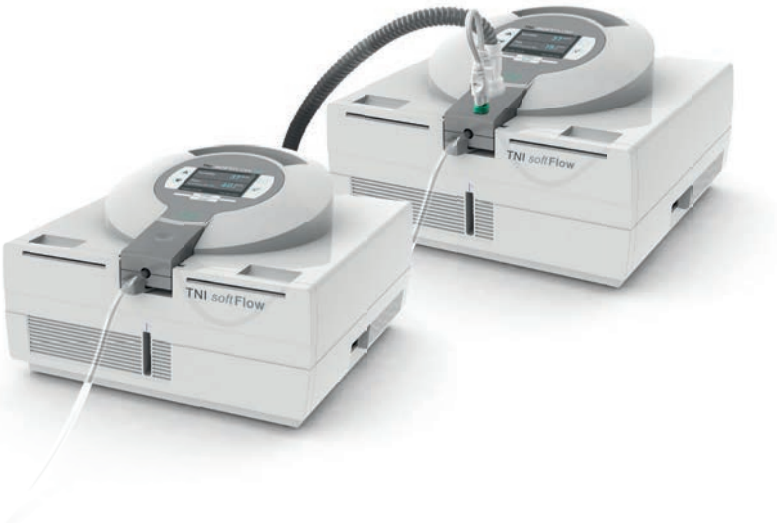
Instructions for Use TNI *soft* **Flow**






TNI® medical

First notes

- These instructions for use are intended for healthcare professionals and patients using a TNI softFlow system.
- These instructions for use apply to TNI 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 TNI 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 TNI medical AG representative.

Table of Content

1 Overview

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

If the patient additionally requires supplemental oxygen, an external oxygen source can be connected to the TNI 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

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

The intended operators are healthcare professionals, adult patients, or adult third persons mentally and physically able to operate the device. Although no special education or skills are required to operate the TNI softFlow, training on the device is necessary. For information on training contact your TNI medical AG representative.

1.2 Safety notes

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 TNI softFlow system is appropriate for the patient.
- Thanks to humidification of the applied air and a thin and soft nasal silicon applicator, irritations of the nasal mucosa, bleeding and nasal obstruction are very unlikely when using the TNI softFlow system. In the rare case when such symptoms occur, the humidity should be increased (see chapter Humidity).
- 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 TNI softFlow system within the product specifications and for the intended use only to allow the system to operate within given tolerances (see chapter product specifications).
- The system may only be used by prescription by a physician as per his/her instructions.
- The TNI 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 local TNI medical AG representative.
- 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 and keep it stationary during use.
- 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 chapter Reprocessing.
- 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

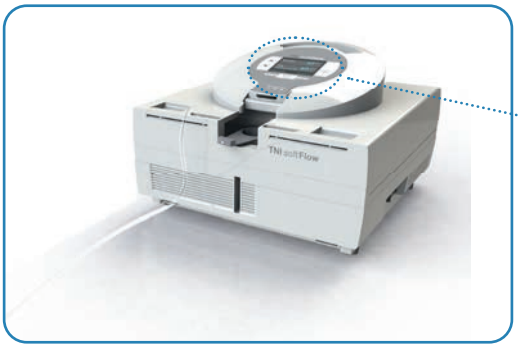
- Do not operate the device without appropriate training.
- Do not operate the device if you are mentally or physically unable to follow the instructions given in this manual.
- Do not use the device in a potentially explosive or easily flammable environment.
- Do not smoke or use open fire if a supplemental 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.
- Do not connect unauthorized components to the power socket.
- Ensure that the characteristics of the local power supply correspond to the requirements of the TNI softFlow system. See the device's name plate and chapter Product specifications.
- Do not supply any gases other than oxygen via the lateral oxygen inlet port.
- Do not use the TNI 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 TNI softFlow at high altitudes as the therapy quality might be affected negatively 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.

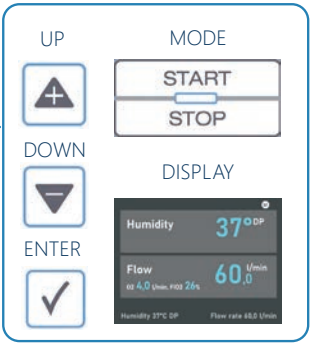
Contraindications

- Do not use the TNI softFlow applicators if you are allergic to silicon.
- The TNI softFlow system is not intended as a life-supporting measure.
- The TNI softFlow system may not be used for invasive ventilation.
- The nasal application of high flow by means of TNI softFlow must not be used if the patient's upper respiratory tract is completely obstructed.
- The nasal application of high flow by means of TNI softFlow must not be used if the patient's upper respiratory tract has been bypassed using a bypass.
- TNI softFlow system must not be used in patients who have a history of anamnestic seizures or restless sleep.
- 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



TNI *soft***Flow**

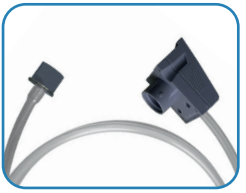


CONTROL PANELS

softFlow Mode

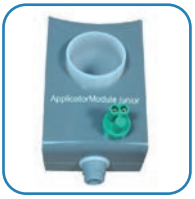
APPLICATOR PLUG

PATIENT INTERFACE



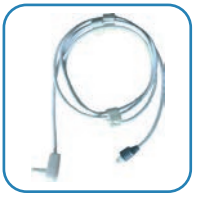
TRACHEAL-APPLICATOR

junior Mode



APPLICATOR MODULE

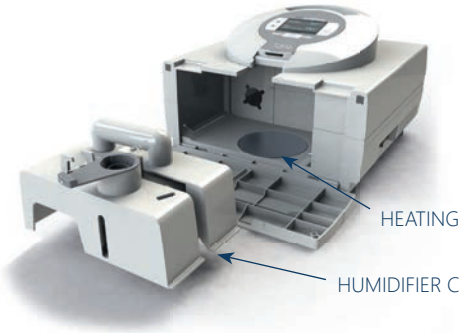
INNOTUBE



TEMPERATURE MEASURING ELEMENT

PATIENT INTERFACE

Clinical Use

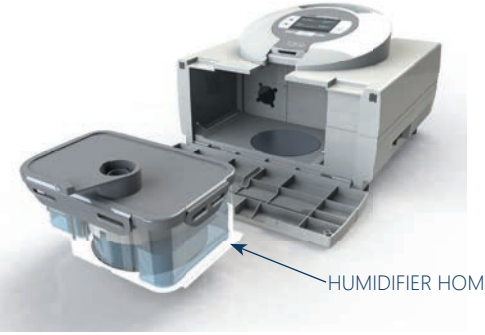


HUMIDIFICATION CHAMBER AUTO-FILL

AIR BRIDGE

CLEAR GUARD 3 BREATHING FILTER

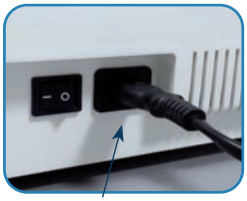
Homecare Use



WATER TANK HUMIDIFIER HOMECARE

LID HUMIDIFIER HOMECARE

CYCLONE



POWER CORD and CONNECTOR

DUST FILTER

PROTECTION CAP OXYGEN INLET

Scope of delivery

Component	Art. No.
TNI *soft*Flow	40610250
Humidifier Rack Clinic (when delivered to health care institutions)	40641107
Humidifier Clinic Hygiene Set (when delivered to health care institutions)	40620040
Humidifier Homecare (when delivered to patients)	40620000
Power Cord	Depending on country of delivery
Dust Filter Reserves, 5 Pieces	40620060
Protection Cap for Oxygen Inlet, 5 Pieces	40620061
Instructions for Use, TNI softFlow	Depending on country of delivery

General accessories

Components of humidifier Clinic	Art. No.
Humidifier Rack Clinic	40641107
Air Bridge Humidifier Clinic	40641108
Humidification Chamber Auto Fill, with Fill Set	40641110
Clear-Guard 3 Breathing Filter	40641111
Components of humidifier Homecare	
Water Tank Humidifier Homecare	40641104
Lid, Humidifier Homecare	40641105
Cyclone, Humidifier Homecare	40641106

Accessories softFlow Mode

Applicators	Art. No.	Recommended max. flow rate
Clinic*		
Applicator Clinic Small	40630001	20 l/min
Applicator Clinic Standard	40630002	25 l/min
Applicator Clinic Standard-Plus	40630005	35 l/min
Applicator Clinic Large	40630013	60 l/min
Applicator Clinic Tracheal-Interface	40630019	50 l/min
Homecare**		
Applicator Homecare Small	40630101	20 l/min
Applicator Homecare Standard	40630102	25 l/min
Applicator Homecare Standard-Plus	40630105	35 l/min
Applicator Homecare Large	40630113	60 l/min
Applicator Homecare Tracheal-Interface	40630119	50 l/min
Applicator Accessories		
Applicator Headgear	40630334	-
Stretch Band Applicator Headgear, 1 Piece	40630335	-
Stretch Band Applicator Headgear, 5 Pieces	40630336	-
Applicator Clip	40630331	-

*All applicators are for single use * max. usage time is 360 therapy hours ** max. usage time is 720 therapy hours*

Accessories junior Mode

Nasal Cannulas***		Flow rate	Art. No.
NeoFlow nHOT Cannula	Premature, Red	2-8 L/min	40630126
NeoFlow nHOT Cannula	Infant, Light Purple	4-10 L/min	40630128
NeoFlow nHOT Cannula	Large Infant, Dark Purple	5-15 L/min	40630129
NeoFlow nHOT Cannula	Pediatric, Green	7-15 L/min	40630130
Accessories			
Temperature Measurement Element	InnoTube softFlow		40641114
ApplicatorModule junior	softFlow junior		40641115
InnoTube *softFlow* ****			40643606

*** All applicators are for single use; max. usage time is 7 days. **** For single use; max. usage time is 30 days.*

For further information, please see www.tni-medical.com.

2 Setup

- For highest efficiency, use the TNI 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 TNI 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.*

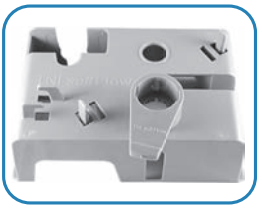
WARNING

- *Ensure that the interior of the TNI softFlow unit is dry before connecting it to the power supply.*

2.1 Humidifier

2.1.1 Components of Humidifier Clinic

The Humidifier Clinic consists fully equipped of four parts.



Humidifier Rack Clinic

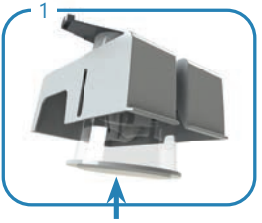
Clear Guard 3 Breathing Filter

Humidification Chamber Auto-Fill

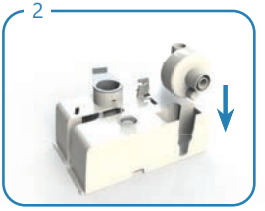
Air Bridge TNI softFlow

2.1.2 Assembly of Humidifier Clinic

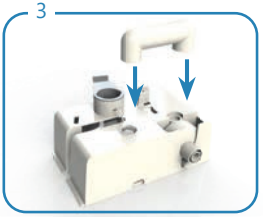
Assemble the humidifier according to following descriptive picture sequence:



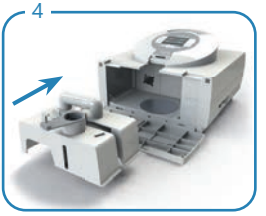
Slide the Humidification Chamber Auto-Fill from below into the dedicated socket of the rack.



Push the Breathing Filter from above into the dedicated socket of the rack.



Place the Air Bridge from above onto the dedicated openings of the rack to connect the filter and the humidification chamber.



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. Close the front lid of the casing by flipping it up.

2.1.3 Water Bag installation

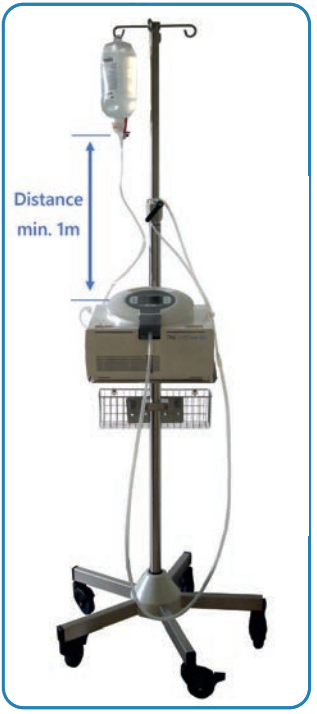
- When installing or changing the bag with sterile water the device has to be switched off.
- Place the water bag so that the opening is 1 m above the upper edge of the device (see figure below as example).
- Push the spike of the chamber hose into the dedicated opening at the bottom of the water bag.
- 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.*
- *Switch off the TNI softFlow system if not in use.*

WARNING

- *Ensure that the water level is always between the black marking lines (see Example Image).*
- *Use sterile water only. Do not use any additives.*
- *Empty the humidification chamber completely before transporting or moving the device.*
- *Do not use the humidification chamber if it shows visible damage.*



Example image

2.1.4 Components of Humidifier Homecare

The Humidifier Homecare consists of three parts.

Lid Humidifier Homecare

Cyclone Element Humidifier Homecare

Water Chamber Humidifier Homecare

2.1.5 Assembly of Humidifier Homecare

Assemble the humidifier according to following descriptive picture sequence:

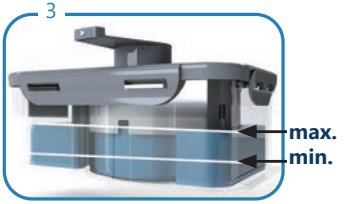
1

Fill the water chamber with boiled tap water (max. lukewarm), non-carbonated drinking water or sterile water, up to the "max." mark.

2

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

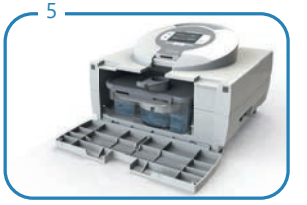
3



4

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

5



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 transporting or moving 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 recently boiled tap water (max. lukewarm), non-carbonated drinking water or sterile water

2.2 Applicators

NOTE

- *To meet the requirements of the ongoing therapy, be sure to choose the appropriate applicator type. Choose an applicator type whose cannulas do not close the nostrils completely.*
- *Keep the heated applicator tube away from any electronic monitoring electrode (EEG, ECG, EMG, etc.) to avoid potential interference with the monitored signal.*
- *Do not jam or bend the tube.*
- *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:

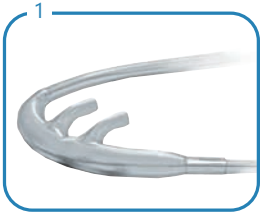
- *Do not use accessories that are not authorized by TNI medical AG.*
- *Do not use insulating sleeves and do not cover the applicator when in use (e.g. by a blanket).*
- *Do not use any external source (a radiant heater, e.g.) to heat the applicator.*
- *Do not modify the applicator in any way.*
- *Do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

To avoid the risk of electric shocks:

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

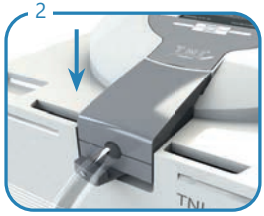
2.2.1 Applicator installation (softFlow accessories)

1



Choose appropriate applicator type (see chapter System components).

2



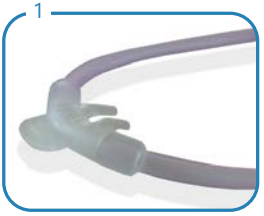
Insert the applicator plug from above into the dedicated socket and push it down gently and fully.

NOTE

- *To meet the requirements of the ongoing therapy, be sure to choose the appropriate applicator type (see chapter System components: accessories softFlow Mode).*

2.2.2 Applicator installation (junior accessories)

1

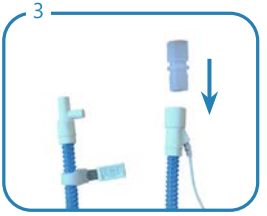


Choose appropriate Nasal Cannula (see chapter System components).

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 into the InnoTube

4

Insert the InnoTube section from above into the dedicated socket on the applicator module.

5

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

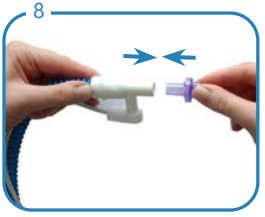
6

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 from the packaging and insert it into the InnoTube.

9

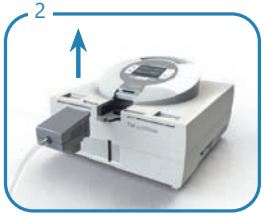
The TNI is now equipped correctly with the Applicator. Put the system into operation according to the instructions of the manual and attach the applicator correctly.

NOTE

- *To meet the requirements of the ongoing therapy, be sure to choose the appropriate nasal cannula (see chapter System components: accessories junior Mode)*

2.2.3 Uninstalling the applicator (softFlow accessories)

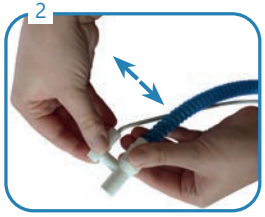
Move the locking lever under the applicator plug to the right. The applicator plug is released from its lock.



Carefully pull the applicator plug straight up from the socket.

2.2.4 Uninstalling the applicator (junior accessories)

Remove the plug of the sensor cable from its socket on the on the front side of the applicator module.



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

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

Remove the end of the InnoTube from its socket on the applicator module.

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

Pull the applicator module straight up from the socket.

2.2.5 Nasal Application

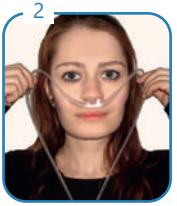
Switch on the TNI softFlow device before attaching an applicator. Attach the applicator to the patient's face according to the following picture sequence.

- *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

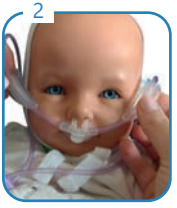
To fix the applicator's position, pull the fixing sleeve towards the chin.

- *junior mode*

1

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

2



Carefully insert the prongs into the nose.

3

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

4

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

5

To hold the InnoTube in the right position, use the applicator clip by fixing it on the patients shirt.

6

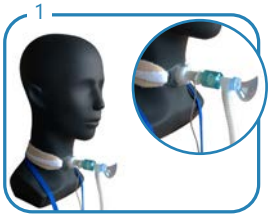
Check, if the applicator fits properly.

NOTE

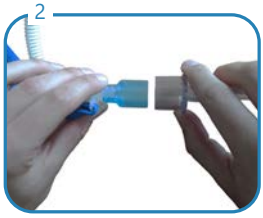
- *The use of the self-adhesive pads is optional. They can be removed if desired.*

2.2.6 Tracheal Application

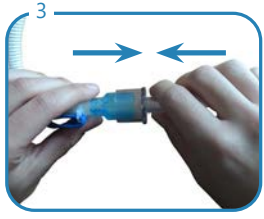
Turn on the TNI softFlow device before attaching an applicator. Attach the applicator to the patient's tracheostomy interface according to the following sequence of images.



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

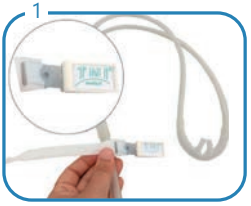
- *The applicator tube connector has an inner diameter of 22mm. Only use suitable interfaces when selecting the patient interface compliant with ISO 5367 or ISO 80601-2-74.*
- *This accessory can only be used with the system operated in softFlow mode.*
- *Humidification system output during tracheal application is >33 mg / l.*

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.*
- *During tracheal application the humidity is automatically set to 37°C DP and cannot be changed as long as the tracheal applicator is in use.*
- *Recommended ambient temperature during tracheal application is 20° - 28°C which differs from the recommended range of 18° - 28°C for nasal application.*

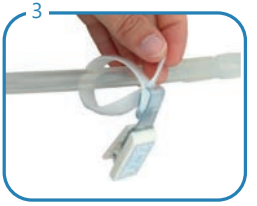
2.2.7 Applicator-Accessories

Applicator-Clip



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

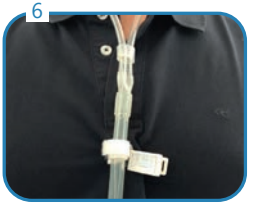
Place the band around the applicator hose.



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



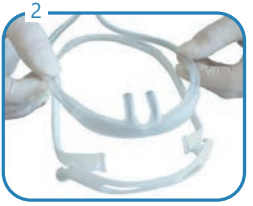
Open the fastening clip and attach it to the desired position on your clothing.

NOTE

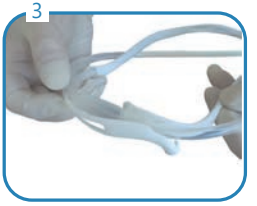
- *This accessory can be used with the system operated in softFlow mode and in junior mode alike.*

Applicator Headgear

Pull the stretch band over the applicator bracket



Place the applicator bracket and nasal cannula in the correct position on top of each other



Ensure that the prongs of nasal cannula are located in the middle of the applicator bracket.

Push the nasal cannula correctly into the applicator bracket

Guide the completed applicator bracket towards the face.

Carefully guide the prongs of the nasal cannula in the nose and pull the stretch band over the head.

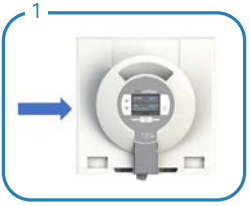
NOTE

- *This accessory can only be used with the system operated in softFlow mode.*

2.3 Oxygen supply

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

1



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

2

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

3

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

NOTE

- *Please follow the instructions for use of the external oxygen source closely. If you have any questions concerning the use of the oxygen source, please contact your oxygen vendor or our hotline (see chapter Service/User assistance information).*
- *Incorrect connection of the oxygen source may lead to inefficient oxygen therapy. Ensure a stable connection.*

WARNING

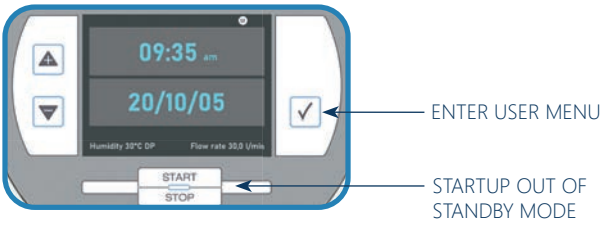
- *Secure the oxygen source against falling over, to prevent damage and injury.*
- *Smoking and open fire are strictly forbidden when using supplemental oxygen due to the risk of explosion.*
- *Do not operate the device in closed rooms producing or using anesthetics and/or nitrous oxide.*
- *Keep the oxygen valves free of oil, grease or any flammable liquids.*

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.

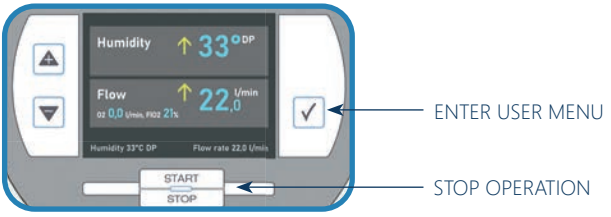
2.4.1 Modi and operating keys

Standby mode



Operation mode

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



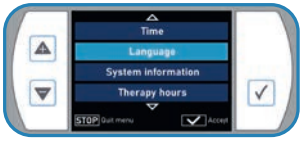
User menu

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.

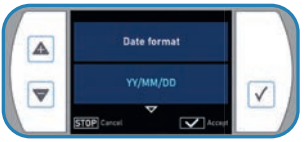
User menu: Example:

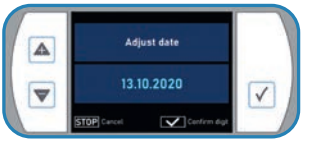


Date

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:

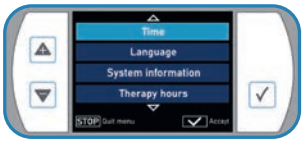


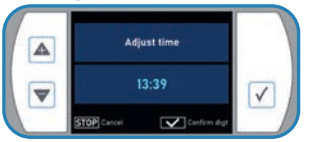


Time

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

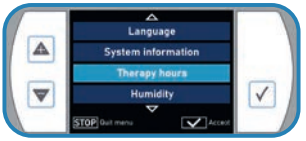
Enter the user menu and select the tab „Alarm volume". Select the desired alarm volume and confirm the selection.

User menu: Example:

2.4.4 Therapy hours

The TNI softFlow system continuously records the patient's therapy hours. Enter the user menu and select "Therapy hours" to display the therapy hours.

User menu:



Display of therapy hours:

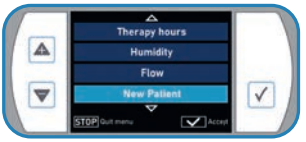
NOTE

- *All data on operation and dysfunction are recorded and can be displayed by TNI medical AG technical staff or an authorized TNI medical AG representative.*
- *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.*

2.4.5 New patient

Before the TNI 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:

NOTE

- *This menu item is hidden in homecare mode.*

3 Operation

In order to achieve the best possible therapeutic success with TNI 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!*
- *Ensure that the interior of TNI softFlow device is dry!*
- *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 TNI 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. Each mode allows the use of a specific set of accessories. For a list of corresponding accessories see chapter “system components”.

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 

3.1.1 Switching between softFlow Mode and and junior Mode

Enter the user menu and select the tab “Switch mode”.

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

WARNING

- *Operation modes must be set by qualified health professionals only. For this reason this menu item is hidden in homecare mode.*

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 %).

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

- 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.

User menu: Setting: Nominal value in the footer:

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 hidden in homecare mode.*

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.

User menu: Setting: Nominal value in the footer:

- Alternatively, the nominal value can be changed directly in the operation mode by pressing the arrow keys.

WARNING

- *During tracheal application the humidity is automatically set to 37°C DP and cannot be changed as long as the tracheal applicator is in use.*

NOTE

- *For optimal humidification of the patient's mucosa, humidity of 34-37°C DP during therapy is recommended.*
- *If the patient feels dryness in the nose, check if the humidification chamber contains enough water and/or increase the humidity value.*
- *The system requires a setup-time of about 10 min to adjust a newly set nominal value of humidity.*
- *If water condenses excessively in the applicator / heating tube, the chosen humidity value might be too high for the present ambient conditions. Reduce the dew point value.*
- *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°TP, if using flow rates less than 5 l/min.*
- *Humidification system output is >12 mg / l for any setting during nasal application.*
- *Humidification system output is >33 mg / l for any setting during tracheal application.*

3.2.3 Oxygen

If required, oxygen can be additionally mixed into the air flow by connecting an external oxygen source to the TNI softFlow device (see chapter Oxygen supply).

- Switch on the TNI softFlow device first.
- Wait until the target flow is reached.
- Start the oxygen supply by opening the valve of the external oxygen source.
- 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.

Display of the oxygen flow rate and the FiO_2

NOTE

- *The admixture of oxygen is limited to 20 liter per minute using an applicator tracheal interface*
- *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.*
- *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.*
- *Do not place a connected applicator on the TNI softFlow device or any other electrically driven device when the device is running.*
- *Keep a min. distance of 1 m from other electrical devices when using oxygen.*

3.3 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 TNI medical AG representative.*
- *If an error is displayed, which is not listed in the following table, please contact your TNI medical AG representative.*

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.
102	II	Sensor defective	O_2 flow sensor is defective.*
103	II	Sensor defective	Air flow sensor is defective.*
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.
153	I	Flowrate too high	Measured flow is higher than the set flow. Please check air flow.
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 chapter Oxygen.
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 product specifications.
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 product specifications 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.*
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.*
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 flowrate or use a larger applicator.
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 chapter system components.
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 TNI medical AG representative.
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 TNI medical AG representative for further help.
757	I	Low SD card memory	Please insert a new SD card.
851	I	Change dust filter	Change the dust filter.

** Turn off the main switch of the device. Wait at least 30 sec. before restarting the device. If the error persists, please contact your TNI medical AG representative.*

4 Reprocessing

The following instructions define the procedures for cleaning and disinfecting the TNI 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.*
- *The manufacturer's instructions for the cleaning/disinfecting detergent must be observed.*
- *Switch off the device and disconnect it from the power supply before processing.*
- *Check all components for visible damage after cleaning/disinfection.*
- *Assemble the TNI softFlow components according to these instructions for use and check for proper functioning.*
- *Automatic cleaning procedures must not be performed.*
- *Sterilization procedures must not be performed.*
- *Excessive use of disinfectants may damage the housing.*

WARNING

- *Liquids may not enter the device since they may damage the electronics assembly!*
- *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

- 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 TNI softFlow and the patient interface and allow the condensate to drain off.

4.1.2 Manual disinfection

- After cleaning, some TNI softFlow components (see chapter Cleaning and reprocessing cycles) 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 chapter Detergents and disinfectants).
- 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 Automatic disinfection

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

- has been used in the clinic application without or with a defective Clear-Guard 3 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 TNI medical AG or another authorized company / institute. Three Keredusy procedures may be performed at maximum. If you have any questions, please contact TNI medical AG.*

4.2 Detergents and disinfectants

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

Product name	Producer	Description
TNI 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%
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 *	Hydrox	USP Isopropyl Alcohol 70%
Chlorhexidine *	HIbiclens	Chlorhexidine 4.0%
Applicator Headgear softFlow		
mikrozid® AF liquid	Schülke & Mayr GmbH	Ready-to-use alcoholic disinfectant
WILAsil Reinigungskonzentrat	WILAmed GmbH	Ready-to-use alcoholic disinfectant
Sagrotan Allzweckreiniger	Sagrotan	Ready-to-use alcoholic disinfection for spraying or wiping
Isopropanol 70%	-	Is used pure, without dilution

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. **also suitable to disinfect Humidifier Rack Clinic*

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).*
- *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 chapter Manual cleaning).

Component	Cleaning cycle	Cleaning method	Replacement cycle	Usage
TNI softFlow system	daily	manual cleaning wipe disinfection	-	reusable
Accessory softFlow mode				
Applicator Clinic series	daily	manual cleaning wipe disinfection	360 hours	single use
Applicator Homecare series	daily	manual cleaning wipe disinfection	720 hours	single use
Accessory junior mode				
ApplicatorModule junior	daily	manual cleaning wipe disinfection	-	reusable
Temperature Measuring Element	daily	manual cleaning wipe disinfection	-	reusable
NeoFlow nHFOT Cannula	daily	wipe disinfection	7 days	single use
InnoTube softFlow	daily	wipe disinfection	30 days	single use
Clinic system				
Humidifier Rack Clinic	on patient change	manual cleaning wipe disinfection	-	reusable
Humidification Chamber Auto-Fill	-	-	weekly	single use
Air Bridge Humidifier Clinic	-	-	weekly	single use
Clear-Guard 3 Breathing Filter, Angled	-	-	daily	single use
Homecare system				
Water Tank, Humidifier Homecare	daily	manual cleaning	once a year	single use
Cyclone, Humidifier Homecare	daily	manual cleaning	once a year	single use
Lid, Humidifier Homecare	daily	manual cleaning	once a year	single use
Miscellaneous				
Dust Filter	weekly	rinsing	every 3 months	reusable
Water in Water Tank	-	-	daily	-
Applicator Headgear	weekly	manual cleaning wipe disinfection	once a year	single use
Stretchband Applicator Headgear	weekly	manual cleaning	-	-
Applicator Clip				single use

4.3.1 Dust filter change

- Weekly, rinse the dust filter under running water, wring out and let it dry completely before putting it back in the holder.
- Change the dust filter every 3 months or when error "851 – Change dust filter" is displayed (whichever is earliest).

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

Replace the dust filter by 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 against the upper edge.

NOTE

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

5.1 Product specifications

Performance data softFlow mode

Flow rate	10 to 60 l/min (adjustable in 0.5 l/min steps)
Admixture of oxygen	0 to 60 l/min

Performance data junior mode

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 - < 10 l/min: ± 1 l/min 10 - < 25 l/min: ± 2 l/min 25 - < 50 l/min: ± 4 l/min > 50 l/min: ± 5 l/min
Oxygen Flow	0 - < 10 l/min: ± 0.5 l/min 10 - < 25 l/min: ± 1 l/min 25 - < 50 l/min: ± 2 l/min > 50 l/min: ± 2.5 l/min
FiO_2	21 – 100%: ±10%

NOTE:

- *Humidification system output is > 12 mg / l for any setting during nasal application.*
- *Humidification system output is > 33 mg / l for any setting during tracheal application.*

Device parameters

Technical data	
Medical product class (93/42/EWG)	IIa
Safety class, electrically	II
Alarm signal sound pressure	> 45 dB(A)
Safety type	IP21 (Protected from touch by fingers and objects >12 mm and vertically 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, without water)	5.6 kg
Humidification chamber auto-fill	max. 144 ml
Sterile water bag or bottle	< 1000 ml
Water tank humidifier homecare	max. 650 ml
Applicators softFlow mode	
Changing cycle applicator clinic series Changing cycle applicator homecare series	≤ 360 therapy hours; single-patient use ≤ 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 Changing cycle InnoTube softFlow	7 days; single use 30 days; single use
Safety level (applied part)	BF
Tube length	160 cm
Max. temperature of air leaving device	43 °C

Humidifier	
Typical humidity nasal application	30-37°C DP (70-90% RH)
Typical humidity tracheal application	37°C DP (70-90% RH)
Humidification system output	> 12 mg/l at 2 - 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	10-30°C
Recommended ambient temperature	18°-28°C (nasal application) 20°-28°C (tracheal application)
Ambient humidity	15-93% RH
Altitude	0 – 3000 m MSL
Environmental conditions concerning storage and transport	
Temperature	-29°C to +70°C
Humidity	< 93% RH
Ambient air pressure	700-1060 hPa
Electromagnetic compatibility	EN 60601-1-2: 2007
Filter class of dust filter	G4 (EN 779: 2003)
Expected operating time (expected service life) TNI *soft* **Flow** *50*	3-6 years; depends on daily usage
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

WARNING

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

NOTE

- *All values regarding gas volume, flowrate and leakage are expressed at ATPS.*

5.2 System information

Clinic mode

The TNI softFlow 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 TNI softFlow is used at home, the health care 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 TNI medical AG representative if you intend to deactivate the clinic menu.*

NOTE

- *The "Service menu" can be accessed by a TNI medical AG technical staff or representative only.*

Homecare mode

If the TNI softFlow is used at home, its configuration needs to be changed to homecare mode to prevent accidental access to therapy parameters. To unlock such a device again (once or permanently) and to access all parameters please contact your TNI medical AG representative.

5.3 Ambient conditions

See chapter Product specifications: Environmental conditions

Ambient temperature:	10 - 30°C
Ambient humidity:	15 - 93% RH
Altitude:	0 – 3000 m MSL

WARNING

- *Operating the device at high altitudes may have negative impact on therapy quality.*

Storage and transport conditions

See chapter Product specifications: Environmental conditions concerning storage and transport.

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

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.

5.4 Data storage

All data on operation and dysfunction of the TNI softFlow system are recorded during therapy hours and can be accessed by TNI medical AG 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.

5.5 Symbols

	Manufacturer	O	Power switch: OFF
	Production date	I	Power switch: ON
	Applied part of type BF		Ambient temperature
IP 21	IP-protection class		Follow the instructions for use!
LOT	Batch code	max. 60 l/min O2 max. 200 mbar	Max. flow Max. pressure
REF	Item/article number		Caution: hot surface
SN	Serial number	CE 0297	CE sign
	Disposal		MR unsafe
	Prescription only		Use-by date
	Warning: Do not remove caps		

5.6 Disposal

You may dispose of the following parts with the domestic waste: applicators, humidifier rack clinic, air bridge humidifier clinic, Clear-Guard 3 breathing filter, dust filter, humidification chamber auto-fill. The TNI softFlow unit contains electronic components. Do not discard with regular waste. Please contact your local TNI medical AG representative regarding the unit's disposal.

6 Warranty

LIMITED WARRANTY: THE TNI 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:

- ASSEMBLY, EXTENSIONS, RESETTING, CHANGES OR REPAIRS BY UNAUTHORIZED PERSONS
- NON-COMPLIANCE WITH THE INSTRUCTION FOR USE
- DAMAGE CAUSED BY OPERATING ERRORS
- IMPROPER USE OR HANDLING
- USE OF NON-ORIGINAL SPARE PARTS
- FORCE MAJEURE (E.G. LIGHTNING ETC.)
- TRANSPORT DAMAGES CAUSED BY IMPROPER PACKAGING WHEN RETURNING
- OPENING OF THE HOUSING BY UNAUTHORIZED PERSONS

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 TNI MEDICAL AG REPRESENTATIVE. IF THE TNI 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 TNI softFlow system during operation. Please contact your TNI medical AG representative if any unexpected event, operation or malfunction occurs. We recommend the TNI softFlow system be checked every 2 years after commissioning by a TNI medical AG representative to maintain the system's effectiveness and to ensure the user's safety. The user menu point "Service menu" can be accessed by TNI medical technical staff/representative only.

NOTE

- *Maintenance of the TNI softFlow system lies within the responsibility of the user / clinic.*
- *Repair / service may only be carried out by a service technician authorized by TNI medical AG.*
- *The device housing may only be opened by authorized personnel. This also includes replacing fuses.*

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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 STM-32F1xxx V3.6.1 • STM32 USB Library v4.1.0 • STM32 DFU library V3.2.1

Appendix: Electromagnetic compatibility (EMC)

NOTE

- *The TNI 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.*
- *Portable and mobile RF (radiofrequency) communication equipment can affect proper functioning of the TNI softFlow system.*
- *The TNI 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.*
- *The TNI softFlow system may be interfered with by other electrical devices even if the other devices comply with applicable emissions requirements.*
- *The additional use of unauthorized accessories, cables or converters can increase the emissions and reduce the electromagnetic immunity of the TNI softFlow system.*
- *In accordance with the applicable standard the TNI softFlow System has the essential performance warmed and humidified airflow with a humidification output > 12 mg/l during nasal application and > 33 mg/l during tracheal application.*

Guidance and manufacturer's declaration - electromagnetic emissions		
The TNI softFlow system is intended for use in the electromagnetic environment specified below. The user must ensure that these requirements are met.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
Conducted emissions CISPR 11	Group 1 / Class B	The TNI 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.
RF emissions CISPR 11	Group 1 / Class B	The TNI 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 TNI 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 made of 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 610004-4	± 2 kV for power supply 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 comply with 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 comply with 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.
Rated 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 a.c. mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	6 V for ISM and RF communications between 150 kHz and 80 MHz 3 V between 150 kHz and 80 MHz	6 V for ISM and RF communications between 150 kHz and 80 MHz, 3 V between 150 kHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to the TNI 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.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 TNI softFlow system, its correct operation has to be regularly verified. If malfunction is observed, additional measures may be necessary such as relocating the TNI softFlow system.

Over the frequency range of 150 kHz to 80 MHz, field strength should be less than 6 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the TNI softFlow system

The TNI softFlow system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of 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 testlevel** 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.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The Unique Non-Invasive TNI Ventilation

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Instructions for Use TNI softFlow
For patent information see http://www.tni-medical.com/ip