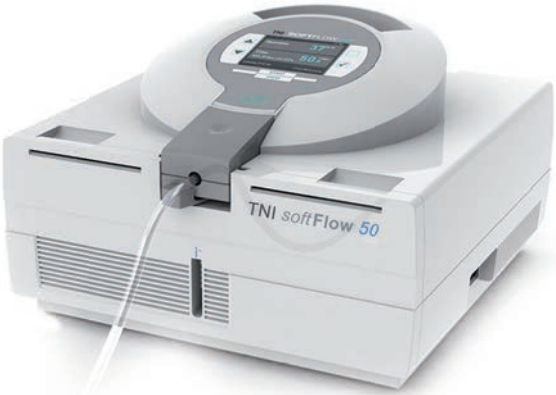
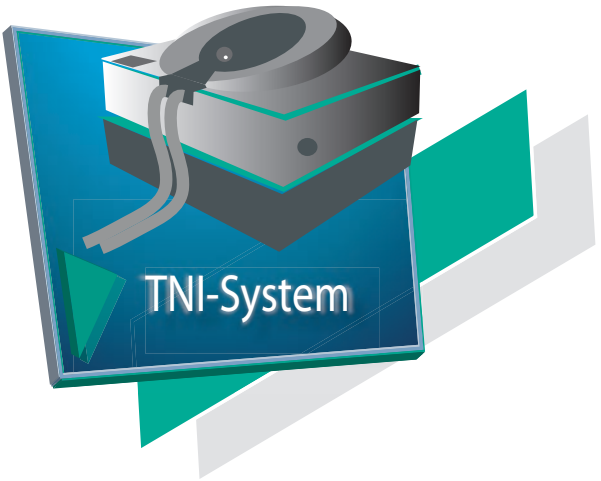
TNI softFlow® 50 Clinic System

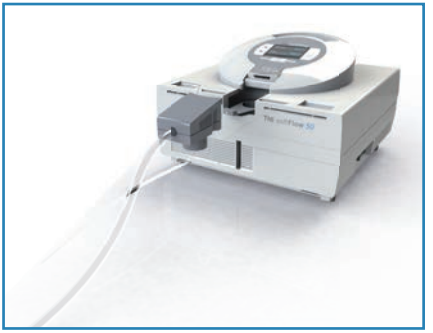
Instructions for Use

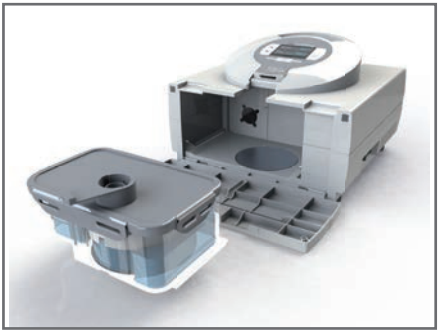


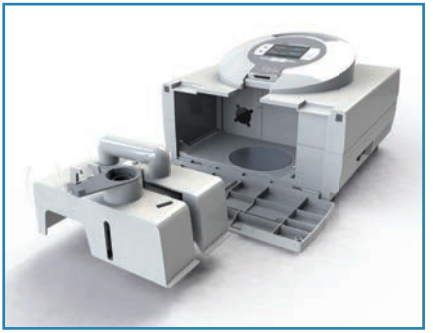

TNI-System


TNI softFlow


TNI softFlow 5







First notes

First notes

- These instructions for use are intended for healthcare professionals.
- These instructions for use apply to TNI softFlow systems manufactured in 2015 or later.
- 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 moistening the therapy air.

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.

1.1 Intended use and therapeutic benefit

TNI *soft*Flow *50* is a breathing support for spontaneously breathing patients who would benefit from a supply of warmed and moistened respiratory gases with high flow.

The TNI *soft*Flow *50* is suitable for adults, adolescents and children, that have a therapeutically indicated flow of min. 10l/min. The system can be used in hospitals, long-term care facilities, as well as in homecare treatment. The TNI soft Flow system can be used in a long-term as well as in a short-term-therapy. The flow rate ranges from 10 to 50l/min.

TNI *soft*Flow *50* is not intended for life-sustaining measures.

TNI *soft*Flow *50* can be connected to an open tracheostomy interface using the tracheal interface applicator in patients with an existing upper respiratory tract bypass.

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 3.1.2 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.
- 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 4. Reprocessing.
- Check the connection between the applicator tube connector and the patient interface for strong hold.

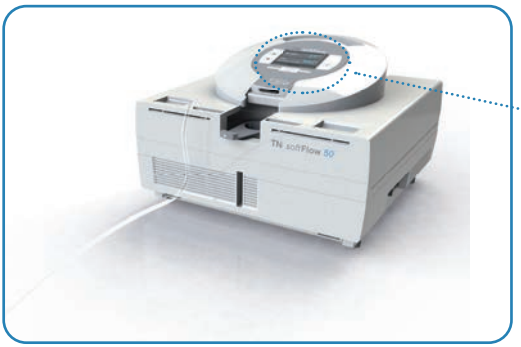
Warnings

- 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 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 5.1 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!
- 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!

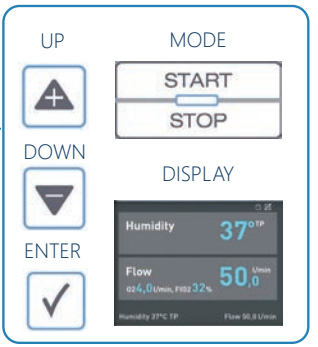
Contraindications

- 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 in connection with an open tracheal interface.
- Do not use the applicator headgear if you have enormous pressure marks from it or in the event of material incompatibility of the stretch band or applicator headgear.

1.3 System components



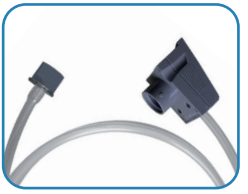
TNI *soft*Flow *50*



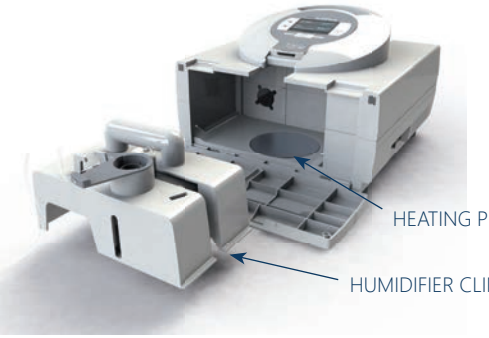
CONTROL PANELS

APPLICATOR PLUG

PATIENT INTERFACE



TRACHEAL-APPLICATOR



HUMIDIFICATION CHAMBER
AUTO-FILL

AIR BRIDGE

CLEAR GUARD 3
BREATHING FILTER

POWER CORD and
CONNECTOR

DUST FILTER

PROTECTION CAP
OXYGEN INLET

Scope of delivery

Components	Art. No
TNI *soft*Flow *50*	40610021
Humidifier Rack Clinic	40641107
Humidifier Clinic Hygiene Set	40620040
Power Cord, 1,8m, Euro-Plug	40641150
Dust Filter Reserves, 5 Pieces	40620060
Protection Cap for Oxygen Inlet, 5 Pieces	40620061
Instructions for Use, softFlow 50 Clinic EN	30221041

Accessories

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	50 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	50 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*

Individual Components	Art. No
Clinic	
Air Bridge Humidifier Clinic	40641108
Humidification Chamber Auto Fill	40641110
Clear-Guard 3 Breathing Filter	40641111
Homecare	
Water Tank Humidifier Homecare	40641104
Lid, Humidifier Homceare	40641105
Cyclone, Humidifier Homecare	40641106

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

2 Setup

- 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 an adaptation to the ambient conditions (room temperature, e.g.) before startup. This can take 2-4 hours
- 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

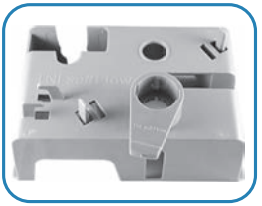
- *Ensure that the interior of the TNI softFlow unit is dry before connecting it to the power supply.*

2.1 Humidifier

The TNI softFlow system can be operated with two different humidifier types. The TNI softFlow system is used with the Humidifier Clinic for patients in the clinic or in a care facility, with the Humidifier Homecare for patients at home. Accordingly, the respective humidifier type must be selected in the user menu, tab "Humidifier type".

2.1.1 Components of Humidifier Clinic

The Humidifier Clinic consists fully equipped of four parts.



Humidifier Rack Clinic

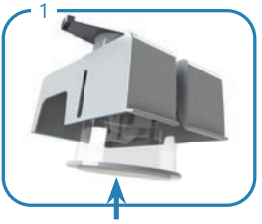
Clear Guard 3 Bacterial Filter

Humidification Chamber Auto-Fill

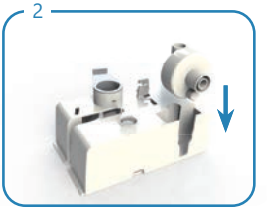
Air Bridge TNI softFlow

2.1.2 Assembly of Humidifier Clinic

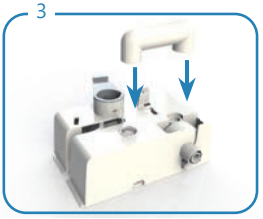
Assemble the humidifier according to following descriptive picture sequence:



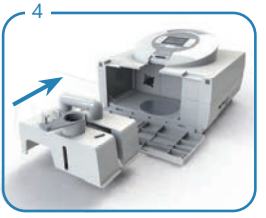
Slide the Humidification Chamber Auto-Fill from below into the dedicated socket of the rack.



Push the Bacterial 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

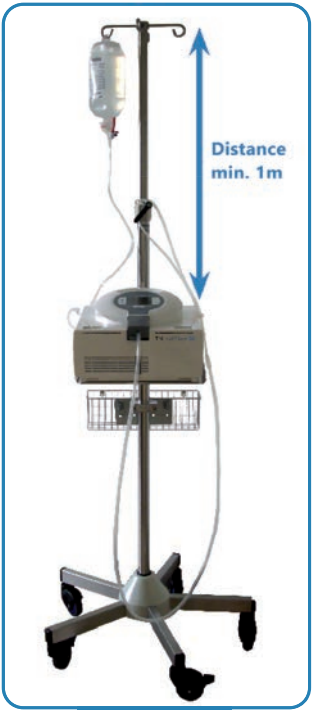
- When installing or changing the bag with sterile water the device has to be switched off.
- Place the water bag so that the opening is 1 m above the upper edge of the device (see figure below as example).
- Push the spike of the chamber hose into the dedicated opening at the bottom of the water bag.
- 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 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

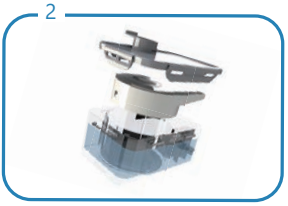
Cyclone Element Humidifier Homecare

Water Chamber Humidifier Homecare

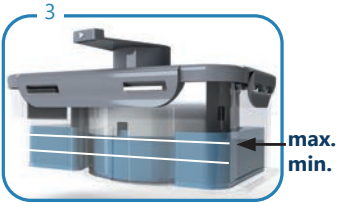
2.1.5 Assembly of Humidifier Homecare

Assemble the humidifier according to following descriptive picture sequence:

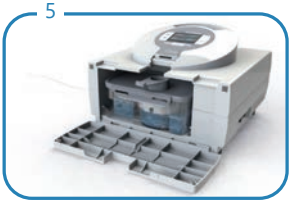
Fill the water chamber with boiled tap water (max. lukewarm), non-carbonated drinking water or sterile water, up to the "max." mark.



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



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



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

WARNING

- *The Humidifier Homecare must not be used if it has run dry and the "Refill water" alarm has been triggered!*
- *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.*
- *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.*

WARNING

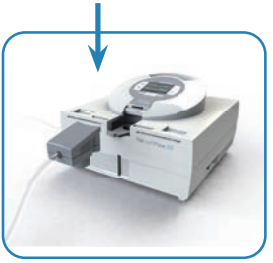
To avoid the risk of burns:

- *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.*

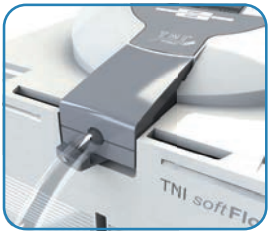
To avoid the risk of electric shocks:

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

2.2.1 Applicator installation



Choose appropriate applicator type.



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

2.2.2 Uninstalling the applicator

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.

2.2.3 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.

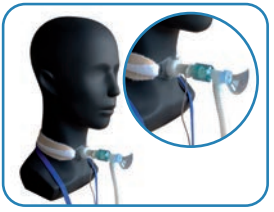
Make sure that the slightly curved prongs point towards the face.

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

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

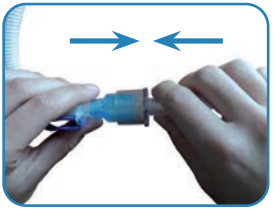
2.2.4 Tracheal Application

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.



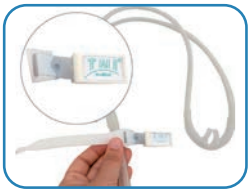
Check the connection between the applicator and patient interface for strong hold.

NOTE

- *The applicator tube connector has an inner diameter of 22mm. Only use suitable interfaces when selecting the patient interface!*

2.2.5 Applicator-Accessories

Applicator-Clip



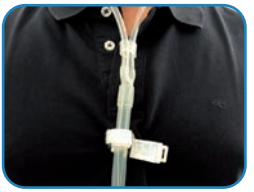
Place the applicator clip at the desired position on the applicator tube with the TNI medical label facing upwards.

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.

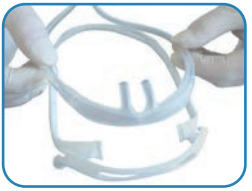
Wind the band completely.



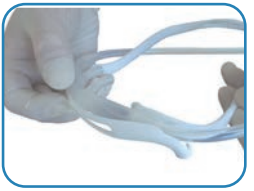
Open the fastening clip and attach it to the desired position on your clothing.

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.

Insert the nasal cannula through the loops on both sides.

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.

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.

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 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 7. 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.

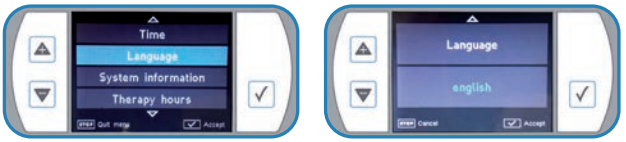
User menu

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.

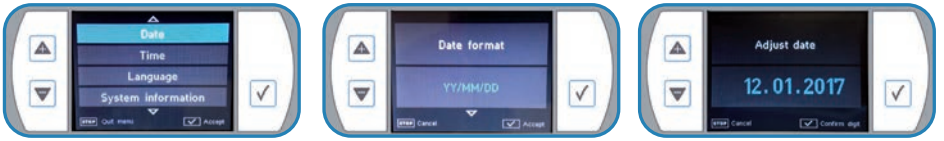
User menu: Example:



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.

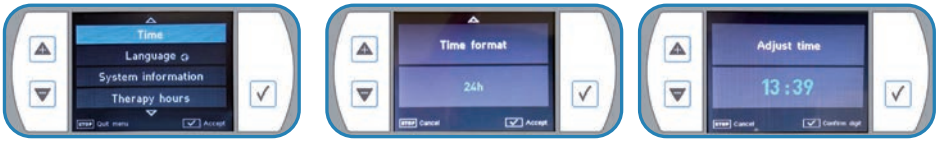
User menu: Example: Setting:



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.

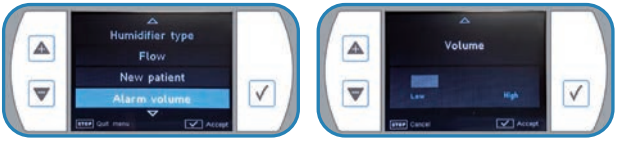
User menu: Example: Setting:



2.4.3 Alarm volume

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

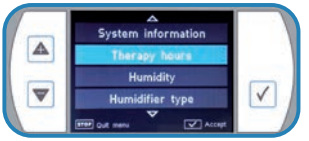
User menu: Example:



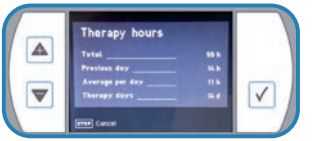
2.4.4 Therapy hours

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

User menu:



Display of therapy hours:



NOTE

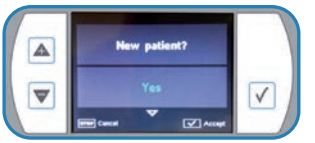
- *All data on operation and dysfunction are recorded and can be read out by TNI medical AG technical staff or an authorized TNI medical AG representative.*
- *All data that are recorded internally or on SD-Cards are for information purposes only and cannot be used as a basis for an evaluation of the 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:

3 Operation

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

NOTE

- *Before commissioning, ensure that the humidification chamber is filled with 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 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.

3.1.1 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.*
- *Due to technical reasons, the total flow rate has to be at least 3 l/min higher than the oxygen flow rate.*

WARNING

- *Flow rates must be set by qualified health professionals only.*

3.1.2 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.

NOTE

- *For optimal humidification of the patient's mucosa, humidity of 34-37°C DP during therapy is recommended.*
- *For optimum humidification of the respiratory tract during tracheal therapy, humidity of 37° TP 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.*

3.1.3 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 2.3 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 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

- *Due to technical reasons, the total flow rate has to be at least 3 l/min higher than the oxygen flow rate.*

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.*

3.2 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	1 audible signal, cyclically repeated	Please follow the instructions below. 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.
medium	II	3 audible signals, cyclically repeated	The alarm cannot be switched off. The device can no longer operate. Restart the device. If the error persists, please contact your TNI medical AG representative.

Error codes

Error code	Severity code	Notification	Interpretation
101	II	Pressure too high	Internal pressure is too high (>90 mbar). 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 3.1.3 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.
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.*
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 1.4
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. If error persists, contact your TNI medical AG representative.
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.

** If the fault persists, 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 some 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 4.3 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 4.2 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 bacterial 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 *soft***Flow** *50*		
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
Applicator Headgear softFlow 50		
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.

NOTE

- *The cleaning detergent must be: pH-neutral, non-abrasive, non-toxic and non-corrosive. Do not use any detergents incompatible with polycarbonate plastic (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 4.1.1 Manual cleaning).

Component	Cleaning cycle	Cleaning method	Replacement cycle	Usage
TNI *soft*Flow *50*	daily	manual cleaning wipe disinfection	-	reusable
Clinic system				
Applicators clinic series	daily	manual cleaning wipe disinfection	360 hours	single use
Humidifier rack clinic	daily	wipe disinfection	-	reusable
Humidification chamber auto-fill		-	weekly	single use
Air Bridge Humidifier Clinic	daily	wipe disinfection	weekly	single use
Clear-Guard 3 Breathing Filter	-	-	daily	single use
Homecare system				
Applicators Homecare series	daily	manual cleaning wipe disinfection	720 hours	single use
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 filterr	weekly	rinsing	every 3 months	single use
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

- Wash the dust filter weekly under running water, wring it out and allow it to dry completely before you insert the dust filter back into the holder.
- Every 3 months, change the dust filter.

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.

5 Technical information

5.1 Product specifications

Performance data

Flow rate	10 to 50 l/min (adjustable in 0.5 l/min steps)
Admixture of oxygen	0-20 l/min
Humidity dew point	30-37°C DP (adjustable in 1°C DP steps)
Event memory	Data storage of the last 12 therapy months

Device parameters

Technical data	
Medical product class (93/42/EWG)	IIa
Safety class, electrically	II
Sound level	< 30 dB(A)
Alarm signal sound pressure	> 60 dB(A)
Safety type	IP21
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
Applicator	
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

Humidifier	
Typical humidity nasal application Typical humidity tracheal application	30-37°C DP (70-90% RH) 37°C DP (70-90% RH)
Humidification system output	> 10 mg/l at 10-50 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
Ambient humidity	15-93% RH
Ambient air pressure	700-1060 hPa
Environmental conditions concerning storage and transport	
Temperature	-25 to +70 °C
Humidity	< 93% RH
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

5.2 System information

Clinic mode

The TNI 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 system information. System information such as firmware version, serial number, etc. is accessible via the user menu point "System information". The "Service menu" can be accessed by a TNI medical AG technical staff or representative only.

WARNING

- *After setting the therapy parameters, the health care personnel must deactivate the clinic menu with a PIN code so that the patient cannot change the settings during operation.*

Homecare mode

The configuration of a TNI softFlow device needs to be changed from clinic to homecare mode if a patient continues therapy at home. Likewise, the humidifier type clinic must be changed to homecare beforehand. Please contact your representative of TNI medical AG.

5.3 Ambient conditions

See chapter 5.1 Product specifications: Environmental conditions

Ambient temperature:	10 - 30°C
Ambient humidity:	15 - 93% RH
Ambient air pressure:	700 – 1060 hPa

Storage and transport conditions

See chapter 5.1 Product specifications: Environmental conditions concerning storage and transport.

The device should be stored and transported at temperatures between -25 to +70°C, ≤93% RH, 7001060 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 read out 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		Power switch: OFF
	Production date		Power switch: ON
	Applied part of type BF		Ambient temperature
IP 21	IP-protection class		Follow the operating instructions!
	Batch code		Max. pressure Max. flow
	Item/article number		Caution: electrostatically sensitive
	Serial number		Caution: hot surface
	Disposal		CE sign

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 INSTRUCTIONS 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 *soft***Flow** *50 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.*

TNI medical AG
Hofmannstr. 8
D-97084 Wuerzburg
Phone: +49 931 20 79 29 02
Fax: +49 931 20 79 29 18
Email: info@tni-medical.de

The software on the device uses FreeRTOS and the CMSIS library, for Licence information, see https//: freertos.org and http://arm-software.github.io/CMSIS_5/General/html/LICENSE.txt

Appendix: Electromagnetic compatibility (EMC)

NOTE

- *The* TNI *softFlow 50 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 50 has no essential performance.*

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 50* 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 50* is suitable for use in all institutions, including hospitals and long-term care facilities.
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	± 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 150 kHz to 80 MHz	6 V for ISM between 150 kHz and 80 MHz, 3 V 150 kHz to 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 *soft*Flow *50* 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 *soft*Flow *50* 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 bis 390	TETRA 400	Pulsmodulation 18 Hz	1,8	0,3	27
450	430 bis 470	GMRS 460, FRS 460	FM ± 5 kHz Hub 1 kHz Sinus	2	0,3	28
710 745 780	704 bis 787	LTE Band 13, 17	Pulsmodulation 217 Hz	0,2	0,3	9
810 870 930	800 bis 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulsmodulation 18 Hz	2	0,3	28
1720 1845 1970	1700 bis 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulsmodulation 217 Hz	2	0,3	28
2450	2400 bis 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulsmodulation 217 Hz	2	0,3	28
5240 5500 5785	5100 bis 5800	WLAN 802.11 a/n	Pulsmodulation 217 Hz	0,2	0,3	9

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

CE 0297

WEEE-No: DE 92934592

TNI medical

TNI medical AG • Hofmannstraße 8 • 97084 Würzburg
+49 931 20 79 29-02 • +49 931 20 79 29-18
info@tni-medical.de • www.tni-medical.de

Art. No.: 30221041 Rev 2.4, 2020-04-16
Instructions for Use **TNI *soft*Flow *50*** clinic system
For patent information see http://www.tni-medical.com/ip