilled or sterile water up to the "max." mark.

In the event purified, distilled or sterile water is not available, use boiled tap water that has cooled to a lukewarm temperature.

2 Put the cyclone and the lid from above onto the water chamber.

3 Close the lid and lock it by lowering the locking tabs.

4 Carefully push the Humidifier Homecare complete into the device. Close the housing front lid by flipping it up.



WARNING: Empty the humidification chamber completely before shipping the device!

2.1.6 Water Refill in Humidifier Homecare

- Change of water in the Humidifier Homecare is due daily.
- Disassemble the individual components of the Humidifier Homecare and rinse them under running water.
- Soak a soft, lint-free cloth in lukewarm water with a little amount of mild, standard household cleaning detergent and wring it afterwards.
- Rub and wipe the damp cloth over the surfaces of the unit and its components and along the edges and joints to remove visible dirt deposits and calcifications.
- Rinse the components under running water.
- Wipe dry all components with a dry, soft, lint-free cloth to avoid calcifications.
- Just before the next use, refill the water chamber with purified, distilled or sterile water. In the event purified, distilled or sterile water is not available, use boiled tap water that has cooled to a lukewarm temperature.

2.2 Applicators

Note: To meet the requirements of the ongoing therapy, be sure to choose the appropriate applicator type. Choose an applicator type size whose prongs do not completely occupy the nostrils. The prongs should not provide an occlusive fit.

Note: Keep the heated applicator tube away from any electronic monitoring electrode (EEG, ECG, EMG, etc.) to avoid potential interference with the monitored signal.

Note: Do not jam or bend the tube.

Note: The applicator must be changed with every patient or by the end of the life cycle hours (whichever occurs first).

Warning: To avoid the risk of injuries and damage:

- Do not use accessories that are not authorized by Masimo.
- Do not use insulating sleeves and do not cover the applicator when in use (e.g. by a blanket).
- Do not use any external source (a radiant heater, e.g.) to heat the applicator.
- Do not modify the applicator in any way.
- Do not use the applicator if you see any foreign object in the applicator.

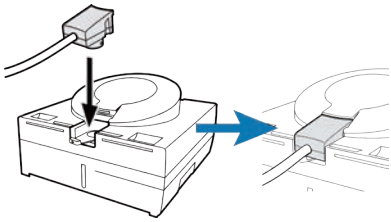
Warning: To avoid the risk of electric shocks:

- After the applicator has been attached, the patient should not touch the electrical connections of the Masimo softFlow system.

2.2.1 Applicator Installation (softFlow Accessories)

1 Choose appropriate applicator type (see *1.3 System Components* on page 8).

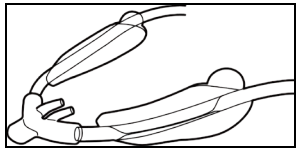
2 Insert the applicator plug from above into the dedicated socket and push it down gently and fully.



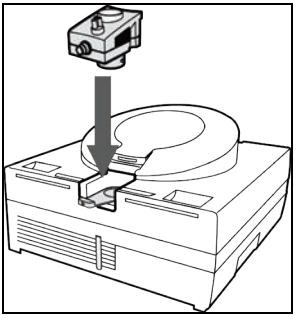
Note: To meet the requirements of the ongoing therapy, be sure to choose the appropriate applicator type.

2.2.2 Applicator Installation (junior Accessories)

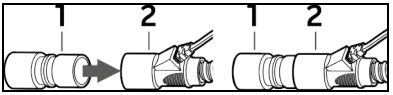
1 Choose appropriate Nasal Cannula (see *1.3 System Components* on page 8).



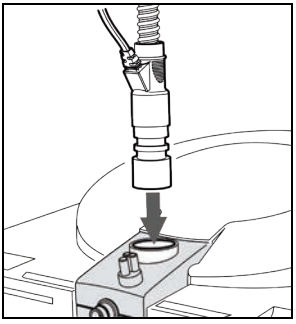
2 Insert the ApplicatorModule junior from above into the dedicated socket and push it down gently and fully.



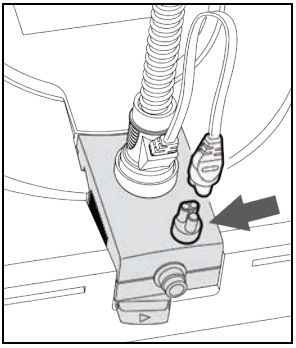
3 Remove the InnoTube and the connection plug from the packaging and insert the connection plug (1) into the InnoTube (2).



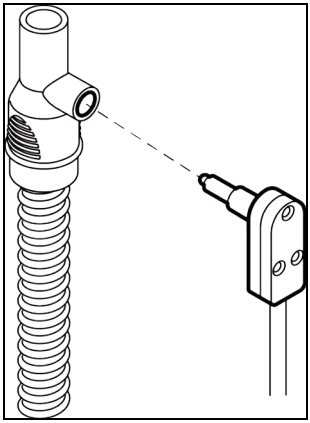
4 Insert the InnoTube section from above into the dedicated socket on the ApplicatorModule.



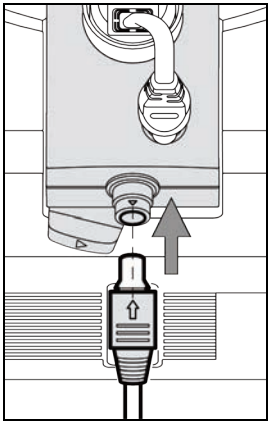
5 Insert the plug of the heating cable of the InnoTube from above into the dedicated socket on the ApplicatorModule junior.



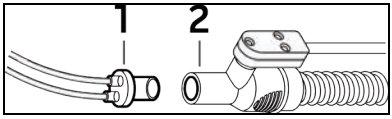
6 Insert the angled connector of the Temperature Measuring Element into the dedicated socket at the front end of the InnoTube



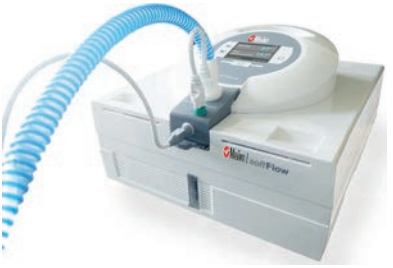
7 Insert the plug of the sensor cable into the dedicated socket on the front side of the ApplicatorModule junior. Mind the corresponding arrows on the cable and the socket indicating the correct orientation.



8 Remove the Nasal Cannula (1) from the packaging and insert it into the InnoTube (2).



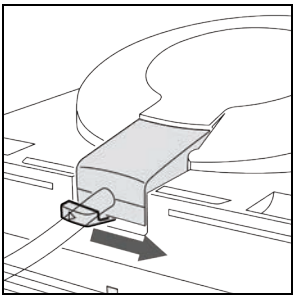
9 The Masimo softFlow is now equipped correctly with the Applicator. Put the system into operation according to the instructions of the manual and attach the applicator correctly.



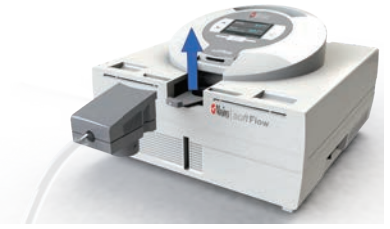
Note: To meet the requirements of the ongoing therapy, be sure to choose the appropriate nasal cannula.

2.2.3 Uninstalling the Applicator (softFlow Accessories)

1 Move the locking lever under the applicator plug to the right. The applicator plug is released from its lock.

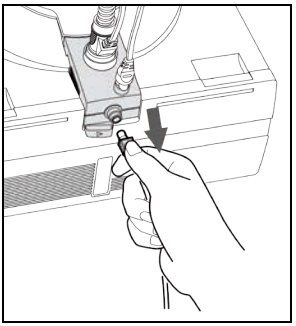


2 Carefully pull the applicator plug straight up from the socket to remove.

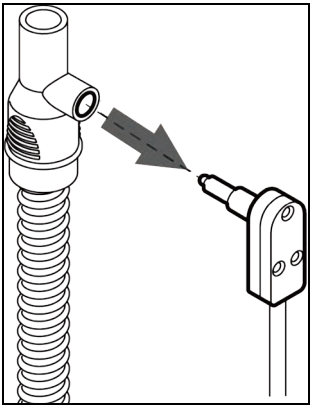


2.2.4 Uninstalling the Applicator (junior Accessories)

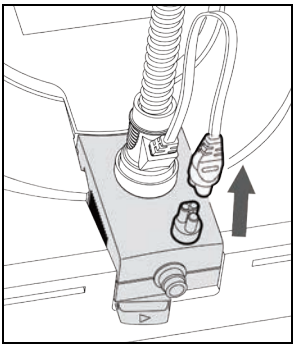
1 Remove the plug of the sensor cable from its socket on the on the front side of the ApplicatorModule.



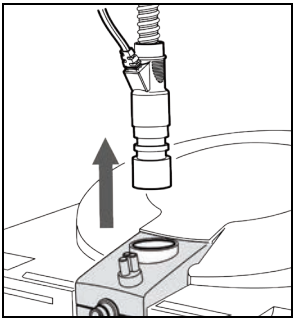
2 Remove the temperature measurement element from its socket on the free end of the InnoTube.



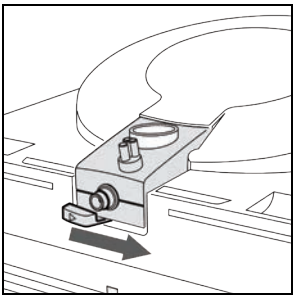
3 Remove the plug of the heating cable of the InnoTube from its socket on the applicator ApplicatorModule.



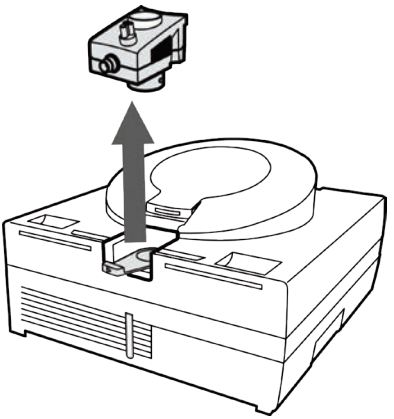
4 Remove the end of the InnoTube from its socket on the ApplicatorModule.



5 Move the locking lever under the ApplicatorModule to the right. The ApplicatorModule is released from its lock.



6 Pull the ApplicatorModule straight up from the socket.



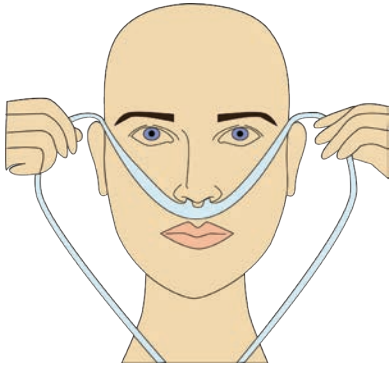
2.2.5 Nasal Application

Turn on the Masimo softFlow device to start therapy before attaching an applicator. Attach the applicator to the patient's face according to the following picture sequence.

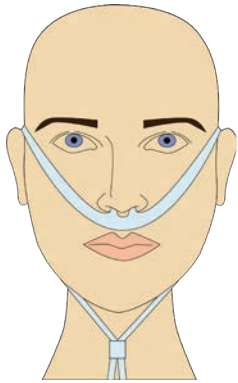
softFlow Mode

1 Make sure that the slightly curved prongs point towards the face.

2 Carefully insert the prongs into the nose. Slide the tube over the ears.



3 To fix the applicator's position, pull the fixing sleeve towards the chin.



junior Mode

Make sure that the slightly curved prongs point towards the face.

Carefully insert the prongs into the nose.

Remove the protective sheet from the self-adhesive pads and fix them on the cheeks of the patient.

Note: The self-adhesive pads can be removed if not needed.

To fix the applicator´s position, pull the fixing sleeve towards the chin.

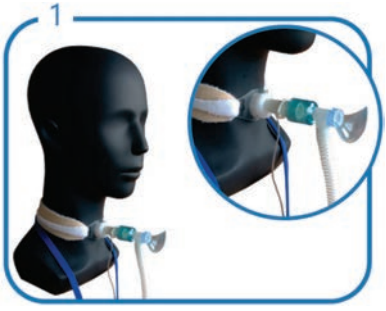
Check, if the applicator fits properly.

Attach the applicator clip to the patient's clothing to help prevent the nasal cannula from being pulled out of place.

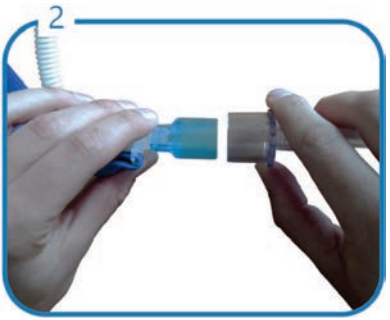
2.2.6 Tracheal Application

Turn on the Masimo softFlow device to start therapy before attaching an applicator. Attach the applicator to the patient's tracheostomy interface according to the following sequence of images.

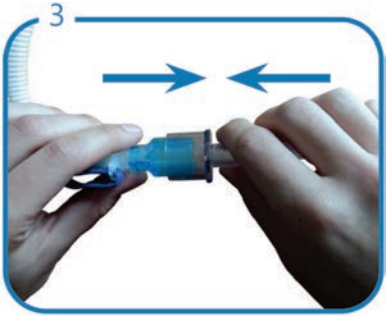
Connect the tracheal interface to the patient connection according to manufacturer specifications.



Connect the applicator tube adapter to the matching counterpart of the tracheal interface.



Check the connection between the applicator and patient interface for strong hold.



Note: The applicator tube connector has an inner diameter of 22mm.

Note: This accessory can only be used with the system operated in softFlow mode.

Note: When the Tracheal Interface Applicator is connected to softFlow, the dew point setting is automatically set to 37°C to allow >33 mg/l for tracheal applications. The dew point setting cannot be adjusted when the Tracheal Interface Applicator is connected.

WARNING: In extreme ambient conditions and maximum flow rates, it is possible that the humidification of 33 mg/l cannot be reached with tracheal application.

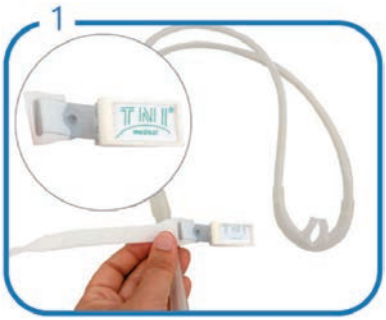
WARNING: Oxygen admixture is limited to 20 l/min when using the Applicator Tracheal-Interface! This must be taken into consideration when making therapy decisions and adjustments.

WARNING: To ensure adequate humidification, the ambient temperature range of 20°C to 28°C should be used for tracheal applications.

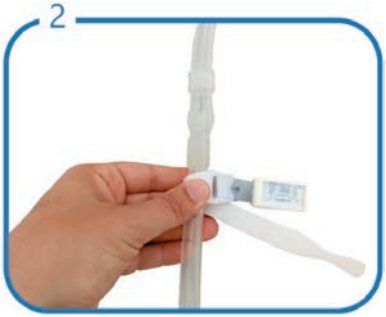
2.2.7 Applicator-Accessories

Applicator-Clip

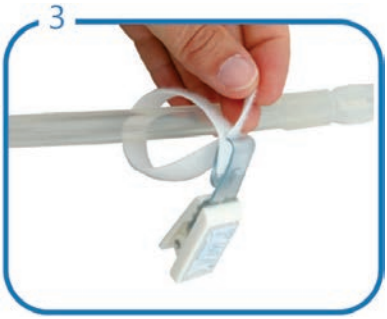
Place the applicator clip at the desired position on the applicator tube with the label facing upwards.



Place the band around the applicator hose.

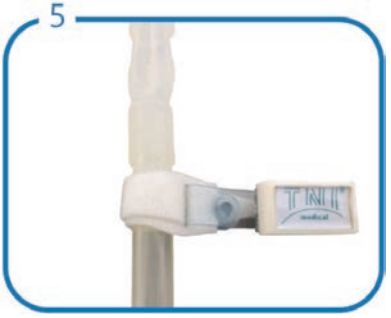


Pull the band through the provided opening of the clip.

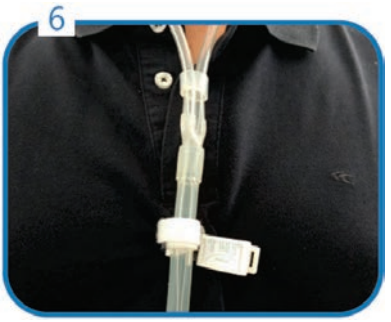


Tighten the band only to the extent that the hose is not squashed in any case.

Wind the band completely.



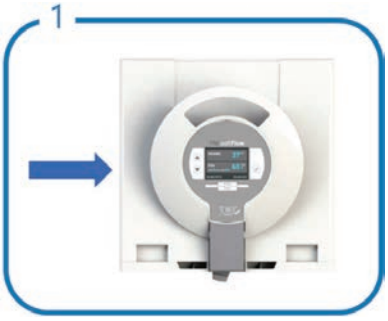
Open the fastening clip and attach it to the desired position on your clothing.



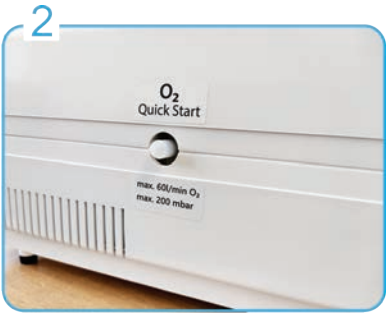
2.3 Oxygen Supply

If supplemental oxygen is required, an external, medically approved oxygen source can be connected to the Masimo softFlow device using the lateral oxygen inlet port.

The oxygen inlet port is located on the left side of the device casing.



If no oxygen supply is needed, the oxygen inlet port must be kept sealed by the protective cap.



Connect an external oxygen source to the oxygen inlet port of the device using a dedicated oxygen tube.

Note: Please follow the operating instruction of the external oxygen source closely. If you have any questions concerning the use of the oxygen source, please contact your oxygen vendor.

Note: Incorrect connection of the oxygen source may lead to inefficient oxygen therapy. Ensure a stable connection.

WARNING: Mount the oxygen source safely to prevent damage and injury.

WARNING: Smoking and open fire are strictly forbidden when using supplemental oxygen due to the risk of explosion.

WARNING: Do not operate the device in closed rooms producing or using anesthetics and/or nitrous oxide.

WARNING: Keep the oxygen valves free of oil, grease or any flammable liquids.

WARNING: Keep the device at a min. distance of 40 cm from the floor and from the wall and a min. distance of 1 m to other electrical devices when using supplemental oxygen.

2.4 Configuration

The user menu can be entered in standby or operation mode. Use the arrow keys to scroll up or down in the user menu and to increase or decrease values. Once parameter settings have been selected and confirmed, they are saved in the system's internal memory and booted with the next startup. The settings can be readjusted at any time.

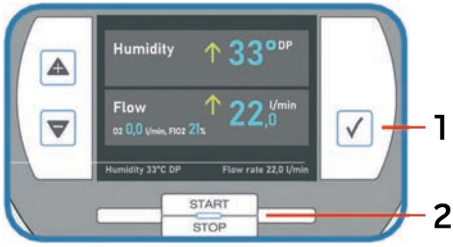
2.4.1 Mode and Operating Keys

Standby Mode

1 Enter User Menu
2 Startup out of Standby Mode

Operation Mode

The display illumination darkens after 10 min. By pressing any function key, the display illumination is reactivated.



1 Enter User Menu
2 Stop Operation

User Menu

1 Scroll Up or Increase Value
2 Scroll Down or Reduce Value
3 Confirm Selection/Adjusted Value
4 Exit User Menu

2.4.2 Language, Date and Time

Language

Enter the user menu and select the tab *Language*. Scroll to the desired language and confirm the selection.

User Menu:

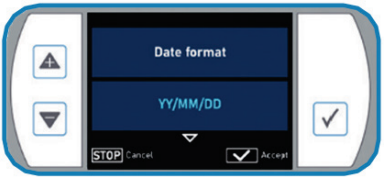
Example:

Date

Enter the user menu and select the tab *Date*. Select the desired format and confirm the selection. Use the arrow keys to set the correct date. Confirm the setting. It is saved in the system's memory.

User Menu:

Example:

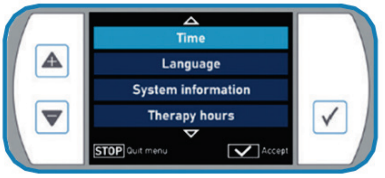


Setting:

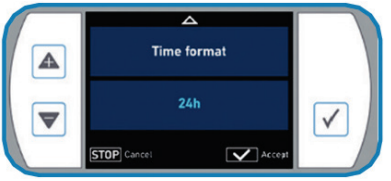
Time

Enter the user menu and select the tab *Time*. Select the desired format and confirm the selection. Use the arrow keys to set the correct time. Confirm the setting. It is saved in the system's memory.

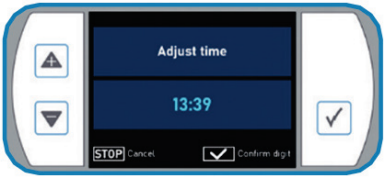
User Menu:



Example:



Setting:



2.4.3 Alarm Volume

Note: This menu item is not accessible in the Homecare mode.

Enter the user menu and select the tab *Alarm volume*. Select the desired alarm volume and confirm the selection.

User Menu:

Example:

2.4.4 Therapy Hours

The Masimo softFlow system continuously records the patient's therapy hours. Enter the user menu and select *Therapy hours* to read out the therapy hours.

Note: All data on operation and dysfunction are recorded and can be read out by Masimo technical staff or an authorized Masimo representative.

Note: All data that are recorded internally or on SD-Cards are for information purposes only and cannot be used as a basis for an evaluation of the therapy effectivity.

User Menu:

Display of Therapy Hours:

2.4.5 New Patient

Note: This menu item is not accessible in the Homecare mode.

Before the Masimo softFlow system is used by another patient, therapy hours of the previous patient should be set to zero. Enter the user menu and select the tab *New patient*. Select *Yes* and confirm the selection.

User Menu:

Selection:

Therapy Hours are Deleted:

3 Operation

In order to achieve the best possible therapeutic success with Masimo softFlow, follow these installations and instructions for use carefully.

Note: Before commissioning, ensure that the humidification chamber is filled with a sufficient quantity of water.

WARNING: Ensure that the water level is always between the black marking lines!

WARNING: Ensure that the interior of Masimo softFlow device is dry!

WARNING: Do not reach into the interior of the device during or immediately after use, since the internal components could be hot!

3.1 softFlow and junior Mode

The Masimo softFlow system can be operated in two modes: softFlow mode and junior mode. The softFlow mode enables flow rates from 10 to 60 l/minute while the junior mode is used for flow rates from 2 to 15 l/min.

softFlow mode is indicated by the SF icon in the top line of the display 

junior mode is indicated by the pacifier icon in the top line of the display 

Each mode allows the use of a specific set of accessories. For a list of corresponding accessories see *1.3 System Components* on page 8.

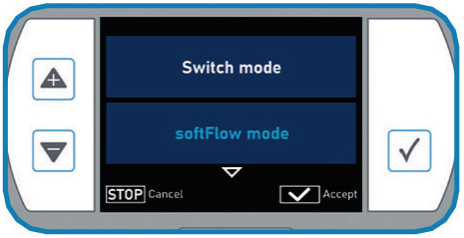
3.1.1 Switching between softFlow Mode and junior Mode

WARNING: Operation modes must be set by qualified health professionals only. For this reason this menu item is not accessible in the Homecare mode.

Before modes can be changed, select a *New Patient*. See *2.4.5 New Patient* on page 35.

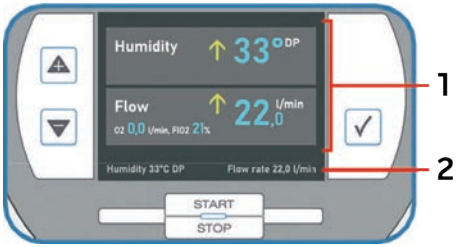
Enter the user menu and select the tab *Switch mode*.

Select the desired mode by using the arrow keys and confirm the setting.



3.2 Therapy Parameters

In operation mode, the display shows the current output humidity (dew point temperature in °C DP), flow rate (in l/min), oxygen flow rate (in l/min) and FiO_2 (in %).



1 Current Values
2 Nominal Values

Numbers in the bottom line show the programmed nominal values. Arrows in front of the output values indicate that the nominal values are not reached yet and the device is currently up or down-regulating the respective parameter.

3.2.1 Flow Rate

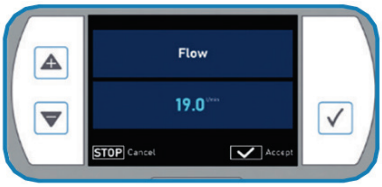
- Turn on the Masimo softFlow device to start therapy.
- Select the parameter *Flow* in the user menu.
- Adjust the flow rate in 0.5 l/min steps to the value, that is suitable to the particular applicator type, and confirm the selected nominal value.
- The newly set nominal value is shown in the footer at the bottom of the display.

Note: Set the flow rate before attaching the applicator to the patient to prevent discomfort.

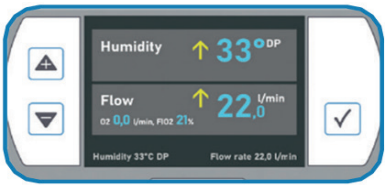
WARNING: Flow rates must be set by qualified health professionals only. For this reason this menu item is not accessible in the Homecare mode.

User Menu:

Setting:



Nominal value in the footer:



3.2.2 Humidity

- Select the parameter *Humidity* in the user menu.
- Increase the dew point temperature (in 1°C DP steps, within the range from 30-37°C DP) to increase the humidity or vice versa by pressing the arrow keys. Confirm the new nominal value.
- The newly set nominal value is shown at the bottom of the display.
- Alternatively, the nominal value can be changed directly in the operation mode by pressing the arrow keys.

User Menu:

Setting:

Nominal value in the footer:

Note: For optimal humidification of the patient's mucosa, humidity of 34-37°C DP during therapy is recommended.

Note: When the Tracheal Interface Applicator is connected to softFlow, the dew point setting is automatically set to 37°C to allow >33 mg/l for tracheal applications. The dew point setting cannot be adjusted with the Tracheal Interface Applicator connected.

Note: If the patient feels dryness in the nose, check if the humidification chamber contains enough water and/or increase the humidity value.

Note: The system requires a setup-time of about 10 min to adjust a newly set nominal value of humidity. If water condenses in the applicator / heating tube, the chosen humidity value might be too high for the present ambient conditions. Reduce the dew point value.

Note: When operated in junior mode condensation in the cannula may occur in certain ambient conditions at flow rates less than 5 l/min. To minimize condensation it is recommended not to set the humidity higher than 34°C, if using flow rates less than 5 l/min.

3.2.3 Oxygen

If required, oxygen can be added into the air flow by connecting an external oxygen source to the lateral oxygen inlet port on the Masimo softFlow device (see *2.3 Oxygen Supply* on page 30).

Newer Masimo softFlow devices identified with the O_2 Quick Start label affixed above the lateral oxygen inlet permit supplemental oxygen to be added prior to starting the device or at any point during therapy. In contrast, for older devices without the O_2 Quick Start label, the device should be turned on and the selected flow rate should be reached before supplemental oxygen is added.

- The oxygen flow rate is displayed in l/min and the resulting oxygen concentration of the air flow is shown as FiO_2 value in %.
- Adjust the oxygen supply by adjusting the opening of the valve of the external oxygen source.
- Stop the oxygen supply by closing the valve of the external oxygen source.

1 Display of the oxygen flow rate and the FiO_2

Note: The admixture of oxygen is limited to 20 liters per minute using an applicator tracheal interface

Note: When starting or restarting the device make sure the oxygen supply is closed. Slowly open the oxygen supply after the device has reached set air flow completely.

Note: If the FiO_2 exceeds 95% a value of 99% will be displayed.

WARNING: Smoking and open fire are strictly prohibited when using supplemental oxygen due to the risk of explosion.

WARNING: Do not place a connected applicator on the Masimo softFlow device or any other electrically driven device when the device is running.

WARNING: Keep a min. distance of 1 m from other electrical devices when using oxygen.

3.3 Start Therapy

When Masimo softFlow is turned on, therapy begins. To ensure Masimo softFlow is providing therapy properly, ensure these steps are followed:

New Patient

1. Turn Masimo softFlow by pressing the rocker switch next to the power socket. Wait for device self test to be completed.
2. Press Start/Stop key to pause therapy. See *Operation Mode* on page 32.
3. Press the √ key to access the settings menu to review and change settings as needed. See *3.2 Therapy Parameters* on page 38.
4. Prepare the device for a new patient by selecting *New Patient* from the menu. See *2.4.5 New Patient* on page 35.
5. Turn O_2 on if needed and set flow. See *3.2.3 Oxygen* on page 40.
6. Install the applicator. See *2.2 Applicators* on page 18.
7. Set the mode to softFlow or junior to match the applicator. See *3.1 softFlow and junior Mode* on page 37.
8. Press Start/Stop key to start therapy.

Current Patient

1. If the device was turned OFF - Turn Masimo softFlow by pressing the rocker switch next to the power socket. Wait for device self test to be completed.

2. If the device was not turned OFF and therapy was paused - Press Start/Stop key to resume therapy.
3. Once flow reaches set value, review to determine if still appropriate for patient. See *3.2 Therapy Parameters* on page 38.
4. If removed, install the applicator.

3.3.1 Pause Therapy

If therapy needs to be paused for any reason, press the Start/Stop key. See *Operation Mode* on page 32.

To resume therapy, press the Start/Stop key again.

3.4 Troubleshooting

- The user is notified about an error by an acoustic signal and a notification on the display. The delay between the malfunction and the error signal may take up to one minute.
- Please refer to the instructions in the error code table.

Note: Alarm system functionality can be checked in operation mode. To do so, uninstall the applicator and note visual and acoustic alarm signals. Do not use the device if either signal does not occur in this test. Please contact your Masimo representative. See *7 Service/User Assistance Information* on page 65.

Note: If an error is displayed, which is not listed in the following table, please contact your Masimo representative. See *7 Service/User Assistance Information* on page 65.

Error Priorities

Priority (acc. to IEC 60601-1-8:2006)	Severity code	Alarm	Meaning
low	I	2 audible signals, cyclically repeated	Please follow the instructions below.
medium	II	3 audible signals, cyclically repeated	The alarm cannot be switched off. The device can no longer operate. Please follow the instructions below.

Error Codes

Error code	Severity code	Notification	Interpretation
101	II	Pressure too high	Internal pressure is too high. Please check air flow. Verify the applicator for any obstructions or kinks.
102	II	Sensor defective	O_2 flow sensor is defective.*
103	II	Sensor defective	Air flow sensor is defective.*

Error code	Severity code	Notification	Interpretation
104	II	No flow	Flow rate is zero.*
151	I	Flow rate not reachable	Measured flow is lower than the set flow. Please check air flow and applicator type. Verify the applicator for any obstructions or kinks.
153	I	Flow rate too high	Measured flow is higher than the set flow. Please check air flow.
154	I	Leakage detected	Components in the gas path are either missing or improperly assembled. Please check and ensure complete and proper assembly of components in the gas path. Note: This error code is only available on newer devices with the O_2 Quick Start label affixed above the lateral oxygen inlet.
155	I	Ambient pressure off limits	Ambient pressure is out of permitted range. Please refer to the product specifications.
156	I	O_2 flow over nominal value	Set O_2 flow rate is too high. Please refer to Oxygen Flow.
157	I	Sensor defective	Pressure sensor is defective.*
158	I	Oxygen connection open	Close the oxygen inlet port by a protective cap or check the proper set-up of the oxygen source.
191	I	Check application hose	Warning: Flow obstruction detected. Check if application hose was kinked.
201	II	Air flow too hot	Therapy air temperature is too high. Please check environmental conditions and refer to the product specifications.
251	I	Ambient temperature off limits	Ambient temperature is out of permitted range. Please refer to the product specifications.
252	I	Ambient humidity off limits	Ambient humidity is out of permitted range. Please refer to the *5 Product Specifications* on page 53.
254	I	Sensor defective	Ambient temperature / humidity sensor is defective.*
255	I	Dew point not reachable	Set dew point cannot be reached. Please refer to the *5 Product Specifications* on page 53 and check the correct set-up of the system components.
301	II	Heating plate gets too hot	Hardware error.*
302	II	Heating plate defective	Heating plate electronic is not working properly.*

Error code	Severity code	Notification	Interpretation
351	I	Please refill water	Please refill the humidification chamber with water.
352	I	Heating plate defective	Heating plate is not working properly.*
353	I	Sensor defective	Temperature sensor of humidifier is defective.*
354	I	Heating plate defective	Heating plate is not working properly.*
355	I	Sensor defective	System failure.*
401	II	Blower defective	Blower is blocked.*
402	II	Blower gets too hot	Blower is overheated. Please refer to the product specifications and check the air flow.
403	II	Blower sensor defective	Blower temperature sensor is defective.*
404	II	Fan defective	Fan blower is defective.*
501	II	-	Display defective; an acoustic alarm signal is given.*
502	II	System failure	Sensor errors detected on system startup.*
503	II	Calibration Error	Restart device with closed oxygen supply. Slowly reopen oxygen after the device has reached set air flow completely.* Note: This error code will not appear on newer softFlow devices with the O_2 Quick Start label affixed above the lateral oxygen inlet.
601	II	Sensor defective	Temperature sensor of applicator is defective; please replace by a new applicator.
605	II	Air flow too hot	Therapy air temperature is too high. Please check environmental conditions and refer to the product specifications.
606	II	Applicator heating defective	Hardware error.*
651	I	Applicator heating defective	Applicator heating is defective; please replace by a new applicator.
652	I	Applicator not found	Applicator cannot be detected; please replace by a new applicator.
653	I	Applicator type	The selected flow rate is too high for this type of applicator; reduce flow rate or use a larger applicator.

Error code	Severity code	Notification	Interpretation
654	I	Applicator type	The selected flow rate is too low for this type of applicator; use a smaller applicator.
655	I	Applicator not supported	The connected applicator is not supported by this device. Please use an applicator according to accessories table in *1.3 System Components* on page 8.
701	II	System failure	EEPROM (internal memory) is defective.*
702	II	System failure	Operating system error.*
703	II	System failure	EEPROM (internal memory) is defective.*
704	II	System failure	User settings are damaged.*
705	II	System failure	Firmware error.*
706	II	Wrong hardware	Hardware error.*
707	II	System failure	System error.*
708	II	System failure	EEPROM (internal memory) is defective.*
752	I	SD card or file defective	SD card checksum error; please change SD card and restart system.*
753	I	System failure	Battery voltage is too low.*
754	I	System failure	Firmware checksum error.*
755	I	System failure	Firmware error. Please remove SD card and contact your Masimo representative. See *7 Service/User Assistance Information* on page 65.
756	I	Font could not be loaded	Font of selected language cannot be loaded. File is defective or missing. Please select standard font (English, e.g.). Contact your Masimo representative for further help. See *7 Service/User Assistance Information* on page 65.
757	I	Low SD card memory	Please insert a new SD card.
851	I	Change dust filter	Change the dust filter. Note: The message 851 "Change dust filter" must be acknowledged on the device after the filter has been changed. Press the enter button (checkmark) to acknowledge.

* Turn off the main switch of the device. Wait at least 30 sec. before restarting the device. If the error persists, please contact your Masimo representative. See *7 Service/User Assistance Information* on page 65.

4 Reprocessing

The following instructions define the procedures for cleaning and disinfecting the Masimo softFlow device and components. Follow these instructions unless the directives of your institution state other requirements.

Note: Follow the cleaning and replacement cycles listed below to minimize the risk of a contamination of the device which may harm the patient.

Note: The manufacturer's instructions for the cleaning/disinfecting detergent must be observed.

Note: Switch off the device and disconnect it from the power supply before processing.

Note: Check all components for visible damage after cleaning/disinfection.

Note: Assemble the Masimo softFlow components according to these instructions for use and check for proper functioning.

Note: Automatic cleaning procedures must not be performed.

Note: Sterilization procedures must not be performed.

Note: Excessive use of disinfectants may damage the housing.

WARNING: Liquids may not enter the device since they may damage the electronics assembly!

WARNING: Do not reach into the housing immediately after use. Wait until the inner parts, the heating plate e.g., have cooled down!

4.1 Cleaning and Disinfection

Choose a clean environment for the cleaning procedure. Wipe the surface the device rests on with a damp cloth with household cleaning agent. Wipe dry afterwards with a dry, lint-free cloth.

4.1.1 Manual Cleaning

Masimo softFlow

- Soak a soft, lint-free cloth in hand-hot water with a little amount of mild, household cleaning detergent and wring it afterwards.
- Rub and wipe the damp cloth over the surfaces of the unit and its components and along the edges and joints to remove visible dirt deposits and calcifications.
- Wipe dry the surfaces with a dry, soft, lint-free cloth to avoid calcifications.
- If condensation forms in the applicator tube during tracheal application, disconnect the applicator from Masimo softFlow and the patient interface and allow the condensate to drain off.

Applicator Headgear

- Spray applicator headgear with solution.
- Wipe with a lint-free cloth over the surfaces and along any edges and joints to remove visible dirt deposits.
- Wipe dry the surfaces with a dry, soft, lint-free cloth.

4.1.2 Manual Disinfection

Masimo softFlow

- After cleaning, some Masimo softFlow components (see *4.3 Cleaning and Replacement Cycles* on page 49) must be disinfected by manual wipe disinfection.
- The surfaces of the components must be evenly and carefully wiped with a soft, lint-free cloth soaked with a disinfectant or with disinfectant wipes (see *4.2 Detergents and Disinfectants* on page 48).
- Concerning the exposure time, please follow the instructions given by the disinfectant's manufacturer.
- After the exposure time, wipe dry the surfaces with a dry, soft, lint-free cloth.

4.1.3 System Disinfection

Masimo softFlow

Disinfection of the complete system is required when the Masimo softFlow system:

- has been used in the clinic application without or with a defective breathing filter (for example, if the indicated change cycle has not been observed).
- has been used in the clinic application with a homecare humidifier.
- has been contaminated with MRSA (methicillin-resistant staphylococcus aureus).

Note: The disinfection procedure according to the Keredusy procedure can be performed by the manufacturer Masimo or another authorized company / institute. Three Keredusy procedures may be performed at maximum. If you have any questions, please contact Masimo. See *7 Service/User Assistance Information* on page 65.

4.2 Detergents and Disinfectants

Use a mild, standard household cleaning detergent for the cleaning procedure. The material compatibility of the Masimo softFlow device has been validated for the following disinfectants:

Product Name	Producer	Description
Masimo softFlow		
mikrozid® AF liquid	Schülke & Mayr GmbH	Ready-to-use alcoholic disinfectant
mikrozid® sensitive liquid	Schülke & Mayr GmbH	Ready-to-use alcohol-free rapid disinfectant
MediWipes	Medicare Medizinische Geräte GmbH	Ready-to-use alcohol-free disinfection moistened tissues
Meliseptol® rapid	B. Braun	Ready-to-use alcoholic disinfection for spraying or wiping
Oxivir Tb*	Diversey	Hydrogen Peroxide 0.5%
MetrCide Plus 30*	Metrex	Glutaraldehyde 3.4%

Product Name	Producer	Description
Super Sani-Cloth*	PDI	Dimethyl Ethylbenzyl Ammonium Chloride 0.25% Dimethyl Benzyl Ammonium Chloride 0.25%
Chlorine Bleach*	Clorox	10% Sodium Hypochlorite (8.25%) in Water
IPA*	Hydrow	USP Isopropyl Alcohol 70%
Chlorhexidine*	Hibiclens	Chlorhexidine 4.0%
Applicator Headgear softFlow		
Isopropyl Alcohol	-	Isopropyl Alcohol 70%
Ethyl Alcohol	-	Ethyl Alcohol 70%

* Also suitable to disinfect the Humidifier rack Clinic.

The agent's disinfecting efficiency was validated by the respective disinfectant manufacturer. Please follow the instructions for use provided by the cleaning / disinfectant's manufacturer.

Note: The cleaning detergent must be: pH-neutral, non-abrasive, non-toxic and non-corrosive. Do not use any detergents incompatible with polycarbonate plastic or PC&ABS blends (including but not limited to ammonia, ammonium hydroxide, caustic soda, iodine, methanol, methylated spirits, turpentine and alkaline bleaches such as sodium hypochlorite).

Note: Any detergent or disinfectant residue must be removed with a clean, lint-free cloth.

4.3 Cleaning and Replacement Cycles

The following cleaning and replacement cycles must be followed strictly. Between patients, single use components must be replaced. If necessary, carry out a manual cleaning, for example if superficial dirt is visible (see *4.1.1 Manual Cleaning* on page 47).

Component	Cleaning Cycle	Cleaning Method	Replacement Cycle	Usage
Masimo softFlow Device	Daily	Manual cleaning Wipe disinfection	-	Reusable
Accessory softFlow Mode				
Applicator Clinic series	Daily	Manual cleaning Wipe disinfection	360 Hours	Single patient multiple use
Applicator Homecare series	Daily	Manual cleaning Wipe disinfection	720 Hours	Single patient multiple use
Tracheostomy Interface	-	-	Follow manufacturer's guidance.	Single patient multiple use
Accessory junior Mode				
ApplicatorModule junior	Daily	Manual cleaning Wipe disinfection	-	Reusable
Temperature Measuring Element	Daily	Manual cleaning Wipe disinfection	-	Reusable

Component	Cleaning Cycle	Cleaning Method	Replacement Cycle	Usage
junior Cannula	-	-	Follow cannula manufacturer's guidance.	Single patient multiple use
InnoTube softFlow	-	-	30 days	Single patient multiple use
Clinic System				
Humidifier rack clinic	Between Patients	Manual cleaning Wipe disinfection	-	Reusable
Humidification chamber auto-fill	-	-	Weekly	Single patient multiple use
Air bridge humidifier clinic	-	-	Weekly	Single patient multiple use
Breathing Filter	-	-	Follow filter manufacturer's guidance.	Single patient multiple use
Homecare System				
Water Tank, Humidifier Homecare	Daily	Manual cleaning Wipe disinfection	Once a Year	Single patient multiple use
Cyclone, Humidifier Homecare	Daily	Manual cleaning Wipe disinfection	Once a Year	Single patient multiple use
Lid, Humidifier Homecare	Daily	Manual cleaning Wipe disinfection	Once a Year	Single patient multiple use
Miscellaneous				
Dust Filter	Weekly	Rinsing	Every 3 Months	Reusable
Water in Homecare Water Tank	-	-	Daily	-

4.3.1 Dust Filter Change

- Weekly, rinse the dust filter under running water, wring it out and let it dry completely before putting it back in the holder.
- At least every 3 months or with error “851-Change dust filter” is displayed (whichever is earliest). After servicing the filter, press the enter button (checkmark) to acknowledge the message.

Take the dust filter cover out of the holder at the back of the device by pressing gently on the upper edge of the cover and take out the dust filter.

Replace the dust filter with a new one or put the cleaned dust filter back, respectively. Insert the dust filter cover by hooking up the bottom edge first. Lock the dust filter cover by softly pressing onto the upper edge.

Note: Follow these instructions to prevent the system from taking damage from lint, dust, etc. and thus compromising the therapy.

5 Product Specifications

Performance Data

softFlow Mode Performance Data	
Flow Rate	10 to 60 l/min (adjustable in 0.5 l/min steps)
Admixture of oxygen	0 to 60 l/min

junior Mode Performance Data	
Flow Rate	2 to 15 l/min (adjustable in 0.5 l/min steps)
Admixture of oxygen	0 to 13 l/min

General Performance Data	
Humidity dew point	30-37°C DP (adjustable in 1°C DP steps)
Event memory	Data storage of the last 12 therapy months

Tolerances of Displayed Values	
Total Flow Rate	0 to < 10 l/min: ± 1 l/min
	10 to < 25 l/min: ± 2 l/min
	25 to < 50 l/min: ± 4 l/min
	> 50 l/min: ± 5 l/min
Oxygen Flow	0 to < 10 l/min: ± 0.5 l/min
	10 to < 25 l/min: ± 1 l/min
	25 to < 50 l/min: ± 2 l/min
	> 50 l/min: ± 2.5 l/min
FiO_2	21 to 100%: ±10%

Note: Humidification system output is > 12mg/l for any humidity setting. The system delivers a humidity of > 33 mg/l for tracheal application for any combination of flow rate and oxygen.

Device Parameters

Technical Data	
Medical product class (93/42/EWG)	IIa

Technical Data	
Safety class, electrically	II
Alarm signal sound pressure	> 45 dB (A)
Safety type	IP21: Protected from touch by fingers and objects >12 mm and dripping water
Applied part (applicator)	BF
Electrical safety	According to EN 60601-1 UL 60601-1 CSA C22.2/No 60601-1
Electromagnetic compatibility	According to EN 60601-1-2
Operating voltage (nominal voltage)	100-240 V~, 50-60 Hz
Maximum power system	300 VA
Maximum power applicator heating	20 VA

Device Dimensions	
Width	320 mm
Depth	320 mm
Height	210 mm
Weight (without humidifier and without water)	5.7 ±0.1 kg
Humidification chamber auto-fill	max. 144 ml
Water tank humidifier homecare	max. 650ml

Applicators	
softFlow Mode	
Changing cycle applicator Clinic series	≤ 360 therapy hours; single-patient use
Changing cycle applicator Homecare series	≤ 720 therapy hours; single-patient use
Safety level (applied part)	BF
Tube length nasal application	1.8 m
Tube length tracheal application	2.33 m
Max. temperature of air leaving device	43°C

Applicators	
junior Mode	
Changing cycle NeoFlow nasal Cannula	7 days; single-use
Changing cycle InnoTube softFlow	30 days; single-use
Safety level (applied part)	BF
Tube length	160 cm
Max. temperature of air leaving device	43°C

Humidifier	
Typical humidity	30°C to 37°C DP (70% to 90% RH) (nasal application) 37°C DP (70% to 90% RH) (tracheal application)
Humidification system output	> 12 mg/l at 2 to 60 l/min
Compliance	< 1.2 ml/kPa/m
Gas leakage at max. operating pressure	< 10 ml/min
Warm-up time	< 30 min

Environmental conditions	
Ambient temperature	10°C to 30°C
Recommended Ambient temperature	18°C to 28°C (nasal application) 20°C to 28°C (tracheal application)
Ambient humidity	15% to 93% RH
Altitude	0 to 3000 m MSL
Environmental Conditions Concerning Storage and Transport	
Temperature	-29°C to +70°C
Humidity	< 93% RH
Ambient air pressure	700 hPa to 1060 hPa
Electromagnetic compatibility	EN 60601-1-2: 2007
Filter class of dust filter	G4 (EN 779: 2003)
Expected operating time (expected service life) Masimo softFlow	6 years

Attached Oxygen Source	
Type	Only medically approved oxygen sources may be connected (that includes, but is not limited to oxygen sources complying with IEC 60601-1:2005). For more information, please consult the oxygen source user manual or your oxygen retailer. For handling and adjustment, please refer to the oxygen source user manual.
Max. pressure allowed at the oxygen intake	200 mbar (60 l/min)

WARNING: Operating the device outside specified parameters or at high altitudes may have negative impact on therapy quality.

Note: All values regarding gas volume, flow rate and leakage are expressed at ATPS.

5.1 System Information

Clinic Mode

The Masimo softFlow system is delivered in clinic mode; the *clinic menu* is activated. The qualified health professional is enabled to set all therapy parameters and system configurations and to access the menu item 'system information' which provides additional information such as firmware versions and serial number.

WARNING: If a Masimo softFlow is used at home, the health personnel must deactivate the clinic menu after setting the therapy parameters so that the patient cannot change the settings during operation. This procedure requires a PIN code. Please contact your Masimo representative if you intend to deactivate the clinical menu.

Note: The Service menu can be accessed by a Masimo technical staff or representative only.

Homecare Mode

The configuration of a Masimo softFlow device needs to be changed from clinic to homecare mode if a patient continues therapy at home. Please contact your Masimo representative. See *7 Service/User Assistance Information* on page 65.

5.2 Ambient Conditions

See Environmental Specifications in *Device Parameters* on page 53.

Ambient Conditions	
Ambient temperature	10°C to 30°C
Ambient humidity	15% to 93% RH
Ambient air pressure	0 to 3000 M MSL

WARNING: Operating the device at high altitudes may have negative impact on therapy quality.

Storage and Transport Conditions

See Environmental conditions in *Device Parameters* on page 53 concerning storage and transport.

The device should be stored and transported at temperatures between -29°C to +70°C, ≤93% RH, 700 hPa to 1060 hPa. The device may be transported only in upright position and if completely dry.

Note: Ensure that the humidification chamber is removed and completely emptied of water prior to packaging and shipping the device.

List of compatible Gases

Room air enters the device through the air slot and the dust filter at the rear side.

Oxygen is provided by an external oxygen source.

5.3 Data Storage

All data on operation and dysfunction of the Masimo softFlow system are recorded during therapy hours and can be read out by Masimo technical staff. These data are stored in the internal memory. The internal memory has the capacity to store all data collected during the previous 12 months. Additionally, an SD card can be used to save data independently of the internal memory.

5.4 Electromagnetic Compatibility (EMC)

Note: The Masimo softFlow system is a medical electrical device and requires special precautions regarding EMC. It must be set up and put into operation consistent with the EMC information provided below.

Note: Portable and mobile RF (radio frequency) communication equipment can affect proper functioning of the Masimo softFlow system.

Note: The Masimo softFlow system should not be used adjacent to or stacked with other electrical devices. If adjacent or stacked use is necessary, correct operation within the configuration setting must be regularly verified.

Note: The Masimo softFlow system may be interfered with by other electrical devices even if the other devices comply with applicable emissions requirements.

Note: The additional use of unauthorized accessories, cables or converters can increase the emissions and reduce the electromagnetic immunity of the Masimo softFlow system.

Note: In accordance with the applicable standard the Masimo softFlow System has the essential performance of warmed and humidified airflow with a humidification output > 12mg/l during nasal application and > 33 mg/l during tracheal application.

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
The Masimo softFlow system is intended for use in the electromagnetic environment specified below. The user must ensure that these requirements are met.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1/Class B	The Masimo softFlow system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.

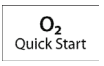
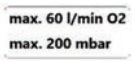
Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
RF Emissions CISPR 11	Group 1/Class B	The Masimo softFlow system is suitable for use in all institutions, including hospitals, long-term care facilities and in homecare settings.
Harmonic Distortion IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Masimo softFlow system is intended for use in the electromagnetic environment specified below. The user must ensure that these requirements are met.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	+8 kV contact ± 2, ± 4, ± 8, ± 15 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 lines, 100 kHz +/- 1 kV for input/ output lines, 100 kHz	± 2 kV for power supply lines, 100 kHz [no input/output lines with > 3 m present] 100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5, ± 1 kV line(s) to line(s) ± 0.5, ± 1, ± 2 kV line(s) to earth	± 0.5, ± 1 kV line(s) to line(s) [no earth present]	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	0% UT for 0.5 cycle at 0°, 45°,90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at 0° 0% UT for 250/300 cycles	0% UT for 0.5 cycle at 0°, 45°,90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at 0° 0% UT for 250/300 cycles	Mains power quality should comply with that of typical commercial or hospital environment. If continuous operation is critically required, the use of an uninterruptible power supply or battery is recommended.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should comply with levels in a typical commercial or hospital environment.
Note: UT is the AC mains voltage prior to application at the test level.			
Conducted RF IEC 61000-4-6	6 V for ISM and RF communications between 150 kHz and 80 MHz 3 V 150 kHz to 80 MHz	6V for ISM between 150 kHz and 80 MHz 3V, 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to the Masimo softFlow system, including accessories and cables, than the recommended separation distance, which depends on the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Recommended separation distance *d* in meters (m) 0.3 P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Field strengths of fixed RF transmitters as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note: At 80 MHz and 800 MHz, the higher frequency range applies. Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Note: Field 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 with accuracy. To assess the electromagnetic environment owing to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength exceeds the applicable RF compliance level of the Masimo softFlow system, its correct operation has to be regularly verified. If malfunction is observed, additional measures may be necessary such as relocating the Masimo softFlow system. Note: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.			

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the Masimo softFlow system						
The Masimo softFlow system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TNI softFlow system as recommended below, according to the maximum output power of the communication equipment.						
Test frequency MHz	Frequency band MHz	Radio service	Modulation	Maximum power W	Distance m	Immunity test level V/m
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460,FRS 460	FM ± 5 kHz Hub 1 kHz Sinus	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						
WARNING: Portable RF communications equipment (radio equipment) (including their accessories such as antenna cables and external antennas) should not be used at a distance of less than 30 cm (or 12 inches) from the [ME device or ME system] parts and cables specified by the manufacturer. Non-compliance may lead to a reduction in the performance of the device. WARNING: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.						

5.5 Symbols

Symbol	Description	Symbol	Description
	Follow the instructions for use		Consult instructions for use
	European Union Conformity Mark		Separate collection for electrical and electronic equipment (WEEE)
IP21	Protection from ingress of particulates > 12.5 mm and against vertically falling water drops		Type BF applied part
	MR Unsafe		Prescription only
	Caution		Caution: Hot surface!
	Single patient multiple use		Class II Equipment
LOT	Lot Code	SN	Serial number
REF	Catalog number (model number)	 YYYY-MM	Use-by Date YYYY-MM-DD
	Manufacturer		Date of manufacture YYYY-MM-DD
	Storage temperature range		Distributor
I	Power switch: ON	O	Power switch: OFF
	Warning: Do not remove caps		Do Not Ship with Water
	O_2 Quick Start		Max. Flow Max. Pressure
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs Note: eIFU is not available in all countries.		

5.6 Disposal

You may dispose of the following parts with the domestic waste: applicators, humidifier rack clinic, air bridge humidifier clinic, breathing filter, dust filter, humidification chamber auto-fill. The Masimo softFlow unit contains electronic components. Do not discard with regular waste. Please contact your local Masimo representative regarding the unit's disposal. See 7 *Service/User Assistance Information* on page 65.

6 Warranty

LIMITED WARRANTY: THE MASIMO SOFTFLOW DEVICE WAS MANUFACTURED WITH CARE AND TESTED IN DETAIL BEFORE SHIPMENT. THE WARRANTY PERIOD IS 2 YEARS FROM THE DATE OF PURCHASE (ACKNOWLEDGED BY AN INVOICE AND/OR GUARANTEE CERTIFICATE WITH DEALER STAMP). TNI MEDICAL AG WILL REPLACE DEFECTIVE PARTS OF THE DEVICE WITHIN THE WARRANTY PERIOD. NO SUCH REPLACEMENT WILL EXTEND THE WARRANTY PERIOD BEYOND 2 YEARS FROM THE DATE OF PURCHASE. THE WARRANTY DOES NOT COVER ORDINARY WEAR AND TEAR OF THE DEVICE OR OF DISPOSABLE PARTS (E.G. DUST FILTER, HUMIDIFICATION CHAMBER ETC.) OR PARTS SUBJECT TO A DURATION OF USE RESTRICTION PERIOD (E.G. APPLICATOR ETC.). REPLACED PARTS BECOME THE PROPERTY OF TNI MEDICAL AG. ANY FURTHER PURCHASER CLAIMS INCLUDING BUT NOT LIMITED TO WARRANTY OF MERCHANTABILITY AND WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE ARE EXCLUDED.

THE LIMITED WARRANTY EXPIRES THROUGH:

- DISASSEMBLY, REASSEMBLY, CHANGES OR REPAIRS MADE BY ANYONE OTHER THAN A PERSON AUTHORIZED BY TNI MEDICAL AG
- NON-COMPLIANCE WITH THE OPERATING INSTRUCTIONS
- DAMAGE CAUSED BY IMPROPER USE OR HANDLING
- USE WITH SPARE PARTS AND OTHER ACCESSORIES NOT INTENDED OR AUTHORIZED BY TNI MEDICAL AG TO BE USED WITH THE PRODUCT
- FORCE MAJEURE (E.G. LIGHTNING ETC.)
- TRANSPORT DAMAGES CAUSED BY IMPROPER PACKAGING WHEN RETURNING

IF THE COMPLAINT PROVES TO BE UNJUSTIFIED, THE CUSTOMER MUST BEAR THE COSTS OF CHECKING AND SHIPPING THE DEVICE. PLEASE STORE THE ORIGINAL PACKAGING IN CASE SERVICE IS NEEDED. IF THE ORIGINAL PACKAGING IS NO LONGER AVAILABLE CONTACT YOUR MASIMO REPRESENTATIVE. IF THE MASIMO SOFTFLOW SYSTEM IS SENT WITHOUT THE ORIGINAL PACKAGING AND DAMAGED DURING TRANSPORT, THE CUSTOMER WILL BE CHARGED. WE THANK YOU FOR YOUR UNDERSTANDING.

7 Service/User Assistance Information

Please follow the instructions for use closely for safe and long-term device operation. Please perform a visual check before every startup and regularly monitor correct functioning of the Masimo softFlow system during operation. Please contact your Masimo representative if any unexpected event, operation or malfunction occurs. The user menu point *Service menu* can be accessed by Masimo technical staff/representative or a person authorized by TNI Medical AG only.

Note: Maintenance of the Masimo softFlow system lies within the responsibility of the user / clinic.

Note: Repair / service may only be carried out by a service technician authorized by Masimo.

Note: Ensure that the humidification chamber is removed and completely emptied of water prior to packaging and shipping the device.

Masimo Corporation
52 Discovery
Irvine, California 92618
Tel:+1 949 297 7000
Fax:+1 949 297 7001

The software on the device uses • CMSIS V5.1 • FreeRTOS v10.2.0 • Elm-Chan FatFS R0.13c • Ramtex LCD library v7 • STM32F10x Self Test Library / Class B STM32 self test package v2.0.0 • Standard Peripheral Library for STM32F1xxx V3.6.1 • STM32 USB Library v4.1.0 • STM32 DFU library V3.2.1

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