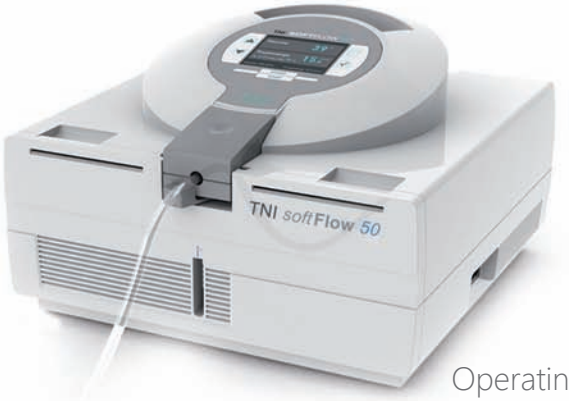
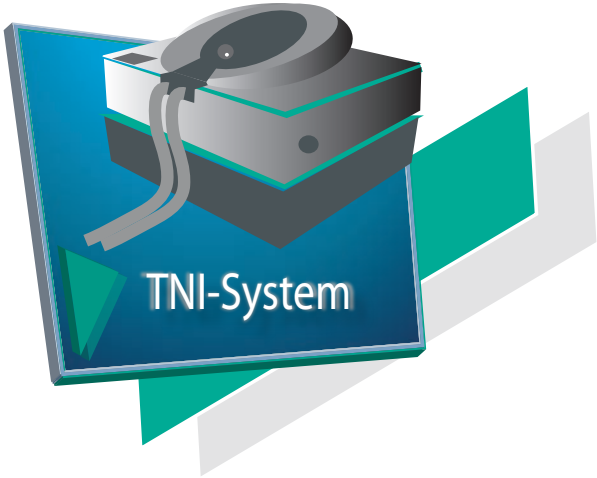
TNI *soft*Flow 50

NIV with TNI

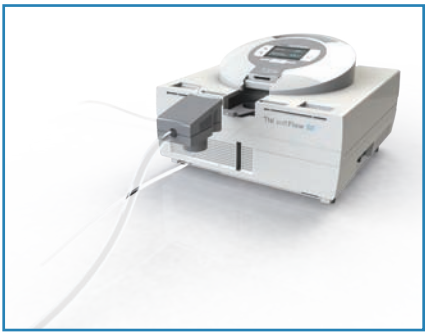


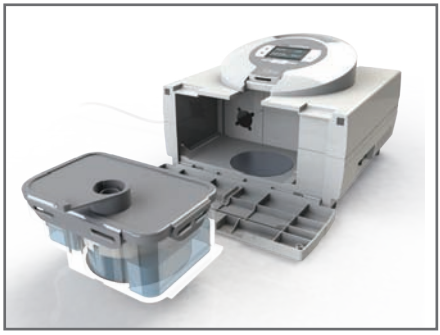
Operating instruction

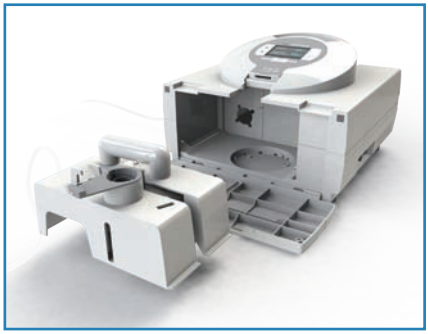

TNI-System


TNI softFlow
37
50


TNI softFlow 5







First Steps

- These operating instructions apply to the TNI *soft* **Flow** *50*, manufactured 2015 or later.
- Please read these instructions and all warnings carefully. Otherwise, injuries could occur. Store them to be usable for subsequent reference.
- Before using TNI *soft* **Flow** *50* for the first time, the device must be configured as instructed in TNI *soft* **Flow** *50* manual.
- The TNI *soft* **Flow** *50* has to be cleaned and disinfected after use and change of patient. Please note operating instructions, chapter 1.3.7
- For additional information and support, please contact your local TNI medical AG customer ser-vice.

Content

TABLES

1) DESCRIPTION of TNI *soft* Flow *50*

1.1) METHOD

TNI soft Flow is a system managing therapy with nasal insufflation which will be used for the treatment of sleep-related breathing disorders in clinical intensive care and stationary settings as well as in homecare settings.

A constant, humidified and warm flow, which may also combined with oxygen, is applied to the nose via applicator (thin nasal cannula which act as an interface to the patient.

Therapy with nasal insufflation basically improves ventilation.

1.2) INTENDED USE

Therapy with nasal insufflation (TNI) is intended for additional treatment on patients with partial or global respiratory failure (insufficiency), such as COPD (chronic obstructive pulmonary disorder, ILD (interstitial lung disease) or sleep apnoea to relieve also breathing (respiratory) musculature and to improve ventilation as well as mucociliary clearance.

Therapy with nasal insufflation may only be commenced with a medical prescription.

Therapy with nasal insufflation is not intended for life-support purposes.

This therapy is done on an individual basis according to the medical diagnosis. It can be applied on a daily basis (e.g. under sleeping period) or sporadically if needed.

TNI soft Flow may be used on adults and children. Please note that different, special applicators are available for adults and children.

The patient should be in good condition if therapy is realized at home and the device is operated by the patient. Otherwise, the operation of the device has to be performed by a qualified third person (e.g. nurse). This has to be considered especially if the device is used by infants or toddlers. For patients which are not compliant to the device, please refer to 1.3)

The TNI can be placed on an even horizontal surface inhouse and is used as a stationary device. The location can be changed as needed but during transit no operation is allowed.

In clinical settings the respective components have to be exchanged after use and change of patient. Please note point 5 (hygiene).

In homecare settings the respective components have to be cleaned periodically.

1.3) SAFETY NOTES

- Please read the following instructions carefully as they contain important information on the safe and responsible handling of the TNI *soft* Flow *50*.
- An initial training has to be performed before the device can be used
- Following instructions are the responsibility of the user of this unit.
- Any non-observance will cause danger!
- The device can be used in a sitting or lying position. It is not allowed to move around with a running device. If an infant or a toddler uses the device, a qualified third person has to ensure proper use
- No modification of this equipment is allowed
- Although a selftest of the device is performed during start-up, it is recommended to remove and insert the applicator after start-up to verify the correct alarm functionality.
- Do not use the TNI *soft* Flow *50* if you show allergic reactions when in contact with silicon

1.3.1) THIS MANUAL

- Exact adherence to the following instructions is a prerequisite for the safe and intended operation of the TNI *soft* **Flow** *50* and its supplied parts. Any non-observance will endanger an effective therapy.
- With regard to the fundamental requirements of the currently valid directive for medical devices, the instructions for use describe the present state of the device, including software and supplies.

1.3.2) APPROPRIATE APPLICATION

- The TNI *soft* **Flow** *50* is not intended for life-support measures!
- A therapy may only be started on prescription.
- Only healthcare professionals may adjust the prescribed flow rate.
- The TNI soft Flow is a system designed for nasal insufflation therapy. It can be used clinically in in-patient and intensive care as well as in homecare to provide respiratory assistance to spontaneously breathing patients.
- A nasal supply of respiratory gases leads to a positive airway pressure (PAP) depending on flow rates. This has to be considered if the PAP could cause the patient to show undesirable results. The TNI *soft* **Flow** *50* is not intended for artificial life-support measures.
- The TNI *soft* **Flow** *50* is not suitable for treating acute failure of respiratory functions.
- The TNI *soft* **Flow** *50* may not be used for invasive ventilation.
- The TNI *soft* **Flow** *50* may not be used in case of complete closure of the upper airways.
- The TNI *soft* **Flow** *50* may not be used on patients whose airways are circumvented by a bypass.
- Due to humidification and a more comfortable aerial application, side effects such as an irritation of the nasal mucosa, blocked nose, and (with patients suffering from blood-clotting disorder) bleedings of the nose, are quite unlikely with the use of the TNI *soft* **Flow** *50*. If such symptoms occur, the humidity needs to be set to a higher level (see chapter 4.1.2 "*Setting Humitity*").
- When not in use, the TNI *soft* **Flow** *50* should not be left switched on for several hours.
- Do not use the device if you suffer from epileptic attacks or very agitated sleep
- Do not let children play with the hoses or the cables to eliminate the danger of strangulation and the inhalation or swallowing of small parts

1.3.3) CORRECT USE

- The unit's housing may only be opened by authorized personnel.
- Excluded from this is equipment which can be removed for usage and cleaning purposes without using tools.
- Prior to opening, the device has always to be switched off and the system has to be disconnected from the mains.
- If the TNI *soft* **Flow** *50* is not being used over a long period of time,
  - o switch off the TNI *soft* **Flow** *50*
  - o disconnect the power cord from the socket
  - o remove the applicator and
  - o make sure that there is no water in the humidification chamber nor in the water container
- Prior to switching on, the TNI *soft* **Flow** *50* always has to be checked for correct assembly.
- Check all parts for damages and defects.

- In case of any abnormality, switch off the power switch and disconnect the system from the power supply in order to prevent any damage or injuries.
- When in doubt, please contact your local TNI medical AG representative.
- During therapy, the applicator tube has to lie freely. It may not be covered by any pillows, blankets or clothes.
- The patient should be careful not to interfere or to restrict the airflow.
- If the applicator is attached and the patient is turning in the same direction around his/her body axis several times (especially during sleep), pressure marks might be caused and the blood flow might be impeded.
- The available USB-Connector is for service purposes only

1.3.4) CORRECT SETUP

- Please make sure that the TNI *soft* **Flow** *50* is set up properly and does not show any damages.
- Position the TNI *soft* **Flow** *50* correctly: It has to be easy to reach from the treatment area and the display should always be easy to read.
- Ensure an unobstructed air supply. The air supply as well as the air passage may not be impeded.
- The TNI *soft* **Flow** *50* and its accessories can be used within patient surroundings. Use only authorized accessories mentioned in the instructions for use.
- Use original accessories only (humidifier chamber, applicator - see chapter 2.2). Using third-party parts may result in function failure and health hazards. Please note that in such cases warranty and liability claim will expire.
- Prior to connecting the device to the power supply system, make sure that the TNI *soft* **Flow** *50* mains voltage (110-230 V) and mains frequency (50-50 Hz) correspond to your local characteristics. The required information is found on the device's name plate as well as in chapter 7, "Technical data".
  Connect only if all data comply!
  Use the supplied mains cable only.
- Prior to switching on, the TNI *soft* **Flow** *50* always needs to be checked for completeness, correct assembly and visible defects.
- Prior to switching on, the TNI *soft* **Flow** *50* always needs to be checked for proper condition (completeness, visible defects, etc.). For this, perform a visual inspection of all single parts and check them for damages. In case of abnormalities, the device may not be switched on. Please contact your local TNI medical AG representative.
- In case of damages, stop using the device. This particularly applies if the housing, plug connection and cables are damaged as well as if liquids got into the device. In such cases, please contact your local TNI medical AG representative immediately.
- Additional parts which need to be connected to the device's analog and digital interfaces have to comply verifiably with their corresponding EN specifications (e.g. EN 60950 for data processing devices and EN 60601 for medical electrical devices).
- Anybody connecting additional equipment to the signal input or output unit configures the system and is therefore responsible that the valid version of the system complies with the system standard EN 60601-1-1. For any queries, please contact your local TNI medical AG representative.
- The PC connection located below the carrying handle of the TNI *soft* **Flow** *50* may only be used to connect a PC.

- Only trained personnel or service technicians may use the system.
- The patient may not touch the connected PC or parts connected to the PC. The user may not touch the patient and the PC (or parts connected to the PC) at the same time.
- The sensor connection located below the carrying handle of the TNI *soft* Flow *50* may only be used to connect the "external temperature measuring element" (item no. 40641018) or other components authorized by the TNI medical AG. Do not connect unauthorized components to this socket!
- Please make sure that the device is positioned in a way that the power plug can be disconnected without difficulties
- An SD-Card can be used to store information independently from the device

1.3.5) ENVIRONMENTAL CONDITIONS

- The TNI *soft* Flow *50* may only be operated under admissible ambient conditions (see chapter 7, "*Technical Data*"). Operating the device under ambient conditions out of the range defined for the guaranteed performance parameters will result in reduced performance parameters. If the ambient conditions are out of the given range, the device should stay in off-mode due to safety reasons.
  In order to ensure proper use, it is important to let the TNI *soft* Flow *50* adapt to the ambient conditions (room temperature). Please wait about 2-4 hours before starting up the device. This applies to the first usage of the TNI *soft* Flow *50* and to transporting the device, i.e. the transport conditions were out of the given range of ambient conditions. Do not use the device in humid and potentially explosive rooms or combustible atmosphere.
- Intended functioning of the TNI *soft* Flow *50* may be impaired when it is operated right next to HF electrosurgery devices, defibrillators, X-rays, transmitted pulses, radio frequency interference or devices designed for short wave therapy.
- Do not use the TNI *soft* Flow *50* while performing the measures mentioned above or during magnetic resonance tomography (MRT, NMR, NMI).
- Active mobile phones may only be placed next to the device when a minimum distance of 1m is being kept.
- The system must not be set up next to a heater and must not be exposed to direct sunlight since this may interfere with a proper operation of the device.
- The sensor measuring the ambient temperature is located on the right in the inside of the device. Do not point any source of heat (e.g. heater,...) towards this sensor.
- In order to ensure a sufficient air circulation around the device, a minimum distance of 25 cm to all sides is to be kept.
- The device may not be covered.
- To avoid a fast accumulation of dust in the air filter, do not place the TNI *soft* Flow *50* near the ground.
- The device is intended to be used indoor and should be placed on an even horizontal surface.
- To avoid damage, contamination or malfunctioning, place the device out of reach from pets, pests or children
- Operating the device at a low ambient air temperature may result in a formation of condensate in the applicator. Keep the boxed applicator away from direct sunlight and store it in a dry place.

1.3.6) USING OXYGEN

- Do not put the applicator on the TNI *soft* **Flow** *50* or any other electrically driven device.
- The TNI *soft* **Flow** *50* may only be operated using the provided connection units. It is not allowed to operate the device using other connection units.
- Please make sure to read the user manual of your oxygen source carefully. If there are any open questions concerning usage or connection of the source, please contact your oxygen vendor or our hotline
- Mount your oxygen source correctly, especially if it's an oxygen bottle, to prevent damage. Please refer to the user manual of the oxygen source.
- Oxygen valves may not come into contact with oil, grease or any flammable liquids. Due to the risk of fire, smoking and open fire are strictly prohibited!
- The device may not be operated in closed areas producing or using anaesthetics and/or nitrous oxide.
- Especially when adding clinical oxygen, the following safety guidelines need to be observed:
  - o Do not place the TNI *soft* **Flow** *50* directly on the floor. Keep a minimum distance of 40 cm.
  - o Keep a minimum distance of 40 cm to the wall.
  - o Keep a minimum distance of 80 cm to other electrical devices.
- Prior to switching on, always make sure that the connection unit(s) is/are connected properly to the intended gas sampling point(s).
- Ensure a safe and solid connection.
- Oxygen supports combustion processes. When using oxygen during therapy, smoking and open fire are strictly forbidden.
- Oxygen valves need to be kept free of grease.
- Improper connection of the external oxygen source may result in an insufficient therapy.
- Caution when handling oxygen! Risk of fire!
- Several deaths occurred in hospitals in the past due to patients who smoked despite being treated with oxygen. In order to take a drag, the oxygen tube was removed from the face and put on the bed. This made it possible for the oxygen to spread across the beddings and the patient's clothes. The patient fell asleep and the lit cigarette set the bedding on fire.
- It was not possible to fight the fire due to the spread oxygen. It kept burning even after the attempts to extinguish it. The patient finally died of the burnings

1.3.7) CLEANING

- The device may only be cleaned when being completely disconnected from the power supply system. Prior to any cleaning measure, switch off the main switch located at the right side of the device and unplug the power cord from the device's female connector.
- Please note chapter 6, "*Hygiene*". Not observing the instructions on cleaning and disinfection can lead to a bacterial contamination and may endanger the patient! Overdosing disinfectants can cause material damages. Avoid calcification (see chapter 6, "Hygiene").
- Please note the replacement cycles of accessories and disposables (see chapter 6, "Hygiene"). When exceeding these time periods or not replacing these items, proper use can no longer be ensured.
- Due to biocompatibility reasons, the applicator may not continuously be worn for longer than 24 hours. Replace the applicator every 24 hours and note the replacement cycles.

- The TNI *soft* **Flow** *50* is always to be cleaned and disinfected prior to the visit of a new patient (for more detailed information, see chapter 6, *"Hygiene"*). The applicator, MRP filter, air lift and humidifier chamber need to be replaced.
- Due to hygienic reasons, not more than one patient may use the same applicator.

1.3.8) FILLING THE WATER CHAMBER

- When opening the device immediately after turning it off, please note that the inner parts of the device (metallic bottom of the water container, heating plate) might be hot and may therefore not be touched. Please wait a couple of minutes until the device has cooled down.
- Under no circumstances must fluids get into the device!
- Always take the water container out of the TNI *soft* **Flow** *50* to fill it up. Marks on the storage container indicate minimum and maximum filling level. Fill up the container within this area, maximum up to the mark labeled "max".
- The water container may only be filled with drinking water. Do not use additives! (see chapter 3.1.1 Humidifier clinic complete, und 3.1.3. Filling and inserting the humidifier homecare). If the device is filled with non-recommended additives, the patient's airways may be impaired!
- As soon as the humidifier is filled up with water and inserted in the TNI *soft* **Flow** *50* again, the TNI *soft* **Flow** *50* should not be moved quickly, be extremely inclined nor transported. With such activities, water might uncontrollably get out of the humidifier into the device which may impair correct functioning of the device.
- Remove the humidifier before transporting the device or changing its position.

1.3.9 TRANSPORT OF THE DEVICE

- In order to avoid damages, be careful when transporting or storing the device!
- The water chamber may not contain water during transportation of the TNI *soft* **Flow** *50*.
- The device may only be transported in an upright and intended position.
- Do not drop the device since this may cause housing damages and impair proper functioning.
- In case of dropping the device nonetheless, make sure that the TNI is in proper condition (completeness, no visible defects, etc.). In order to ensure this, always perform a visual check for damages of the single parts prior to starting up. In case of abnormalities, immediately contact your local TNI medical AG representative.
- If you are transporting the external oxygen source, please consult the user manual of that device for transport instructions.

1.3.10)DISPOSAL

In accordance with the German Electrical and Electronic Equipment Act, the manufacturer is responsible for the disposal of the TNI *soft* **Flow** *50* (for more information on disposal, see chapter 11). To dispose of the unit, contact:

TNI medical AG
Hofmannstraße 8
D-97084 Wuerzburg

Telephone: +49 931 20 79 29 02
Telefax: +49 931 79 29 29 18
Email: info@tni-medical.de
www.tni-medical.de

1.4) DESCRIPTION OF FUNCTION

TNI soft Flow is a system managing therapy with nasal insufflation:

A constant, humidified and warm flow, which may also combined with oxygen, is applied in the nose via applicator (thin nasal cannula which act as an interface to the patient). Technically, it consists of a ventilation unit and a humidifier unit.

The blower absorbs air, compresses it and forwards it via humidifier. Here, the air flows over heated water. The heated and humidified water thus obtained achieves dew points from 30-37° TP (can be set individually).

2 humidification models are provided; both can be used individually, “Humidifier clinic complete” and “Humidifier homecare complete”.

The heated and humidified air / air-oxygen mixture flows in the nose and upper respiratory tract via applicator.

The air outflow at the applicator in the nose simulates nasal cannula used in oxygen therapy. Particular emphasis was given to a high wearing comfort and low noise level.

We wish you a good and recreative time with the TNI *soft* **Flow** *50*

1.5) TRAINING OPTIONS

An initial training is performed by TNI or an authorized partner before the device is used.

For more training options (as an in-depth service training) or other information, please contact your local TNI medical AG customer service.

2) SYSTEM COMPONENTS AND ACCESSORIES

2.1) SCOPE OF SUPPLY of TNI *soft* **Flow** *50* clinic system

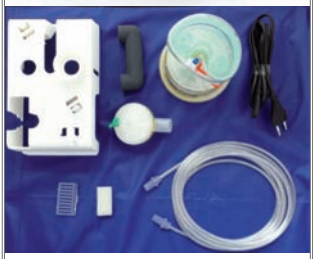
Scope of delivery		Article No.
TNI *soft* **Flow** *50* clinic-System english  		40610021
Humidifier clinic complete	Set	40620100
Power connecting cable TNI *soft* **Flow** *50*, type C,1,8m	1 Unit	40641150
Dust filter reserves	5 Unit	40620060
Oxygen tube, 4m	1 Unit	40641112
Operating instructions TNI *soft* **Flow** *50* clinic system	1 Unit	30221041
Short manual TNI *soft* **Flow** *50* clinic system	1 Unit	30221061
Order form Accessories TNI *soft* **Flow** *50* international	1 Unit	30222201
Declaration	1 Unit	30222220
SD card 4 GB TNI *soft* **Flow** *50*	1 Unit	40641103

Table 1 - Scope of Delivery of the clinic system

2.2) HUMIDIFIER HOMECARE COMPLETE

The standard package of TNI soft Flow 50 clinic system includes the "humidifier clinic system complete" (Art.No. 40620100).

The system may be used alternatively with the "humidifier homecare complete". (Part-No. 40620000)

Details concerning correct use please note chapter 3.1.3.

WARNING

USE OF THE "HOMECARE HUMIDIFIER" IN EVERYDAY HOSPITAL ROUTINES

When using this type of humidifier, there is no MRP filter integrated. If the patient is likely to further use the system in his/her home environment, this type of application is recommended to be used in hospital. The patient will become acquainted with the system and the healthcare professionals can tell a safe continuation of the following homecare therapy. When being reused in hospital, the system is to be disinfected thoroughly before being used on a new patient.

SAFETY NOTE

Please note the hygiene measures (chapter 6).

2.3) ACCESSORIES

Accessories, spare parts and a current list of applicators for respective TNI *soft* **Flow** *50* systems are available at TNI medical AG.

Order form	Article number	30222201
Product catalogue	Article number	30222231

For further information please note www.tni-medical.de

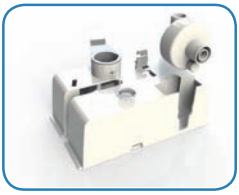
3) STARTUP OF TNI *soft*Flow *50* CLINIC SYSTEM

3.1) ASSEMBLING AND CONFIGURING THE HUMIDIFIER CLINIC COMPLETE

- Place the unit/system horizontally on a plane surface.
- Make sure that the system is located below head height.
- Insert the mains cable into the power socket at the right side of the device.
- then insert the power plug into the power outlet.

3.1.1) HUMIDIFIER CLINIC COMPLETE

- The humidifier clinic complete contains:
  - o Humidifier rack clinic
  - o Clear-Guard 3 bacteria filter; MRP hygienic filter
  - o Humidifier chamber auto-Fill
  - o Air lift
- Remove the humidifier rack clinic and the humidifier clinic-hygienic set from the packaging and assemble them according to the operating instructions.
- Please refer additionally to the descriptive image sequence.
- Push the humidifier clinic complete from front into the device and close the front of the housing.
- Fix a sterile water bag to the respective hose of the auto-fill chamber.



WARNING

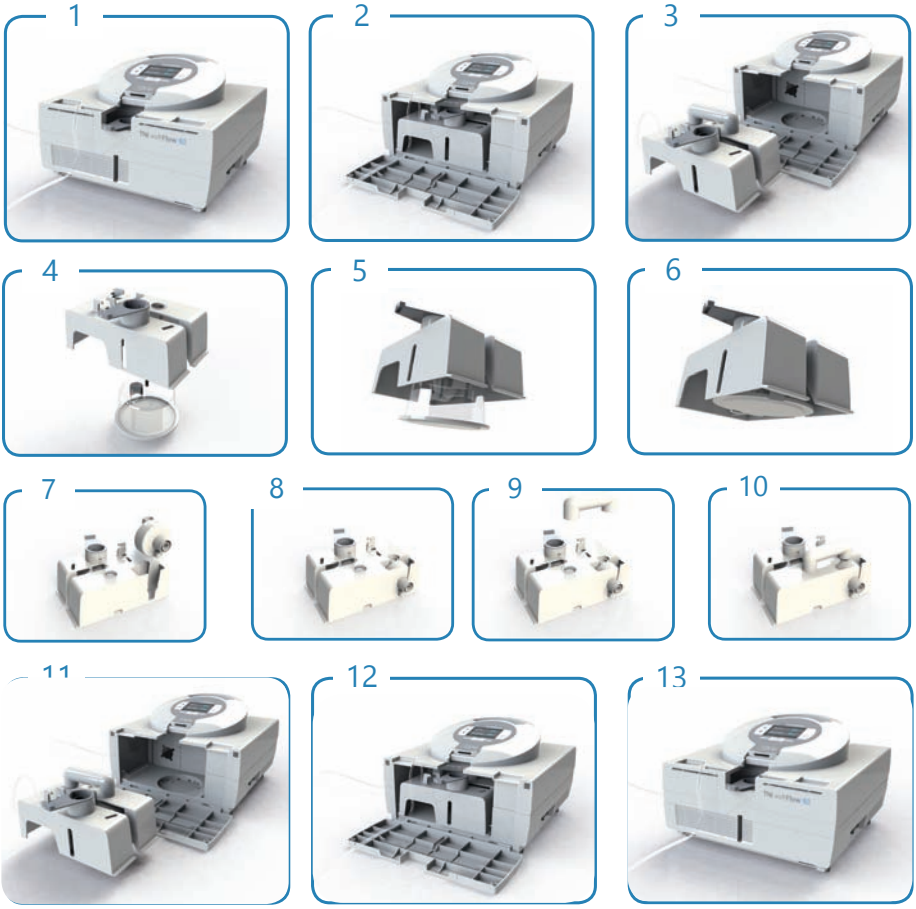
Hygiene

- *Use authorized parts only.*
  Make sure that the hygiene regulations are met.
- *Use originally packed and unexpired parts only.*
- *Do not apply already used disposables, e.g. humidifier chamber, MRP filter, air lift, etc.*
- *Use sterile water in clinical treatment.*

SAFETY NOTE

In order to ensure an optimal treatment,

- *Do not use the humidifier chamber autofill after it had been dropped or run dry, which will trigger the alarm "Refill water".*
- *Remove the clinical humidifier completely BEFORE transporting, tilting or moving the device.*



3.1.2) CONNECTING WATER BAG

- Attach the sterile water bag to the hanging bracket app. 1m above the unit, and push the bag spike into the fitting at the bottom of the bag. Open the vent cap on the side of the bag spike. The chamber will now automatically fill to the required level and maintain that level until the water bag is empty.
- To ensure continual humidification, make sure that the water chamber and/or water bag is always filled with water.
- Check that water flows into the chamber and is maintained below the fill line. If the water level rises above the fill line, replace the chamber immediately.

3.1.3) FILLING AN INSERTING THE HUMIDIFIER HOMECARE

- The Humidifier homecare complete contains:
  - Water chamber
  - Cyclone element
  - Lid
- Remove the preassembled humidifier homecare complete from the packaging or from TNI *soft* **Flow** *50*
- Please refer additionally to the descriptive image sequence
- Remove the lid flapping the locking tab upwards on all sides
- Remove the cyclone element (pull it out upwards)
- Fill the water reservoir with the recommended water up to the "max" mark
  - After filling the water level must be in the area of „min/max"
  - The mark „max" must not be exceeded
- Insert the cyclone element.
- Close the lid and lock it.
- Carefully push the humidifier rack homecare complete into the device
- Make sure that no water can access into the system
- Close the housing front lid.

WARNING

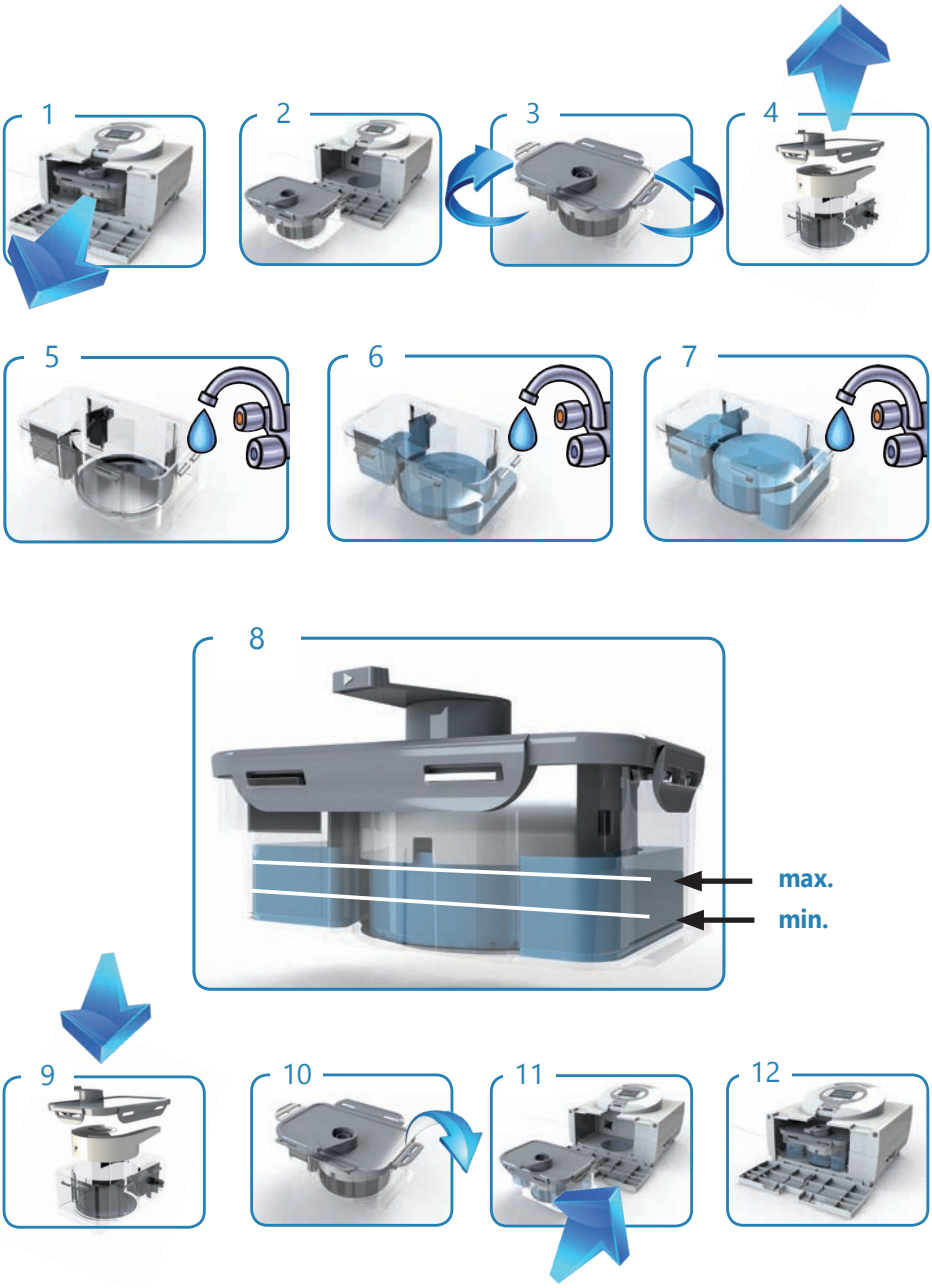
Hygiene

- *Use authorized parts only.*
- *Make sure that the hygiene regulations are met.*
- *Use originally packed and unexpired parts only.*
- *Do not apply already used disposables, e.g. humidifier chamber, MRP filter, air lift, etc.*
- *Use sterile water in clinical treatment*

SAFETY NOTE

In order to ensure an optimal treatment,

- *Do not use the humidifier chamber autofill after it had been dropped or run dry, which will trigger the alarm "Refill water".*
- *Remove the clinical humidifier completely BEFORE transporting, tilting or moving the device.*


1
2
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max.
min.
9
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12

3.1.4) INSERT THE APPLICATOR

- Choose the right applicator.
- Remove it from the packaging and insert the applicator into the designated opening of the device.
  Insert the applicator plug from above into the opening and press down with less force until it snaps in.
- The locking lever moves to the left stop.

WARNING

In order to avoid burnings,

- *Do not modify the applicator in any way*
- *Make sure that the applicator is not heated up to more than room temperature (e.g. by means of a blanket, electric fire...) since this may cause serious injury.*
- *Do not use insulating sleeves or accessories that have not been authorized or recommended by TNI medical AG.*

SAFETY NOTE

- *In order to minimize interference with the supervised signal, position the heated applicator tube away from any electronic monitoring electrode (EEG, ECG, EMG, etc.).*

3.1.5) REMOVING APPLICATOR

WARNING

In order to prevent mechanical destruction,

- *Remove the applicator from the retainer without effort.*
- *Do not use force if it is not possible to remove the applicator right away.*
- *Do not use any tools to remove the applicator.*

SAFETY NOTE

- *Do not let any foreign substances or objects get into the system's applicator opening.*
- Move the locking lever under the applicator to the right
- The applicator is released from its locking
- Remove the applicator plug upwards from the holder
- Now, the system can be used with another applicator.

3.1.6) CONNECTING OXYGEN SUPPLY

WARNING

In order to prevent burnings,

- *do not modify the applicator in any way.*
- *note the safety guidelines in chapter 1.3.6.*
- *do not place the* TNI *soft* **Flow** *50 device on the floor. Keep a minimum distance of 40 cm!*
- *keep the minimum distance of 40 cm to the wall.*
- *keep the minimum distance of 80 cm to other electric devices.*
- *note that an external oxygen source not being completely connected may lead to an inadequate therapy.*
- *Be very careful when handling oxygen! Fire hazard!*

SAFETY NOTE

- *Oxygen supports combustion process. Smoking and open fire are not permitted when oxygen is used during therapy.*
- *Several deaths occurred in hospitals in the past due to patients who smoked despite being treated with oxygen. In order to take a drag, the oxygen tube was removed from the face and put on the bed. This made it possible for the oxygen to spread across the beddings and the patient's clothes. The patient fell asleep and the lit cigarette set the bedding on fire. It was not possible to fight the fire due to the spread oxygen. It kept burning even after the attempts to extinguish it. The patient finally died of the burnings.*
- The connection to the oxygen source is located on the left side of the device.

- Connect the TNI *soft* **Flow** *50* with the oxygen supply via the oxygen tube supplied.
- Do not supply oxygen before the TNI *soft* **Flow** *50* has started.
- The required rate of oxygen will be set / adjusted at the oxygen supply.

3.1.7) REPLACING DUST FILTER

- Please change the dust filter at regular intervals (at least every 3 month)
- Take the dust filter cover out of the holder (at the backside)
- A light downward pressure to the flap releases the lock
- The dust filter cover can be removed downwards. Remove the dust filter.
-

- Insert a new dust filter in case of a change.
- Insert the dust filter cover from below and lock it with light pressure onto the upper part.
- Protect the filter from direct sunlight and humidity.

3.2) STARTING AND STOPPING THE TNI *soft* **Flow** *50*

WARNING

To avoid electric shocks,

- *Make sure that the* TNI *soft* **Flow** *50 is dry before connecting it to the power supply.*
- *Make sure that the voltage (110-230 V) and mains frequency (50-60 Hz) admissible for the* TNI *soft* **Flow** *50 comply with your local characteristics.*

3.2.1) SWITCHING ON / OFF

- To turn on the TNI *soft* **Flow** *50* press the main switch at the right side of the device. Move the rocker switch to „1".

- The device switches on showing for approximately 5 seconds
  - o the firmware-Status and
  - o the selected humidifier type
- and begins to operate
- During the first commissioning the system starts with the factury-set system and parameter values (humidification =34°TP and flow rate = 15 l/min.)
- After the first application the system starts with the previously set values

3.2.2) ACTIVATING STANDBY-MODE

- Press 

- The system turns off.
- The TNI *soft* **Flow** *50* shows the standby display.

3.2.3) DEACTIVATING STANDBY-MODE

- Press 

- The system turns on.
- The display shows the operation mode.

3.3) OPERATING ELEMENTS of TNI *soft* **Flow** *50*

- The TNI *soft* **Flow** *50* is operated via membrane keys

3.3.1) OPERATING ELEMENTS of TNI *soft* **Flow** *50*

The TNI *soft* **Flow** *50* function keys are positioned to the left and right of the display.

KEY	FUNCTION
	Each keystroke increases the respective value or moves the selected cursor upwards through the menu
	Each keystroke decreases the respective value or moves the selected cursor downwards through the menu.
	Activates the setup menu confirms the data input
	Starts and stops the therapy Stops the menu input

3.3.2) BASIC USER MENUE

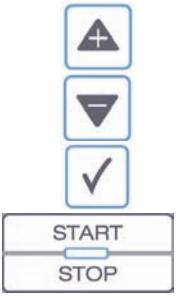
- The TNI *soft* **Flow** *50* has a sophisticated user menu.
  - o Humidity
  - o Type of humidifier
  - o Flow rate
  - o New patient
  - o Therapy hours
  - o System info
  - o Language
  - o Time
  - o Date
  - o Alarm volume
  - o Service menu — access blocked, for technical staff only!
  - o Clinic menu — access is activated!
- Basic system settings and modification of therapy parameters can be realized via menu

 Opens the menu display

 Mark moves upwards

 Mark moves downwards

 Takes the selected menu point



Increases the parameter value

Decreases the parameter value

Takes the modified parameter value

Closes the menu display

- All required settings are provided via that operating procedure.
- The TNI *soft* **Flow** *50* stores these settings in the device memory
- The TNI *soft* **Flow** *50* restarts the system with these settings.

3.4) ATTACHING THE APPLICATOR

WARNING

To avoid electric shocks,

- *Be careful not to touch the electric connections of the* TNI *soft* **Flow** *50 as soon as the applicator has been put on.*

Hygiene

- *Due to biocompatibility reasons, the applicator may not continuously be worn for more than 24 hours.*
- *The applicator of the clinic series should be exchanged after 336 therapy hours (i.e. 14 therapy days of 24 h each).*
- *The applicator has to be exchanged after every patient.*
- *Do not put the heated applicator tube on the device.*
- *Make sure that the applicator is not heated up to more than room temperature (additional heating e.g. by means of a blanket or radiant heater) since this may cause serious injuries.*
- *Do not use accessories which have not been authorized or recommended by TNI medical AG.*

SAFETY NOTE

- *Position the heated applicator tube away from any electronic monitoring electrode (EEG, ECG, EMG, etc.) to avoid potential interference with the supervised signal.*




- Carefully insert the nose pins of the applicator into the nose and move the tube over the ears and place it forward again.
- Make sure that the slightly curved ends will show toward the face (see images)
- To fix the applicator, pull the fixing sleeve towards the chin
- Leave the tube of the applicator free, make sure not to jam or bend the tube.

3.5) CHOOSING THE APPLICATOR

Choosing the applicator

- *Please read the separate operating instructions, including all warnings, for the respective applicator.*
- *The* TNI *soft* **Flow** *50 supports you by means of an integrated recognition technique. Additionally, automatically predefined flow rate limits are considered*

TNI *soft* **Flow** *50* can be used with a large range of applicators.

Applicator type	Recommended max. flow rate	NC in mm
Applicator small	For young and adults max. 20 l/min	40630001
Applicator sStandard	For young and adults max. 25 l/min	40630002
Applikator medium	For young and adults max. 25 l/min	40630003
Applicator large	For young and adults max. 50 l/min	40630013
Applicator Xlarge	For young and adults max. 50 l/min	40630014

3.6) STARTING THERAPY

WARNING

- *Before starting a therapy, please make sure that all components are inserted and /or connected correctly (see chapter 3).*
- *Before switching on the device, make sure that the water container is filled up with water!*
- Set the main power switch to position „I“
- The device switches on showing for approx. 5 seconds
  - o the firmware-Status and
  - o the selected humidifier type
- and begins to operate
- After the first application the system starts with the previously set values
- If the device is in the standby mode:
- Press 

- The system switches on.
- By pressing the function keys, the display illumination is activated in the operation mode.
- The display shows the operation mode and the current parameter
  - o The Humidity, dew point in °DP
  - o The applied flow rate in l/min

- The supplied oxygen volume in l/min
- The oxygen content, FiO_2-value in %

- When none of the function keys has been pressed for a period of >10 minutes, the display reduces brightness.

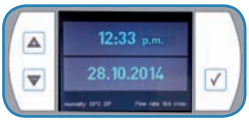
3.7) ENDING THERAPY

WARNING

- *Do not open the device immediately after switching it off since the inner parts of the device are hot.*
- *Please wait a couple of minutes until the device has cooled down.*

- To switch off press 

- The system turns off.
- Remove the applicator
- The TNI *soft* **Flow** *50* shows now the standby display.



- After each use clean the applicator.
- Properly dispose the disposables of the clinic chamber (please note capture 5 "*Hygienic measures*" and capture 11 - "*Disposal*").
- If you do not use the device remove the reservoir for hygienic reasons. So, the residual moisture in the device is able to dry.
- If the TNI *soft* **Flow** *50* is not being used over a long period of time, switch off the TNI *soft* **Flow** *50* (main switch right of the device), disconnect the power cord from the socket, remove the applicator and make sure that there is no water in the humidification chamber nor in the water container.

3.8) STARTING OXYGEN SUPPLY

SAFETY NOTE

- *The connection to the oxygen source needs to be set up correctly as described in chapter 3.1.4.*
- *The oxygen supply may only be released with the* TNI *soft* **Flow** *50 running.*
- *Please note chapter 3.1.6.*

- Press 

- The system goes into operation and supplies the required flow rate at the applicator, the air flow is perceptible, the value is obvious in the display.
- Supply the TNI *soft* **Flow** *50* with the required oxygen, adjust the value.
- The oxygen applied is shown in the display in l/min.

- The system mixes the adjusted air-flow rate with the oxygen.
- The flow rate is referred to as total flow; i.e. the air-oxygen mixture is set to the flow rate specified in the nominal value.
- The real value and the oxygen concentration, resulting from it, FiO_2 in %, is shown in the display.

3.9) STOPPING OXYGEN SUPPLY

SAFETY NOTE

- *The connection to the oxygen source needs to be set up correctly as described in chapter 3.1.6.*
- *The oxygen supply may only be released with the* TNI *soft* **Flow** *50 running.*
- *Do not supply the* TNI *soft* **Flow** *50 with oxygen during standby-mode!*
- *Please note chapter 3.1.6.*

- The system still supplies the required flow rate at the applicator, the air flow is perceptible.
- The real flow rate and the FiO_2, resulting from it, is shown in the display.#
- Switch off the oxygen supply at the oxygen source.
- The oxygen shown in the display rises to 0 l/min
- The FiO2 value shown in the display indicates 21%

With this display, press 

- The system switches off.
- The TNI *soft* **Flow** *50* now indicates the standby display.

4) SELECTING THE THERAPY PARAMETERS AND SYSTEM CONFIGURATION MENU

WARNING

- *In order to set the therapy parameters, the device has to be completely assembled and also needs to be in operating mode as described in chapter 3.*
- *The parameters are called up via the menu and the function keys and also adjusted and stored (please note capture 3.3.)*
- The device has stored the previous parameter settings and is started with these settings after a restart.
  The following therapy parameter can be changed:
  - o Flow rate in l/min
  - o Humidity (dew point) in °DP

  The following menue points are admitted for system configuration:
  - o Humidifier type
  - o New patient
  - o Language
  - o Time
  - o Date
  - o Alarm volume

  The following menue points, supply system information:

- o System info
- o Therapy hours
- o Service menue access blocked, only for technical staff!
- o Clinic menue access is activated

4.1) THERAPY PARAMETERS

4.1.1) STATEMENT ON THE INDICATED DISPLAY VALUES

Nominal and Real value shown on the operating display

WARNING

NOMINAL and REAL VALUE:

- *The nominal value describes the value the system should deliver as a regulated therapy value.*
- *Reaching these therapy values and providing them correctly is described as the real value, meaning:*
- *In the settings, the nominal value defines the targeted value for the system.*
- *In an optimal situation, the real value differs only slightly from the nominal value.*
- *For more information on tolerance specifications see chapter "Technical Data".*

SAFETY NOTE

- *The real value is mandatory for therapy.*
- *The real value ensures a successful therapy.*
- *Alarms and notes on the display indicate deviations from the tolerance limit.*

NOMINAL VALUES

- On the bottom line the display shows the programmed nominal values, which corresponds to the last programmed therapy parameters.
  - o Humidity (dew point) in °DP
  - o Flow rate in l/min

REAL VALUES on the display

- The first line shows the humidity (dew point) real value
- and ↑
  - o the system heats up
- and ↓
  - o the system cools down
- The second line shows the Flow rate real value
  - o this value corresponds to the current exact, regulated flow rate released in l/min
  - o consisting of air or
- Air-Oxygen mixture
- Additionally, the admixture of oxygen
  - o O_2 admixture in l/min
  - o And the resulting oxygen (concentration) in %, FiO_2-value

4.1.2) SETTING HUMIDITY (DEW POINT)

WARNING

Humidity and dew point:

- *In order to set a nominal value, the system requires a setup-time of about 10 minutes.*
- *If the humidity value is altered (no matter if increasing or decreasing the value), the system will always require a physical setup-time of about 10 minutes.*
- *The system is to be used in the corresponding environment (see chapter "Technical data").*

SAFETY NOTE

- *The Real value is obligatory for therapy.*
- *If your nose feels dry during therapy,*
  - o *check for correct choice and setting of the respective humidifier type.*
  - o *make sure that the humidity chamber contains enough water, increase humidity*
- *If you feel a slight stinging in the nose,*
  - o *check for the correct choice and setting of the respective humidifier type.*
  - o *make sure that the humidity chamber contains enough water, increase humidity.*
- *If condensate forms in the applicator tube or interfering water droplets spurt out of the applicator,*
  - o *check for correct choice and setting of the respective humidifier type .*
  - o *check for correct ambient conditions. The room temperature might be too low.*
  - o *reduce humidity; humidity might be set too high for the valid ambient conditions.*

The individual moisture (humidity) content of the applied air / air-oxygen mixture will be provided via this parameter

- It is recommended to perform the therapy with 34°-37° dew point to ensure optimum humidification of the mucosa (mucous membranes)
- The humidification (dew point) can be set from 30 - 37° dew point
- Adjustable in 1°C steps
- **During therapy:**

  Possible via 

  o press 
    - o increases the humidity value by 1°DP
    - o each further keystroke increases the humidity value by 1°DP

  o press 
    - o decreases the humidity value by 1°DP
    - o each further keystroke decreases the humidity value by 1° DP

  o  accepts the value and retains the selected value

- **Setting via menu, the system configuration:**

  o press 

- mark **humidity** via
- confirm via
- set the required value via
- confirm via
- the system stores the therapy parameter
- end the adjustment via START / STOP
- The changed value is displayed in the index value line
- The system readjusts the changed value

4.1.3) FLOW RATE

WARNING

- *It is recommended to set the nominal flow rate before using the applicator*

SAFETY NOTE

- *To set the flow rate is only allowed to be set by qualified personnel*

- The flow rate can be adjusted from 15 to 50 litres/min (l/min)
- Adjustable in 0,5 l/min steps
- Access this parameter via menue
  - press
  - mark the **flow rate** via
  - confirm via
  - Set the required value via
  - Major value changes can be performed via or and keep the key depressed, automatic scrolling starts.
    release the key, when the required value is reached.
  - confirm via
  - End the adjustment via START / STOP
  - The changed value is displayed in the index value line
  - The system readjusts the changed value

4.2) MENU ITEMS WHICH HAS BEEN APPROVED FOR SYSTEM CONFIGURATION

4.2.1) CHOOSING TYPE OF HUMIDIFIER

WARNING

Reaching optimal humidity control:

- *The* TNI *soft* **Flow** *50 can be operated with 2 different types of humidifier:*

o *Humidifier clinic complete*

o *Humidifier homecare complete*

Temperature and humidity control are based on a very sensitive and complex control algorithm. In order to achieve an optimal result, choose the correct type of humidifier and make the corresponding settings under the menu item "type of humidifier".

SAFETY NOTE

- *Choosing the incorrect setting by mistake will not lead to a problem.*
- *Humidity generated by the Humidifier homecare complete is higher than the humidity generated by the clinical humidifier due to the perfected cyclone principle. Unnominal side effects resulting from inconsistent humidity (dew point) may include a slight formation of condensate or the inability of the user to increase the humidity. At no point of time will the patient be endangered (see chapter 4.1).*

o press ✓

o mark the **humidifier type** via ▲ ▼

o confirm via ✓

o choose the required type via ▲ ▼

o **Humidifier clinic**

o **Humidifier homecare**

o Confirm via ✓

o End the adjustment via START / STOP

4.2.2) CHOOSING NEW PATIENT / CHANGE OF PATIENT

WARNING

Registering times of therapy

- *The* TNI *soft* **Flow** *50 is able to save all actions and therapy sessions assigned to a patient.*
- *This gives the hospital the opportunity to register the individual situation of the patient.*
- *This parameter does not influence the therapy.*

SAFETY NOTE

- *Registering the real therapy hours during a hospital stay allows to account for treatment periods correctly.*
- *The system basically records all parameters which were measured in the most recently ending period of 1 year.*
- *It is possible to patient specifically capture the parameters on the integrated SD Card.*

o press ✓

o mark **new patient** via ▲ ▼

o confirm via ✓

o choose the required status ▲ ▼

No	continues counting
Yes	sets the therapy hours to 0

o confirm via ✓

o end the adjustment via START / STOP

4.2.3) SETTING THE LANGUAGE

NOTE

Language selection and language diversity

- *The* TNI *soft* **Flow** *50 basically offers 2 types of languages to select from.*
- *Additionally, it is possible to store 4 additional languages in the system and to select from additional 8 languages via SD Card.*
  Safety note
- *Availability is only realized with the market introduction in the corresponding country.*
- *Please contact your local TNI medical AG agency.*

o press ✓

o mark the **language** via ▲ ▼

- o confirm via ✓
- o choose the required language via ▲ ▼
- o confirm via ✓
- o End the adjustment via START / STOP
- o The previously selected language now is the system language

4.2.4) SETTING THE TIME

NOTE

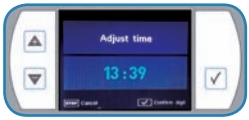
Display format

- *It is possible to select from 2 different clock displays*
  - *o 24 hour mode or*
  - *o 12 hour am / pm mode.*

SAFETY NOTE

- *The time set on the device is considered when entering something in the storage.*
- *The clock is not automatically adjusted for daylight saving changes.*
- *An automatic radio adjustment is not possible.*
- *Please make sure that the local time of the system is set correctly.*
- *In case of any questions, please contact your local TNI medical AG representative.*

- o press ✓
- o mark the **time** via ▲ ▼



- o confirm via ✓
- o choose the required status via ▲ ▼

  - o 24 h
  - o 12 am / pm

  confirm via ✓
- o Choose the required hour via ▲ ▼
- o Confirm via ✓ the system marks the minute display
- o Choose the required minutes via ▲ ▼
- o confirm via ✓

- End the adjustment via START / STOP

4.2.5) SETTING THE DATE

NOTE

Display format:

- *It is possible to choose from 2 different date displays:*
  - *DD:MM:YY (Day:Month:Year)*
  - *YY:MM:DD (Year:Month:Day)*

SAFETY NOTE

- *The date set on the device is considered when entering something in the storage.*
- *Adjustments/Settings do not take place automatically.*
- *An automatic radio-adjustment is not given.*
- *Please make sure that the date of the system is set correctly.*
- *In case of any questions, please contact your local TNI medical AG representative.*

- press ✓
- mark the **date** ▲ ▼

- confirm via ✓
- choose the required status via ▲ ▼
  - TT.MM.JJ
  - TT.MM.JJ

- confirm via ✓
- choose the required **day** via ▲ ▼
- confirm via ✓ the system marks the month display
- choose the required **month** via ▲ ▼
- confirm via ✓
- choose the required **year** ▲ ▼
- confirm via ✓
- end the adjustment via START / STOP

4.2.6) ALARM VOLUME

WARNING

- *The* TNI *soft* **Flow** *50 detects inconsistent situations during operation.*
- *This leads to notifications via display or to alarms.*
- *Alarms can be shown in the display area or be indicated by sounds.*
- *The acoustic alarm sound is adjustable to 4 levels of loudness.*
- *If necessary, contact your local TNI medical AG agency.*

SAFETY NOTE

- *The acoustic alarm can not be suppressed.*
- *It is not possible to suppress the visual alarm on the display.*

o press 

o Mark the **alarm volume** via 

o confirm via 

o Choose the required volume 

- o Level 1 (low)
- o Level 2
- o Level 3
- o Level 4 (high)

o confirm via 

o end the adjustment vi 

4.3) MENUE POINTS, SYSTEM INFORMATION

- o System information
- o Therapy hours
- o Service menue — access blocked, only for technical staff!
- o Clinic menue — access is activated.

4.3.1) SYSTEM INFORMATION

NOTE

Information on the system

- *When being delivered, the* TNI *soft* **Flow** *50 is provided with the latest firmware.*
- *The firmware is defined by the details given in the 3 categories PF/EF/LF.*
- *In case of failure, this information may be helpful to your local TNI medical AG contracting*

partner and should, if necessary, be kept at hand to provide the respective data.

- *In case of additions or updates over the time, modifications can be made via SD card and by your local TNI medical AG contracting partner.*

SAFETY NOTE

- *It is not necessary to modify the firmware.*
- *If required due to occuring errors, the manufacturer will automatically perform an update.*

o press ✓

o mark the **system information** via ▲ ▼

o confirm via ✓

The display shows:

- o **Serial number**
- o **Firmware**
- o **Type**
- o **Applicator**
- o **PF and version number**
- o **EF and version number**
- o **LF and version number**

o end the adjustment via START / STOP

4.3.2) READING OUT THERAPY HOURS

NOTE

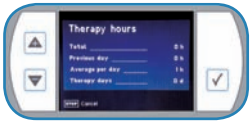
- *The* TNI *soft* **Flow** *50 continuously saves every patient's therapy hours. Since this data may be of interest to the hospital, it is possible to reset the therapy hours via the menu item "New patient" at each change of patient.*
- *Each activity and disfunction data collected during therapy hours is saved to an additional storage and can be read and evaluated by the service or an authorized contracting partner of the TNI medical AG.*

SAFETY NOTE

- *The data is stored on SD Card as well as on internal memory.*
- *The internal memory has the capacity to store all data collected during the previous 12 months.*
- *As soon as the maximum memory capacity is reached, the storage will always hold the data collected during the previous 12 months available.*

o press ✓

- mark the **therapy hours** via 



- confirm via 
  - **Total**
  - **Previous day**
  - **Average day**
  - **Therapy days**
- end the adjustment via 

4.3.3) CLINIC-MENUE

WARNING

- *The clinic menue is activated and enables the setting of all therapy parameters, system configurations and the direct system information.*

4.3.4) SERVICE-MENUE

WARNING

- *Only technically qualified personnel is allowed to access the clinic menu!*

5) HYGIENIC MEASURES

WARNING

- *Prior to each hygiene measures, switch off the main switch on the right side of the device and disconnect the power connecting cable!*
- *Under no circumstances must fluids get into the device!*
- *Non-observance of cleaning- and disinfection instructions may result in bacterial contamination or infection!*
- *Overdosing disinfectors may damage the material.*
- *Please note the replacement cycles for applicator, (MRP) filter and air lift! With the exceeding of this given time period, a proper use of the device cannot be ensured.*
- *Avoid calcification of the respective parts! After a cleaning/disinfection, please check all parts for damages to the surface and for proper functioning!*

5.1) CLEANING

The Cleaning applies to the clinic status conferred upon or or information in accordance with RKI.

The following table concerning cleaning and changing cycles or individual producer information serves as guideline.

When switching from one patient to the next, all components listed in the following table has to be cleaned/replaced:

- Single use components have to be replaced
- Accessory parts have to be cleaned

5.1.1) CLEANING- AND CHANGING CYCLES

Cleaning and changing cycles		Daily or 24 h	Weekly or 7 days	366 Therapy hours or 14 days à 24h	3 months	Single patient use	Single use
Humidifier rack clinic	40641107	Wipe disinfec-tion				X	
Humidifier chamber auto-fill	40641110		Change				X
Air lift humidifier clinic	40641108		Change				X
Clear-Guard 3 bacterial filter, angled filter	40641111	Change					X
Humidifier home-care complete	40620000	Wipe disinfec-tion	Cleaning			X	
Water chamber humidifier	40641104		Wipe disinfection			X	
Lid humidifier homecare	40641105		Wipe disinfection			X	
Cyclone element humidifier home-care	40641106		Wipe disinfection			X	
Oxygen tube	40641112		Change				X
Applicators clinic serie	All approved types	Wipe disinfec-tion		Change			X
Dust filter	40620060		Wash-out		Change		X
TNI *soft* Flow *50* clinic system	40610021	Wipe disinfec-tion				X	

5.1.2) DETERGENTS

Product-name	Producer		Basis material	Con-centra-tion	Plastic	Elas-to-mere	
antifect extra	Schülke & Mayr GmbH		quaternary ammonium compounds and alde-hydes	0,5 to 3%	very good	very good	
mikrozid sensitive liquid	Schülke & Mayr GmbH	Ready-to-use Alcohol-free rapid disinfectant based on quaternary ammonium compounds	Very good				ready for use
mikrozid sensitive wipes	Schülke & Mayr GmbH	Ready-to-use disinfection tissues moistened with non-alcoholic pure substance	quaternary ammonium compounds				ready for use
Pursept-AF	Schülke & Mayr GmbH	disinfectants	Guanidine, N,N‴-1,3-Propandi-ylbis-, NKokosalky-lderivates, Diacetate				
Pursept FD	Merz	Efficient surface disin-fection with extremely benefic effects	9,6 g Glyoxal, 8,0 g Didecyldi-methylam-monium chloride, 3,5 g Formalde-hyde, 2,5 g Glutardial-dehyde, < 5 % non-ionic surfactant, auxiliary materials, fragrances (e. g. Li-monene)				ready for use

Product-name	Producer		Basis material	Con-centra-tion	Plastic	Elas-to-mere	
terralin liquid	Schülke & Mayr GmbH	Alcohol-based disinfectants. Ready for use	Alcohol				ready for use
terralin protect	Schülke & Mayr GmbH	Liquid disinfection and cleaning concentrate based on a combination of aromatic alcohols, quaternary ammonium compounds, amphotere Glycin-derivates and non-ionic surfactant	Alcohol and quaternary ammonium compounds				Ready for use
MELISEPTOL	B.Braun	Ready-to-use disinfec-tion for spraying or wiping.	Alcohol				Ready for use
Descogen	ANTISEP-TICA						
Hexaquart plus	B.Braun	Surface disinfection and cleaning of inventory and floors.	surface disinfec-tion, free of aldehydes and aminel				con-cen-trate
Indicin Extra N	ECOLAP GmbH	Surface disinfection with Glucoprotamin and QAV, free of aldehydes	Alcohol				
Indicin FOAM	ECOLAP GmbH	Ready-to-use foam spray for alcoholic quick disinfection	Alcohol				
Ultrasol F	Fresenius	Surface disinfection	n-Alkylben-zyldimeth-ylammoni-umchloride, Glutaral				
Mucocit-T	Merz	Aldehyd free power-ful free of aldehyde concentrate maintaining high cleaning perfor-mance Safe disinfection approx. from 5 min.					con-cen-trate

Product-name	Producer		Basis material	Con-centra-tion	Plastic	Elas-to-mere	
Sporcid Instr. disinfektion)	Fresenius	Instrument disinfection incl. cleaning used for thermo-labile and thermostable instruments, endoscopes. See more at: http://www.epgonline.org//0rcid%C2%AE/#sthash.sobiobxQ.dpuf	Glutaral 4,5 g, Formalde-hyde 7,6 g.				
Sekusept	ECOLAP GmbH	Cleaning active instru-ment disinfection tion free of aldehydes	Glucoprota-min				

5.1.3) HOUSING SURFACES

Cleaning cycle: daily

Wipe the housing surface of the device down with a damp cloth, moistened with disinfectants. Let the disinfectant work according to the instructions of the manufacturer and make sure that any cleaning residues has been removed. Calcifications should be avoided.

5.1.4) HUMIDIFIER CLINIC COMPLETE

Cleaning cycle: daily

Wipe the housing surface of the humidifier rack down with a damp cloth, moistened with disinfectants. Let the disinfectant work according to the instructions of the manufacturer and make sure that any cleaning residues has been removed. Calcifications should be avoided.

Der humidifier rack clinic is dishwasher safe and can be cleaned with a temperature of 65°C.

Changing cycle: please note the table above

Disposable: Humidifier chamber auto Fill or humidifier chamber manual filling, air lift and Clear Gard 3 bacterial filter

into the respective garbage container (plastic-/domestic waste). Please note also chapter 11 – *Disposal*.

5.1.5) HUMIDIFIER HOME CARE COMPLETE; CLINICAL USE

Cleaning cycle: daily

Wipe the housing surface of the device down with a damp cloth, moistened with disinfectant. Let the disinfectant work according to the instructions of the manufacturer and make sure that any cleaning residues has been removed. Calcifications should be avoided.

Cleaning cycle: weekly

Insert the following individual parts of the disassembled humidifier homecare complete into a container filled with disinfectants: water chamber, cyclone element and lid humidifier. Wipe the housing surface of the device down with a damp cloth, moistened with disinfectant. Let the disinfectant work according to the instructions of the manufacturer. Subsequently, rinse the individual parts with sufficient water and make sure that any cleaning residues has been removed. All individual parts are dishwasher safe and can be cleaned with a temperature of 65°C.

5.1.6) DUST FILTER

Cleaning cycle: weekly

Changing cycle: 3 month

Open the dust filter flap at the backside of the device. Slight pressure on the protruding flapreleases the lock.



The dust filter flap can be removed downwards

Remove the dust filter.

Clean the filter with biodegradable detergents.

- Carefully rinse the air filter with running water.

It is washable to 30°C.

- Wring the filter out and dry well.

Ensure that no moisture can get through a wet air filter.

- Insert a dry air filter.
- In case of a change insert a new air filter.
- Insert the air filter flap with slight pressure until it locks.

Protect the filter from direct sunlight and humidity.

5.1.7) APPLICATOR IN CLINICAL USE

The applicator have to be exchanged after each change of patient.

Cleaning cycle: daily

The applicator is disinfected daily by wiping.

Carefully wipe the nasal cannula down with a damp cloth, moistened with disinfectant. Wipe the complete applicator tube and the plug down with a damp cloth, moistened with disinfectant. Let the disinfectant work according to the instructions of the manufacturer and make sure that any cleaning residues has been removed.

Wipe potentially several times with the damp cloth.

Dispose the applicator into the respective garbage container (plastic-/domestic waste). Please note also chapter 11 – "*Disposal*".

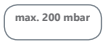
6) DESINFECTION

Using and cleaning instructions are correctly complied with capture 5, a TNI *soft* Flow *50* disinfection is not necessary.

Should a system disinfection be necessary due to a major reason, please contact the manufacturer or your responsible and authorised TNI medical AG representative. They are exclusively allowed to perform this procedure.

7) TECHNICAL DATA

7.1) SYMBOLS ON THE DEVICE

	Manufacturer	TNI medical AG International Hofmannstraße 8 29 01 D-97084 Wuerzburg Phone: +49 931 20 79 29 02 Fax: +49 931 79 29 18 Email: info@tni-medical.de		Power switch: OFF On the switch	The device is disconnected from power supply
	Production date	Indicates the date when the medical product was produced		Power switch: ON On the switch	The device is connected with power supply
	Applied part of type BF	Protection degree for applied part: BF The user is so well isolated by the device that the safety regulations concerning leakage current are met.		CE mark Type label	Confirms conformity with the regulation 93/42/EWG of medical products
IP 21	IP-protection class	Protected against solid foreign objects of 12.5 mm and greater. Protected against Dropt from above		Disposal Type label or only GAW	The **TNI** *soft* **Flow** ***50*** must not be disposed of in household waste. According to the new electric and electronic equipment law (ElektroG) the manufacturer is responsible for the disposal of **TNI** *soft* **Flow** ***50*** . Please contact TNI medical AG regarding the unit`s disposal.
	Batch code	Indicates the batch code of the manufacturer, for that the batch or das Los can be identified		Ambient temperature	The device may only be operated with the ambient conditions
	Item/article number	Indicates the order number of the manufacturer, for that the medical product can be identified.		Attention to the user manual (operating instructions)	Attention to the user manual or please note operating instructions
	Serial number	Indicates the serial number of the manufacturer, for that a particular medical product can be identified.		Max. pressure	Max. pressure allowed at the oxygen intake
	Caution: hot surface	The so marked device parts may get hot surface Heating plate Home care chamber Humidification chamber autofill			

7.2) PERFORMANCE PARAMETERS, TECHNICAL DATA, DEVICE PARAMETERS

TNI *soft*Flow *50*

PERFORMANCE DATA:

Flow rate	10 to 50 l/min
Adjustable in	0,5 l/min steps,
Tolerances	+/- 2 % of index value
Admixture of oxygen	0-20 l/min possible
With l/min – indicator	in the display
FiO_2 indicator	integrated in the display
Humidity dew point	from 30°-37 °DP,
Adjustable in	1°C-steps
Condensate-free gas-air flow	for a pleasant therapy
Event memory	overwiew of the last 12 therapy months
SD-Card	stores all events, mobile data transfer possible
	individual language memory
Language selection for display indicators	available as individual standard german and english

7.3) TECHNICAL DATA, DEVICE PARAMETERS

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 AC, 50-60 Hz
Maximum power system	300 VA
Maximum power heating plate	150 VA
Maximum power applicator heating	48 VA

Device dimensions	
Width	ca. 315 mm
Depth:	ca. 320 mm
Height:	ca. 140 mm
Weight without Humidifier Clinik and without water	< 5,6 kg
Water reserve: Humidification chamber auto Fill Humidification chamber manual filling sterile water bag or bottle water chamber humidifier homecare	 ca. 150 ml ca. 380 ml > 1000ml ca. 650 ml
Applicator	Range of applicators Art-No.
Changing cycle Applicator clinic serie (Expected Service Life):	After < 366 therapy hours, = 14 days á 24 h, Single patient use detailed instructions please note chapter 3.5
Safety level (applied part):	BF
Tube lenght:	1,8 m
Weight: approx.	100 g
typical Humidity	30 ° - 37 ° dew point
Maximum temperature of flow volume escaping to NC	43°C
Shelf life of parts and accessories	Same as TNI *soft* Flow *50*, if no expiration date stated
Environmental conditions	
Ambient temperature:	10° C to 30 °C
Recommended ambient temperature:	18° C bis 28 °C
Ambient Humidity:	15 % to 93 % RH
Ambient air pressure:	700 hPa to 1060 hPa
Flowrate:	10 - 50 l/min.
Average warming-up duration	< 30 min.
Environmental conditions concerning storage and transport	
Temperature:	-25 °C bis 70 °C
Humidity:	< 93 % RH
Air pressure	700 hPa bis 1060 hPa
Electromagnetic compatibility:	EN 60601-1-2: 2007
Filter class of dust filter:	G4 (EN 779: 2003)

Dust filter changing cycle	Please note 3.1.7
Expected operating time (Expected Service Life) of TNI *soft* **Flow** *50*	3-6 years, depends on daily usage
Attached Oxygen source	
Type	Only medical approved oxygen sources may be connected (that includes, but is not limited to IEC 60601-1:2005 and for homecare use IEC 60601-1-11:2010 compliance). For more information, please consult the oxygen user manual or your oxygen retailer. For handling and adjustment, please refer to the according user manual.
Max. pressure allowed at the oxygen intake	200 mbar

8) FEHLERCODES

SAFETY NOTES

- *Some errors lead to the result that the device can no longer be operated*
- *In the case of a fault contact your responsible TNI medical AG representative*
- *Alarm signals will sound to indicate danger for the user to an error that have occurred.*
- *The delay between error condition and error signal can be up to one minute max.*
- *The alarm signals are divided into two steps:*
  - *Alarms with low priority (severity code I):*
    - *1 audible signal sounds*
    - *This procedure is repeated cyclically,*
    - *The error code will be indicated in the display*
    - *When the error is cleared the device is again ready to operate*
    - *The visual indication in the display cannot be switched off.*
  - *Alarms with medium priority (severity code II)*
    - *3 audible signals sounds*
    - *This procedure is repeated cyclically*
    - *The error code will be indicated in the display*
    - *These alarms cannot be switched off via menue*
    - *The device can no longer be operated*
    - *The user is not able to correct the fault*
    - *Contact your responsible TNI medical AG representative*

In the event of failure, the following error codes will be indicated on the display.

Priority acc. to IEC 60601-1-8:2006	
I	low priority
II	medium priority

ALARM- AND ERROR CONCEPT				
Error category	**Priority**	**Error number**	**Indication in the display**	**Description**
10	II	101	Pressure too high	Internal pressure too high(> 90 mbar).
10	II	102	Sensor defective	O2 flow sensor defective
10	II	103	Sensor defective	Air flow sensor defective
10	II	104	No flow	Flow rate is zero
10	I	151	Flowrate not reachable	Measured flow is lower then the set flow (about 2 l/min, depending on the set flow)
10	I	153	Flowrate too high	Measured flow is higher that the set flow (about 2 l/min, depending on the set flow)
10	I	154	Leakage detected	Leakage: Humidification chamber not available or leaking humidification chamber.
10	I	155	Ambient pressure off limits	Ambient pressure off limits (limits see Chapter 7.3)
10	I	156	O_2 flow rate to high	the added O_2 flow rate is to high
10	I:	157	Sensor defective	Pressure sensor defective
20	I	251	Ambient temperature	barometic pressure out of permitted range (limits see Chapter 7.3)
20	II	201	Air temperature too high	Internal air Temperature to high (> 43°C).
20	I	254	Sensor defective	Ambient temperature / humidity sensor defective
20	I	255	Dew point not reachable	Selected dew point not reachable. (difference about 1°C, depending on the set dew point)

Error category	Priority	Error number	Indication in the display	Description
30	II	301	Heating plate overheated	Heating plate overheated. Please check humidifier. Detection: Heating plate temperature is hotter than it should be (Limit depending on set temperature)
30	I	351	Please refill water	Water chamber empty, fill up with water. The water level is not measured directly, but can be determined with the heating plate characteristics.
30	I	352	Heating plate defective	Heating plate defective (no power), contact your responsible TNI medical AG representative.
30	I	353	Sensor defective	Temperature sensor humidifier defective
30	I	354	Heating plate defective	Heating plate defective (no current), contact your responsible TNI medical AG representative.
30	I	355	Sensor defective	System failure, please restart system. In the case of failure contact your responsible TNI medical AG representative
40	II	401	blower defective	Blower blocked, please switch system off/on. In the case of failure contact your responsible TNI medical AG representative
40	II	402	Blower overheated	Blower overheated. Motor temperature is higher than 120 °C.
Motor temperature is higher than 120 °C.	II	403	Blower sensor defective	Blower temperature sensor defective

Error category	Priority	Error number	Indication in the display	Description
40	II	404	Fan blower defective	Fan blower defective, please contact your responsible TNI medical AG representative
50	II	501	-	Display defect, please restart system. In the case of failure contact your responsible TNI medical AG representative. Display defect. Error is not displayed, but you should hear an alarm signal.
50	II	502	System failure	Sensor errors on system startup, please restart system. In the case of failure contact your responsible TNI medical AG representative.
60	II	601	Sensor defective	Temperature sensor applicator defective
60	II	602	Air flow too hot	Air temperature at nasal cannula higher than 43°C (external Measurement mandatory)
60	II	603	ext. Measuring element not detected	External measurement element at nasal cannula not detected, please check.
60	I	651	Applicator heating defective	Applicator heating defective.
60	I	652	Applicator not detected	Applicator not detected, please change.
60	I	653	Type of applicator!	The selected real flow rate is too high for this type of applicator. Reduce flowrate or use a larger applicator.
70	II	701	System failure	EEPROM damaged, please restart system. In the case of failure contact your responsible TNI medical AG representative.

Error category	Priority	Error number	Indication in the display	Description
70	II	702	System failure	Operating system error, please restart system. In the case of failure contact your responsible TNI medical AG representative.
70	II	703	System failure	EEPROM defective, please restart system. In the case of failure contact your responsible TNI medical AG representative
70	II	704	System failure	User settings damaged, please restart system. In the case of failure contact your responsible TNI medical AG representative.
70	II	705	System failure	Firmware not usable with this device, please restart system. In the case of failure contact your responsible TNI medical AG representative.
70	I	751	SD-card not available	SD card not available
70	I	752	SD-card or file defective	SD-card checksum error
70	I	753	System failure	Battery voltage too low, please restart system. In the case of failure contact your responsible TNI medical AG representative.
70	I	754	System failure	Firmware checksum error (on SD card update), please restart system. In the case of failure contact your responsible TNI medical AG representative.
70	I	755	System failure	Firmware not usable with this device (on SD card update), please restart system. In the case of failure contact your responsible TNI medical AG representative.
80	I	851	Clean the filter	NOTE: change filter; filter should be changed every 3 month

Tabelle 5 - Fehlernummern

9) SERVICE/MAINTENANCE

NOTE

- *The user/clinic is responsible for the maintenance of the* TNI *soft* **Flow** *50*
- *Overhauling/service must exclusively be performed by authorized TNI medical AG technical staff*
- *The device housing must exclusively be opened by authorized TNI medical AG technical staff, this includes the changing of the fuses. Excepted: using and cleaning of the removable parts*
- *Only use power connecting cable distributed by TNI medical AG*
- *Disconnect always the power cord from the plug before opening the device*

Due to the technical innovation the TNI *soft* **Flow** *50* does not need any maintenance work, these systems are maintenance-free.
Please follow the instructions concerning security and hygienic measures to guarantee a secure and longterm operation of the device.
Furthermore, please perform a visual check before every application and check the correct functioning of TNI *soft* **Flow** *50*.
Please contact your responsible TNI medical AG representative if any unexpected operation, events, damages or malfunctions occur. The technical service assigns a number in order to guarantee an efficient processing of the incident. Please indicate this number at every further contact with the technical service. The TNI *soft* **Flow** *50* should be checked every 2 years after commissioning by the responsible TNI medical AG representative in order to guarantee the security for the user and to meet the terms of TNI *soft* **Flow** *50*'s quality.

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10) WARRANTY

The device was manufactured with the utmost care und tested in detail before shipment
The warranty period is 1 year from the date of purchase (proving an invoice and/or guarantee certificate with dealer stamp). The TNI medical AG will replace defective parts of the device within the period of guarantee. The period of guarantee will not be extended through the case mentioned above. Warranty does not cover operational wear and consumption parts (e.g. dust filter, water chamber etc.) and assets subject to a restricted period (e.g. applicator etc.).
Replaced parts become the property of TNI medical AG, any further claims (by the purchaser) are excluded.

Warranty expires through:

- Assembly, extensions, resettings, changes or repairs by unauthorized persons.
- Non-compliance with the operating instructions
- Damages caused as a result of operating errors
- Improper use or handling
- Use of non-original spare parts
- Force majeure (e.g. lightning etc.)
- Transport damages due to improper packaging when returning

- Opening of the housing by unauthorized persons. Exception: Using and cleaning of the removable parts without tools.

If the complaint proves to be unjustified, the customer must bear the costs of checking and shipping of the device. Please store the original packaging in the case of service. If the original packaging is no longer available contact the customer service. If you send us your device without the original packaging and damage results from this, we have to charge the repair. Furthermore, we have also to charge the special packaging for the return.
We thank you for your understanding

11) DISPOSAL

The TNI *soft* **Flow** *50* was produced in accordance with the relevant standards. The design together with the simple disassembly facilitate the disposal.

Electronic waste

According to the new electric and electronic equipment law (ElektroG) the manufacturer is responsible for the disposal of TNI *soft* **Flow** *50*

Please contact TNI medical AG regarding the unit`s disposal.

Packaging material TNI *soft* **Flow** *50*

Classification: do not dispose

Please store the original packaging in the case of service. If the original packaging is no longer available contact the customer service. If you send us your device without the original packaging and damage results from this, we have to charge the repair. Furthermore, we have also to charge the special packaging for the return.

Applicator Classification: domestic waste

Used applicators can be disposed with the normal household waste after expiry of change interval.

Classification: domestic waste

- MRP-Hygiene filter,
- MPR air lift
- Humidification camber auto – fill
- Humidification chamber manual filling

Used MRP can be disposed with the normal household waste after expiry of change interval.

Clinic chamber classification: domestic waste

Used clinic chambers can be disposed with the normal household waste

Home care chamber, chamber cover, cyclon element, classification: domestic waste

Used parts can be disposed with the normal household waste

12) ELECTROMAGNETIC COMPATIBILITY (EMC)

SAFETY NOTE

- *The "TNI soft Flow 50" is a MEDICAL ELECTRICAL EQUIPMENT and needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.*
- *Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT!*
- *The "TNI soft Flow 50" should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary the "TNI soft Flow 50" should be observed to verify normal operation in the configuration in which it will be used.*
- *The use of other accessories , cables or converters to the device " TNI soft Flow 50" can increase the emission and reduce the immunity of the " TNI soft Flow 50 " .*
- *In accordance to the applicable standard the "TNI soft Flow 50" has no essential performance.*
- *The "TNI soft Flow 50" may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.*

Guidance and manufacturer's declaration - electromagnetic emissions		
The "TNI soft Flow 50" is intended for use in the electromagnetic environment specified below. The customer or the user of the "TNI soft Flow 50" should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The "TNI soft Flow 50" uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The "TNI soft Flow 50" is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 6 -Guidance and manufacturer's declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic immunity			
The "TNI *soft* Flow *50*" is intended for use in the electromagnetic environment specified below. The customer or the user of the "TNI *soft* Flow *50*" should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 610004-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines [no input/output lines with > 3 m present]	Mains power quality should be that of typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) [no earth present]	Mains power quality should be that of typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of typical commercial or hospital environment. If the user of the "TNI *soft* Flow *50*" requires continued operation during power mains interruptions, it is recommended that the "TNI *soft* Flow *50*" be powered from an uninterruptible power supply or battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 7 - Guidance and manufacturer's declaration - electromagnetic immunity 1

Guidance and manufacturer's declaration - electromagnetic immunity

The "TNI *soft* Flow *50*" is intended for use in the electromagnetic environment specified below. The customer or the user of the "TNI *soft* Flow *50*" should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the "TNI *soft* Flow *50*", including cables, than the recommended separation distance caculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a 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 theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the "TNI *soft* Flow *50*" is used exceeds the applicable RF compliance level above, the "TNI *soft* Flow *50*" should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TNI *soft* Flow *50*. b Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.			

Table 8 - Guidance and manufacturer's declaration - electromagnetic immunity 2

Recommended separation distances between portable and mobile RF communications equipment and the "TNI *soft* Flow *50*			
The "TNI *soft* Flow *50*" is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the "TNI *soft* Flow *50*" can help prevent electromagnetic interference by maintaining a miminum 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.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz d = 1.2√P	**80 MHz to 800 MHz** d = 1.17√P	**800 MHz to 2.5 GHz** d = 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.37	0.73
1	1.2	1.2	2.3
10	3.8	3.7	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

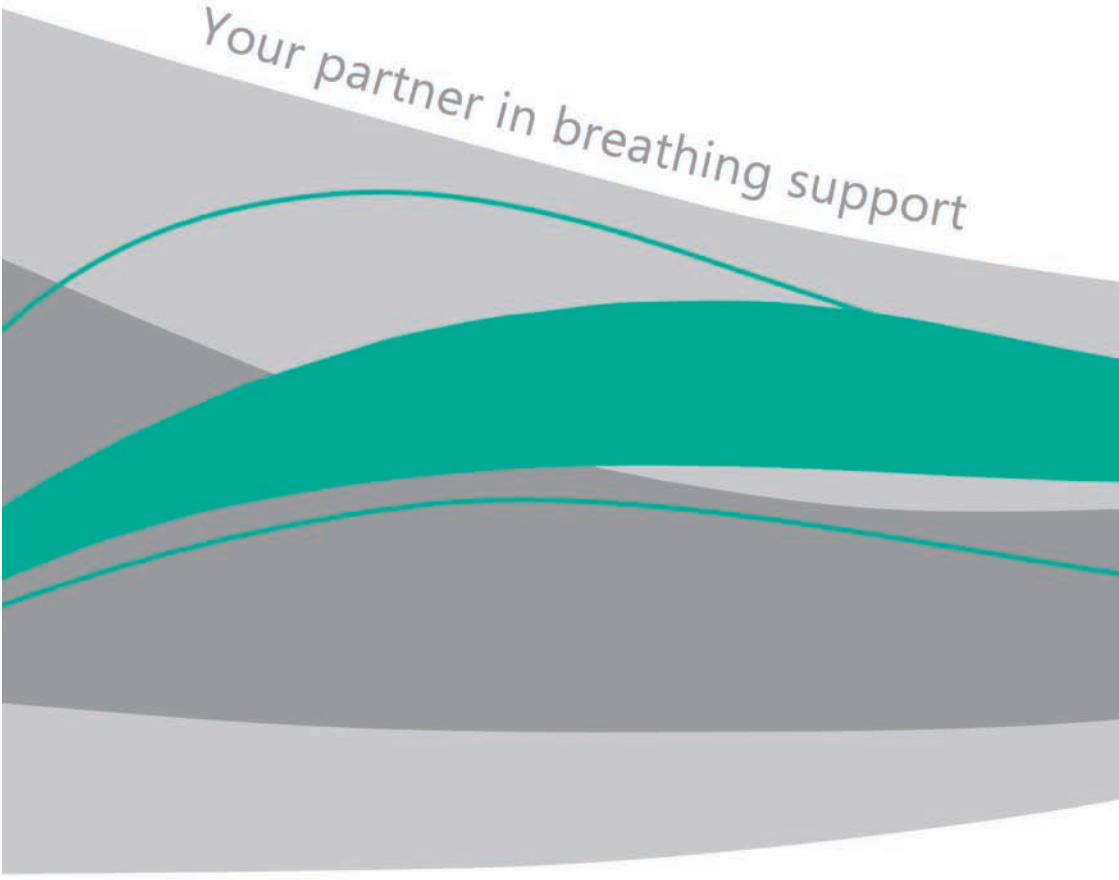
Table 10 - Recommended separation distances between portable and mobile RF communications equipment and the "TNI soft Flow 50"

FROM THE CLINIC TO HOME CARE

- with the TNI *soft* Flow *50* system you will be able to fulfill all clinical requirements
- with the TNI *soft* Flow *50* system you will be able to fulfill all clinical requirements identically and safely in succeeding home care therapy as well

TNI *soft* Flow therapy follows the patient!

Your partner in breathing support



TNI medical

Diagnostik
Therapie
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