User Manual

NanoVi® Devices

Medical Device

Eng3 Corporation

English

M004-rev19

eng3

Life Science Technology

eng3

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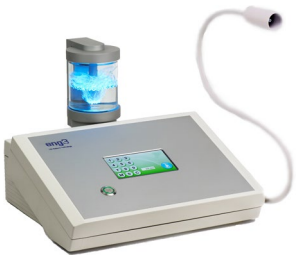
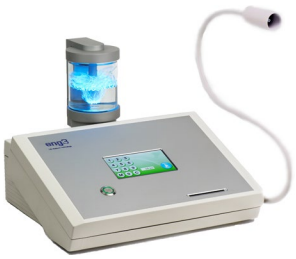
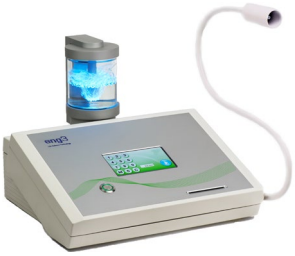
NanoVi® Eco / NanoVi® Pro / NanoVi® Exo

User Manual

User Manual
M004-rev19

eng3

Table of Contents

1 Device Description

The process that takes place within the NanoVi® device occurs in three steps:

1. Creation of a continuous air stream by sucking in ambient air.
2. Humidification of the air stream, enriching the air stream with water molecules.
3. Generation of specific electromagnetic energies/wavelengths/signals that are highly absorbable by water molecules.

The NanoVi® device is designed to assist the natural process of creating ordered water layers (EZ Water) on proteins. NanoVi® devices expose the humidified air stream to specific wavelengths. These wavelengths also include wavelengths that are similar (= bioidentical) to the emitted wavelengths of the reactive oxygen species (ROSs) that occur in the water of cells. The wavelengths / signals from the NanoVi® are emitted to water in a humidified air stream, which strengthens the coherent domains of the water molecules, and which are then transmitted to the user via the humid air stream.

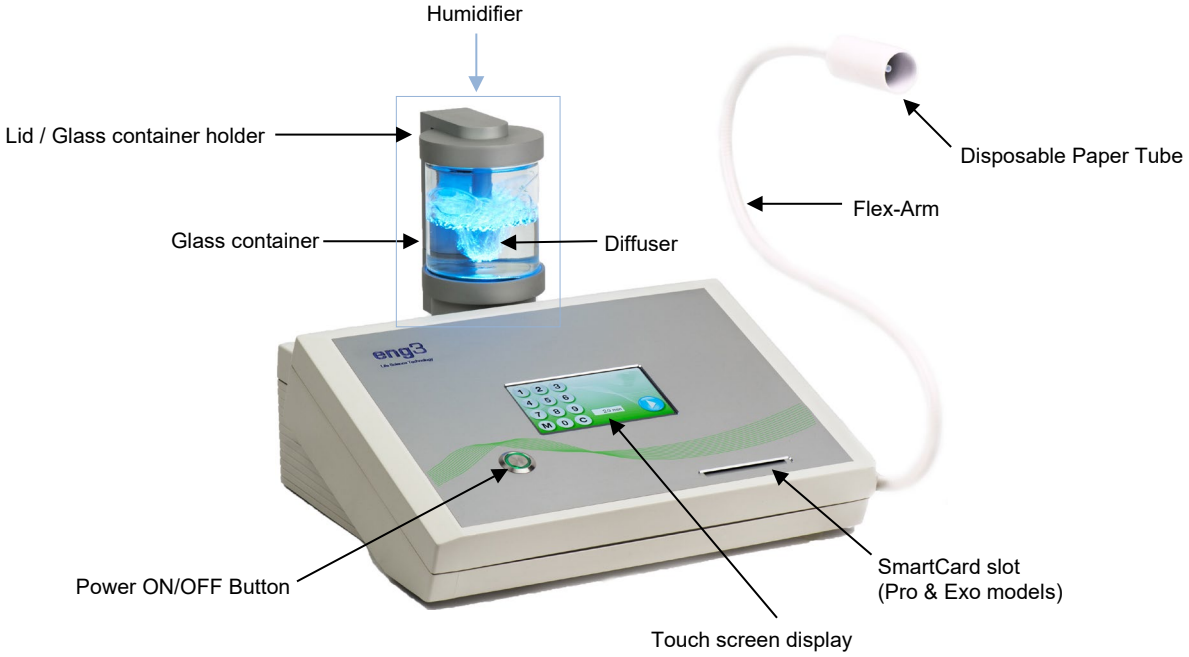


Fig. 1.1: Front view of the NanoVi® Exo device

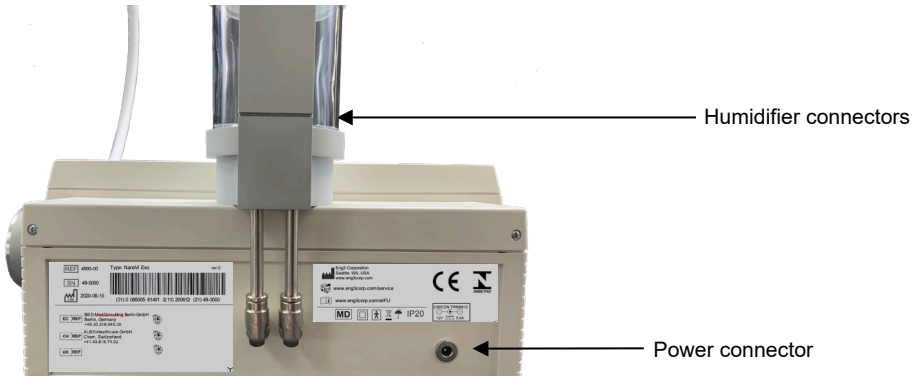


Fig. 1.2: Back view of the NanoVi® device

The NanoVi® device has a universal power supply and is plugged into a standard power outlet, 110V to 220V.

The external power supply provides isolation from supply mains. Do not position the equipment so that it is difficult to operate or connect the external power supply.

4340-00		Power Supply: C8 (2-prong), 110-220V for: For Power Cord with C7 (2-Prong)  The 2-prong Power Supply is the standard power supply used with NanoVi and NanoVi Wellness devices
4350-00 4350-10 4350-20 4350-30	Power Cord C7: to 2-prong 6.5 ft. (2.0m) Type A Type C Type G Type I	 Type A (US, CA, Mexico, Japan) Type C (EU, Asia, Israel, South America) Type G (UK, Malaysia, Singapore) Type I (AUS, New Zealand)
4350-60	Power Cord C7: to 2-prong 6.5 ft. (2.0m) Type A-CH	 Type A-CH (China)

Figure 1.3: Power supplies and power cords

1.1 Intended Use

The NanoVi® device is intended for use by adults, or under the supervision of adults, to provide humidified air without heating for inhalation by the user. The state of water in NanoVi® humidified air ultimately increases the exclusion zone, also known as the order of water (ordered water) on surfaces around small particles.

The NanoVi® device may be used in a home use environment, including offices, spas, sports, and healthcare facilities.

2 Contraindications

There are no contraindications to report with the use of the NanoVi® device.

3 Possible Side Effects

No side effects are attributable to the use of the NanoVi® device.

4 Precautions

Read the User Manual carefully before using the NanoVi® device for the first time.

- Refer to the User Manual whenever questions or uncertainties arise with respect to correct handling of the NanoVi® device.
- Before use, make sure that the water level in the container is between the maximum and minimum levels marked on the container. Never fill above the maximum level as a higher level could cause water drops to enter the tubing.
- Change the water in the glass container regularly. At least once a day if there are multiple users and at least once a week or every five hours of use for individual users. Use only distilled, purified or osmotic water. Normal water could cause chalky deposits in the diffuser and the glass container.
- Never use the device if any part of the humidifier is damaged. A defect can cause leakage and penetration of water into the inner parts of the device. Contact your retailer to purchase a replacement.
- Protect the NanoVi® device from extreme temperatures and moisture during operation or storage. These conditions can damage internal components.
- The device should only be used on a stable surface. The NanoVi® device should not be used during transport.
- The outside surfaces of the system are not a source of potential allergic reaction.
- The effects of lint, dust, and light (including sunlight) will not adversely alter or affect system performance.
- The user is not required to access small parts during normal use of the system. Multiple disassembly steps are required to access small parts, and they therefore are not easily accessible to children and pets. The system is not susceptible to damage or access by pests; the power cord is medical grade.

- The power supply cord is medical grade and of standard length (2m). It is easily detached from the system to minimize entanglement.
- The nasal cannula includes a feature that allows for easy and quick disconnection from system.
- This product is not designed for use on an unconscious USER (unresponsive to stimuli). If the USER is unresponsive to stimuli do not use this product.
- This product is not designed for use in Oxygen-rich environments. Do not use in or near Oxygen-rich environments.
- This product meets basic safety requirements and does not introduce additional hazards used in a home healthcare environment
-  However, this product is not water or drip resistant and should be kept dry. Do not use in wet environments or areas that may have splash or drip issues
- Spilling water on the device may be hazardous and may damage the device. Do not spill water on the device.
- No modification of this equipment is allowed. Any changes could cause harm or increase hazard for the OPERATOR or the USER. The warranty is void if any modification is made to this equipment.
- Do not carry the device with the humidifier installed. The humidifier is not secured to the device and could fall and cause injury to the OPERATOR, USER, or another person or animal, or could damage other objects or surfaces.
- Do not connect or attach any item that is not specified as an attachment by the manufacturer.

The product is intended to be operated within the following environmental conditions:

- a temperature range of 59°F (15°C) to 104°F (40°C);
- a relative humidity range of 15 % to 90 %
- vapor partial pressure greater than 50 hPa; and
- atmospheric pressure range of 700 hPa to 1060 hPa.

The product is intended to be stored and transported within the following environmental conditions:

- -13°F (-25 °C) to 104°F (40°C), and
- 41°F (5 °C) to 95°F (35 °C) at a relative humidity up to 90 %
- 95°F (35 °C) to 158°F (70 °C) at a water vapor pressure up to 50 hPa
- atmospheric pressure range of 700 hPa to 1060 hPa.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

4.1 Device and Accessory Precautions

- If the power cord is damaged or the casing of the power supply is cracked or damaged in any way, DO NOT USE IT.
- Always use the power supply (power adapter) provided by Eng3. Operation is restricted to 12V DC at the device input. If the original power adapter is defective or lost, only replace it with a power supply provided by Eng3. Power supply must be an IEC 60601-1 compliant power supply. Use of any other supply is prohibited.
- If you intend to use the optional nasal cannula, only use the Salter Labs model 1600-1, 1 foot long.

5 Initial Set Up

5.1 Unpacking Device & Accessories

1. Inspect shipping box for damage upon arrival. Contact your retailer immediately if the box is damaged.
2. Unwrap the NanoVi® device carefully and keep the original packing materials for future transportation of the device.
3. Place the NanoVi® device on a flat, clean surface, such as a table.
4. Unpack all accessories and place them beside the device.

5.2 Set Up

There are no special tools or materials required for setup other than distilled, purified or osmotic water to clean and fill the glass container. The user who receives treatment is the USER and when they also operate the device, they are considered the OPERATOR and SERVICE PERSONEL.

Do not connect or attach any item that is not specified as an attachment by the manufacturer.

This product is not meant to be used in temperatures below 59°F (15°C) or temperatures exceeding 104°F (40°C).

Follow these steps to set up your device:

1. Use indoors, away from wet/splash/drips, between 59°F (15°C) to 104°F (40°C).
2. Place the NanoVi® device on a clean, solid surface.
3. Rinse glass container using distilled, purified or osmotic water.
4. Fill the container with distilled, purified or osmotic water. Make sure the water is between the maximum and minimum filling levels on the container.

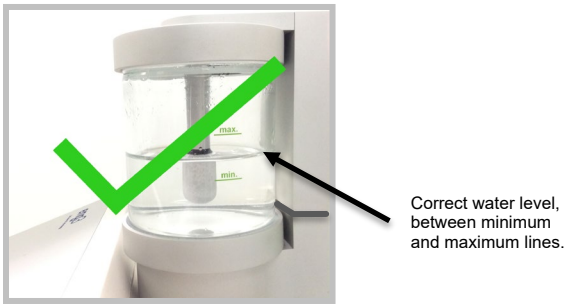


Fig. 5.1: Correct water levels (between min and max)

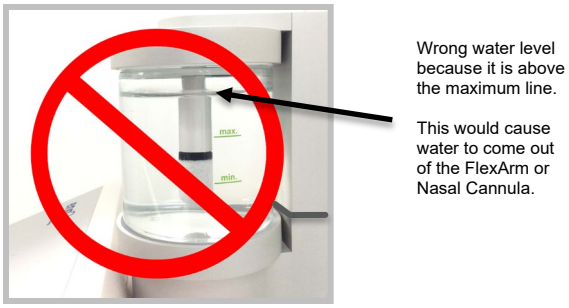


Fig. 5.2: Incorrect water levels (not between min and max)

Fill water at least to the minimum filling level as indicated on the container. Adequate air humidification depends on the amount of available water. (Figure 5.1)

Do not fill the container with more water than the maximum filling level indicates, as water drops or water may enter the tube system or device. (Figure 5.2)

5. Screw the glass container into the glass container holder by hand.
6. Insert humidifier into the fitting on the top of the device, at the back. The connecting tubes protruding from the humidifier slide down into the device as shown in Figure 5.3.

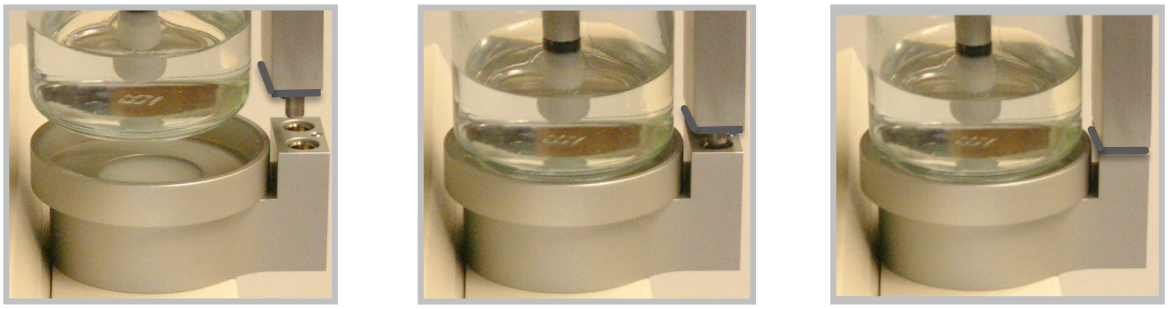


Fig. 5.3: Inserting humidifier into the device

Only insert the humidifier with the glass container facing the front of the device. The glass container must be aligned with the circular metal component on top of the device. Inserting the humidifier in any other position, could injure the USER or damage the device.

Do not tip the container when container is filled with water, as water may enter the tube system or device.

Confirm that there is a proper connection between the humidifier and the device.

Do not force the humidifier into the device; it will fit firmly.

7. Connect the power cord to the power supply. Plug the power supply into the NanoVi® device. Note Figure 1.2 to locate the power connector on the back of the device. Plug the power cord into an electrical outlet.

The NanoVi® device is now ready for operation.

6 Operating Instructions

6.1 General Use

The process that takes place within the NanoVi® device occurs in three steps:

1. Creation of a continuous air stream by sucking in ambient air.
2. Humidification of the air stream, enriching the air stream with water molecules.
3. Generation of specific electromagnetic energies/wavelengths/signals that are highly absorbable by water molecules.

The NanoVi® device is intended to be used on a flat surface. The device may be moved on a cart with the humidifier installed but should never be carried with the humidifier installed because it could fall off and do damage. The USER can be standing, sitting, or lying down. The Flex-Arm bends following its natural curvature and should be positioned for comfort. The device can be used with or without a nasal cannula. When used with a nasal cannula, the USER should be positioned close enough to the device that there is never tension (pulling) on the nasal cannula. The nasal cannula should be worn correctly (see Section 6.3) as show in Fig. 6.1. See Appendix A for proper nasal cannula use. If the USER is using the device with no cannula, the Paper Tube should be positioned 1-3 inches (2-8 cm) away from the nose as show in in Fig. 6.2. The nasal cannula includes a quick disconnect feature which allows for easy connection and disconnection from the system.

Fig. 6.1: Use of Flex-Arm with attached option Nasal Cannula

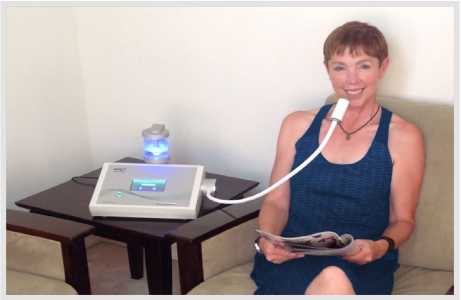


Fig. 6.2: Use of the Flex-Arm with attached Paper Tube

6.2 Use of Flex-Arm

NanoVi® devices come with an installed Flex-Arm, as shown in Fig. 6.3.

Place one of the disposable paper tubes that come with the device onto the end of the arm and push it on to fit snuggly.

Gently pull the Flex-Arm towards your face. The end of the paper tube should be in front of you mouth/nose area, 1-3 inches (2-8 cm) away, as shown in Fig. 6.4. The Flex-Arm can be moved and repositioned for comfort but must not be bent sharply. It is important to be sitting or lying still and to have the Flex-Arm correctly positioned so that you are inhaling the output from the device.

Paper tubes are single person use items. Paper tubes can be used multiple times per person.

Fig. 6.3: NanoVi® Pro Device

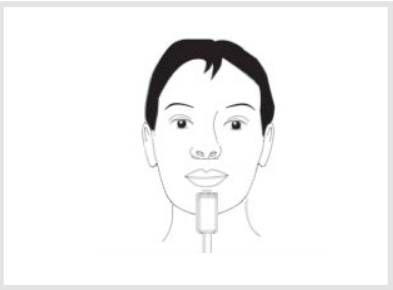


Fig. 6.4: Flex-Arm use

Do not try to bend the Flex-Arm into sharp angles.

Do not move or attempt to lift the device by pulling on the Flex-Arm.

6.3 Nasal Cannula – Optional, Non-Mandatory

The NanoVi® device can be used with an optional nasal cannula inserted on the outlet in the middle of the Flex-Arm. For proper use of the nasal cannula, refer to Appendix A: Accompanying Documents, User Manual for Nasal Cannulas. The NanoVi® device should only be used with the nasal cannula that has the make and model: Nasal Cannula (Adult) Salter Style 1600-1. For proper operation, a short cannula that has one-foot length tubing is used. The one-foot disposable cannula is shown in Fig. 6.5. The user does not have to be still when using the cannula. It allows the user to make small movements and turn their head without interrupting their session. Use of the cannula is shown in Fig. 6.6.

Nasal cannulas are single person use items. Nasal cannulas can be used multiple times per person.

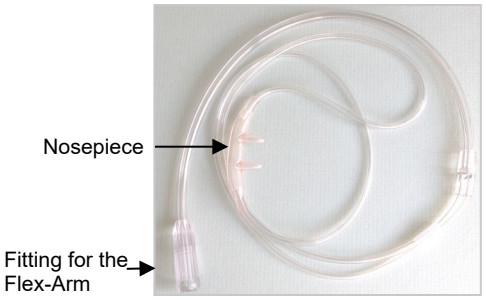


Fig. 6.5: Optional Nasal Cannula

Fig. 6.6: Optional nasal cannula use

Fig. 6.7: Optional nasal cannula connection to outlet

6.4 Power On

Press the large button on the front panel of the device to turn the power on. The power button will illuminate with a green circle and the touch screen display will automatically start with a self-test. Once the device is ready, the screen will display standard user options. Pressing the power button at the end of a session will turn the device off. If you do not turn the device off and it is not used for 15 minutes, it will turn itself off.

6.5 Touch Screen Interface

The touch screen is operated by lightly touching it with a finger. If necessary, a soft blunt object could be used to operate the touch screen. Hard or sharp objects should never be used.

A light vibration occurs each time you press a button, which indicates that your input was registered through the touch screen.

The use of hard or sharp objects to operate the touch screen could result in damage to the device.

6.6 Application Schedule

There is no potential for the device to harm you, even from frequent use, especially once you get used to it. The device can be used for many hours a day if desired to incorporate in your daily life.

Importance of the different power levels of the different NanoVi® devices regarding the session time: The NanoVi® Exo device is twice as powerful as the NanoVi® Pro device and the NanoVi® Pro device is twice as powerful as the NanoVi® Eco device. As a result, a chosen session time for example of 15 minutes with the Exo device is similar to 30 minutes with the Pro device, or 60 minutes with the Eco device.

It is recommended that users start using the device in short increments of time, in order to become familiar with the operation of the NanoVi® Exo, NanoVi® Pro, and NanoVi® Eco.

6.7 Lights Illuminating the Glass Container

This lighting has no bearing on the USER'S treatment and can be set to any preference as needed.

The lights illuminating the glass container are adjusted in the "Color Selection"-Screen (Fig. 6.9). This screen is accessed by touching the Color Wheel button. The Color Wheel button is available in several screens when a session is started.

The default light setting is blue. This can be changed to a different color or to a transition of colors. The device keeps running while you are in the "Color Selection"-Screen" (Fig 6.9) so you can see the effect of any changes before leaving the screen. The Screen shows the color options available. Touch a circle to select a color. Pressing the white circle eliminates the color but leaves the water illuminated.

The *Brightness Level* is adjusted by pressing the *Sun* or the *Moon* symbol. To turn the lights off, press the *Moon* symbol until the illumination disappears. The orange *Brightness Level bar* will be all the way to the left.

Start the *Color Transition* (rotation) by pressing any part of the *Color Transition bar.*
The color transition speed is selected by pressing the *Slow Wave* or *Fast Wave* symbol.

Stop the colors from changing by pressing any individual color circle.

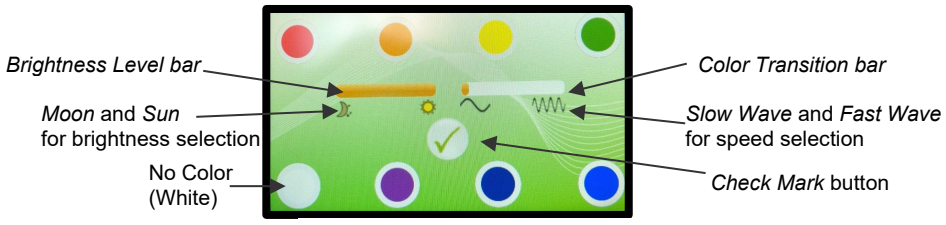


Fig. 6.9: "Color Selection"-Screen

Once you have selected your preferences, press the *Check Mark* button near the middle of the screen (Fig. 6.9). This saves the settings and takes you to the "Start"-Screen to start your session.

6.8 Session Running

When a session is started you will hear a quiet humming sound, see bubbles in the glass container, and, if the lights are turned on, see the illumination of the water in the glass container.

If the water is bubbling, the device is operating correctly. If it is not bubbling, check to make sure the humidifier is correctly seated in the back of the device and that the glass container is firmly screwed into the glass container holder. Correctly seating the humidifier also minimizes the noise.

7 Operating without Smartcards: *Standard-Mode* only

All the NanoVi® devices can be operated without SmartCards. This operation is called *Standard-Mode*.

In *Standard-Mode* everyone has access to sessions of any duration.

Once the device is turned on, the initial “Splash”-Screen (Fig. 7.1) appears. A self-test runs for 10 seconds with progress shown by the bar at the bottom of the screen.

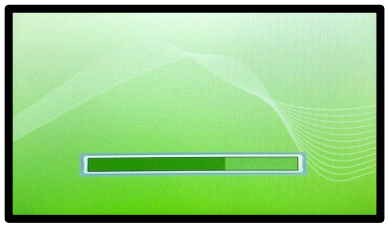


Fig. 7.1: “Splash”-Screen

Upon completion of the self-test, the “Start”-Screen (Fig. 7.2) appears allowing you to enter the number of minutes for the session time. Enter the desired session time by touching the appropriate numbers on the touch screen. The minutes are shown in the session time display in the center of the screen.

Touching the “C” clears a number that has been entered, allowing you to change your input. The “M” on the “Start”-Screen” lets you save the session time in the memory of the device as the default session time for future sessions, unless changed again.

Once the session time is entered, touch the blue start button to begin the session.

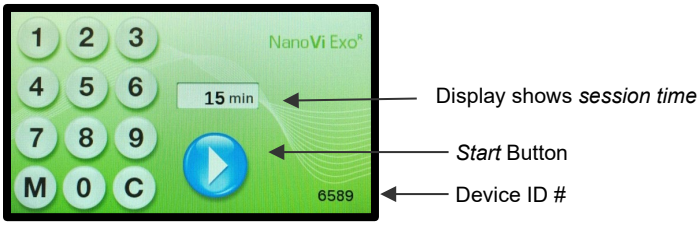


Fig. 7.2: “Start”-Screen
in Standard Mode

The *Start* Button starts the session, and the “Session in Progress”-Screen (Fig. 7.3) is shown. *Rotating dots* to the left indicate that a session is in progress. The *session time* display counts down the minutes and seconds remaining in the session.

Pause Button interrupts a session (Fig. 7.**3**) and changes the screen to “Session Paused”-Screen (Fig. 7.4). Pressing the *Start* Button again resumes the session.

Stop Button terminates a session at any time. Stopping the session takes you back to the “Start”-Screen (Fig. 7.2).

The device will automatically turn off after 15 minutes when a session is not in progress.

Fig. 7.3: “Session in Progress”-Screen
in *Standard-Mode*

Fig. 7.4: “Session Paused”-Screen
in *Standard-Mode*

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8 Operating with SmartCards

The Owner Card can be used by the device owner to access the four “Administration”-Screens.

Insert Owner Card when the monitor shows the self-test is finished in the Initial “Splash”-Screen and the monitor has changed to one of the three “Start” Screens for *Standard-Mode* (Fig. 7.2), for *Infinity-Mode* (Fig. 8.4) or the “User Card Request”-Screens (Fig. 8.7) for one of the two *User-Card-Modes*.

When inserted, it shows the first “Administration”-Screen, the “Mode Setting”-Screen (Fig. 8.1). In this screen you can select an Operation Mode, set device preferences, show the rent time (number of minutes of use), and allows you to reset the rent time by pressing the Reset rent time button.

Pressing the “Page down” button will show the second “Administration”-Screen, the “Programming”-Screen (Fig. 8.16) for User Cards. Pressing the “Page up” button will bring you back.

8.1 Owner Card

The Owner Card can be used by the device owner to access the four administration screens.

Insert Owner Card when the monitor shows the self-test is finished in the “Initial Splash Screen” and the monitor has changed to one of the three “Start Screens” for Standard Mode (Fig. 7.2), for Infinity Mode (Fig. 8.4) or the “User card Request Screen” (Fig. 8.7) for the two User Card Modes (Fig. 8.7, Fig. 8.11).

When inserted, it shows the first administration screen, the “Mode Setting”-Screen (Fig. 8.1). In this screen you can select an Operation Mode, set device preferences, show the rent time (number of minutes of use), and allows you to reset the rent time by pressing the Reset rent time button.

Pressing the “Page down” button will show the second administration screen, the “Programming”-Screen for User Cards. Pressing the “Page up” button will bring you back to an “Start”-Screen.

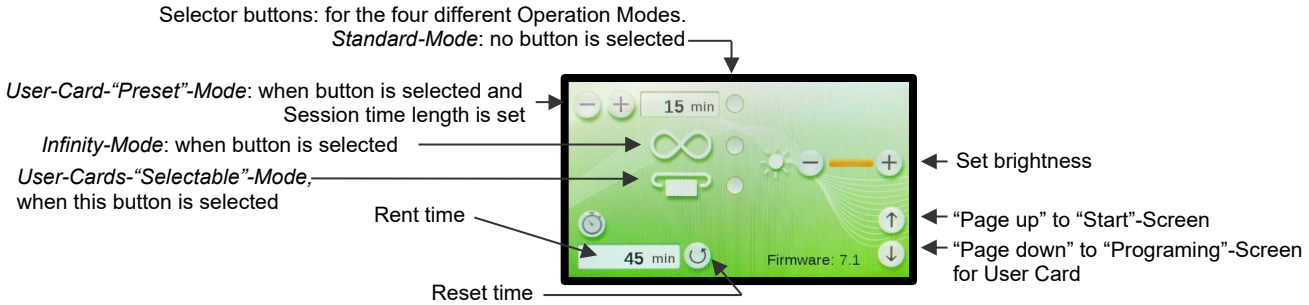


Fig. 8.1: “Mode Setting”-Screen with Owner Card

8.2 Setting Preferences with the Owner Card

Adjust the brightness - of the screen by pressing the appropriate “+” or “–“ symbols. It is not possible to turn the screen off completely by repeatedly pressing the “–“ button.

8.3 Setting *Operating Modes*

With the Owner Card inserted, the first “Administration”-Screen allows you to set the Operation Mode. It can be operated in four different ways: *Standard-Mode*, *Infinity-Mode*, *User-Card-“Timer”-Mode*, and *User-Card-“Preset”-Mode*.

8.3.1 Standard-Mode: Select with the Owner Card and operate without User Card

Selecting: Standard-Mode

To select *Standard Mode*, all three buttons must be deselected, so that no orange dot appears, as shown to the right. Press the buttons to toggle between orange dot and no dot.

When all the mode selector buttons are blank, press the “Page up” button to switch to the “Start”-Screen in *Standard Mode* (Fig. 7.2). Take out the Owner Card.

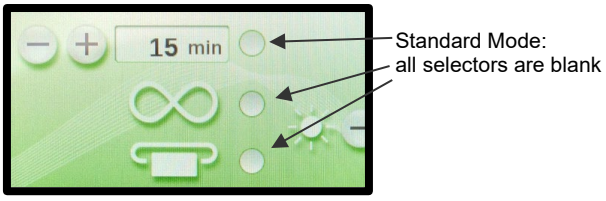


Figure 8.2: Select ‘Standard Mode”

Operating: Standard Mode

To operate in *Standard-Mode* the device does not require a User Card. The device operates as described in Section 7, Operating in *Standard-Mode*.

To operate in *Standard-Mode* make sure that all the mode selector buttons are blank and press the “Page up” button to switch to the “Start”-Screen in *Standard-Mode* (Fig. 7.2). Take the Owner Card out.

8.3.2 Infinity-Mode: Select with the Owner Card and operate without User Card

Selecting: Infinity-Mode

To select the *Infinity-Mode*, the middle button must show an orange dot in the “*Mode Setting”*-Screen (Fig. 8.3). Press button to toggle between orange dot and no dot.

When the *Infinity-Mode* Button is orange, press the “Page up button” to switch to the “Start”-Screen in *Infinity-Mode* (Fig. 8.4). Take the Owner Card out.

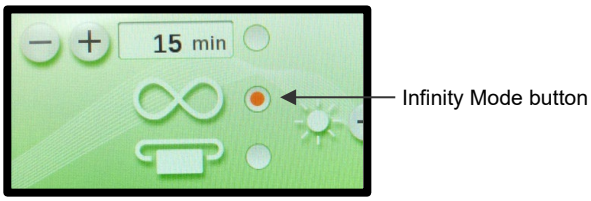


Fig. 8.3: “*Infinity-Mode*” is selected

Operating: Infinity-Mode

To operate in Infinity-Mode the device does not require a User Card.

Start a session by pressing the *Start* Button and the screen will change in to the “Infinity-Session in Progress”-Screen (Fig 8.5). The timer counts and displays the total time that the session is running. The device remains on until the *Pause* or *Stop* Button is pressed.

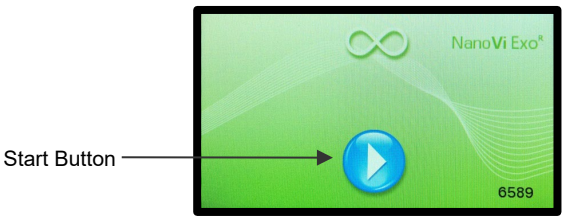


Fig. 8.4: “Start-Infinity”-Screen in *Infinity-Mode*

Fig 8.5: “Infinity-Session in Progress”-Screen in *Infinity-Mode*

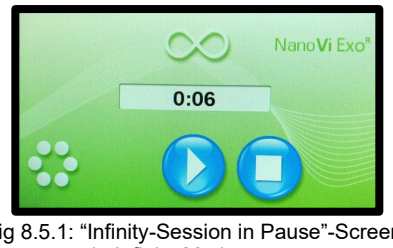


Fig 8.5.1: “Infinity-Session in Pause”-Screen in Infinity-Mode

8.3.3 User-Card-"Timer"-Mode: Select with Owner card and operate with User Card

Selecting: User-Card-"Timer"-Mode

To select the *User-Card-"Timer"-Mode*, the lower button must show an orange dot. Press the button to toggle between orange dot and no dot.

When the mode selector button is orange (Fig. 8.6), press the button "Page up" to switch to the "User Card Request"-Screen**.** Take the Owner Card out.

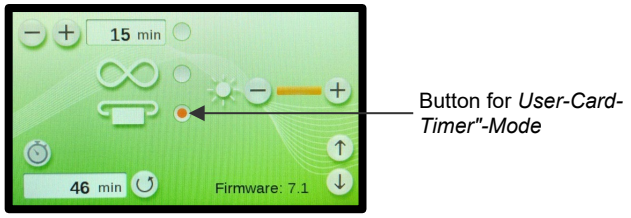


Fig. 8.6: *User-Card-"Preset"-Mode* is selected

Operating: User Card Timer Mode

To operate in *User-Card-"Timer"-Mode* the device requires a User Card.

The "User Card Request"-Screen (Fig. 8.7) shows when a User Card is required.

A valid User Card must be inserted to operate the device.

If the User Card ID #, which is printed on the User Card, is not identical with the device ID#, the "Invalid User Card"-Screen (Fig. 8.7.1) will show.

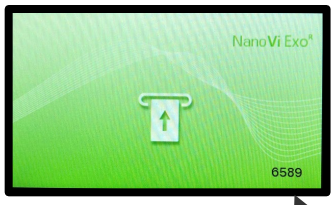


Fig. 8.7: "User Card Request" -Screen

Fig. 8.7.1: "Invalid User Card" -Screen

When the valid User Card is inserted the "Start-Card"-Screen (Fig. 8.8) shows.

The number above the User Card symbol shows the number of minutes remaining on the User Card.

Enter the desired session time by using the number keypad, the minutes entered show in the display. Use "C" to clear entries.

Start the session by pressing the *Start* Button.

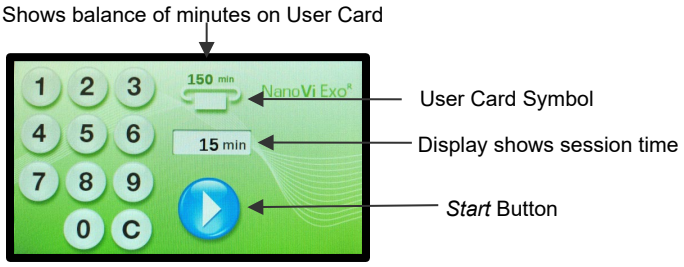


Fig. 8.8: "Start-Card"-Screen in *User-Card-"Selectable"-Mode*

The session time will count down and minutes will be deducted from the User Card.

Pause or stop session at any time by pressing the corresponding blue button in the "Card-Session in Progress"-Screen (Fig 8.9).

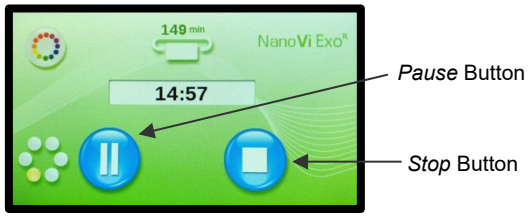


Fig. 8.9: "Card-Session in Progress"-Screen in *User-Card-"Selectable"-Mode*

Restart sessions or stop session at any time by pressing the corresponding blue button in the "Card-Session in Pause"-Screen (Fig 8.9.1).

Stopping the session takes you back to the "Start-Card"-Screen (Fig. 8.8).

Remove the User Card when a session is finished. The screen will return to "User Card Request"-Screen (Fig. 8.7).

Fig. 8.9.1: "Card-Session in Pause"-Screen in User-Card-"Selectable"-Mode

8.3.4 User-Card-“Preset”-Mode: Select with the Owner Card and operate with User Card

The device can be set up with a predetermined session time. In this case the session time cannot be freely chosen, only shortened, or paused.

Selecting: User-Card-“Preset”-Mode

To select the *User-Card-“Preset”-Mode*, the top and the lower selector buttons must show an orange dot. Press button to toggle between orange dot and no dot (Fig. 8.10).

When the two mode selector buttons are orange, press the “Page up” button to switch to the “User Card Request”-Screen (Fig. 8.11).
Take the Owner Card out.

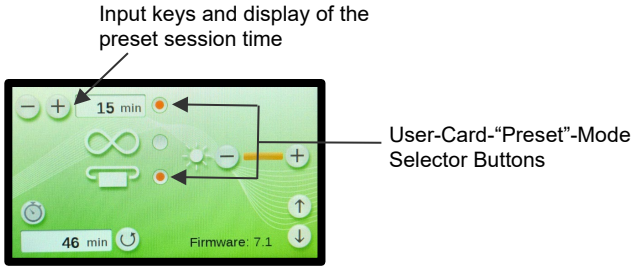


Fig. 8.10: Selected Mode: *User-Card-“Preset”-Mode*

Operating: User-Card-“Preset”-Mode

To operate in *User-Card-“Preset”-Mode* the device requires a User Card.

The “User Card Request”-Screen (Fig. 8.11) shows when a User Card is required.

A valid User Card must be inserted to operate the device.

If the User Card ID #, which is printed on the User Card, is not identical with the device ID#, the "Invalid User Card"-Screen (Fig. 8.11.1) will show.

When a valid User Card is inserted the “Start-Card“-Screen (Fig. 8.12) shows. The number above the User Card symbol shows the number of minutes remaining on the User Card.

In *User-Card-“Preset”-Mode* the session time cannot be modified. The display shows the pre-set session time.

Start the session by pressing the *Start* Button. The session time will count down and minutes will be deducted from the User Card.

Pause or stop session at any time by pressing the corresponding blue button in the “Card-Session in Progress”-Screen (Fig 8.13).

Restart sessions or stop session at any time by pressing the corresponding blue button in the “Card-Session in Pause”-Screen (Fig 8.13.1).

Stopping the session takes you back to the “Start-Card“-Screen (Fig. 8.12).

Remove the User Card when session is finished. Screen will return to the “User Card Request”-Screen (Fig. 8.11).

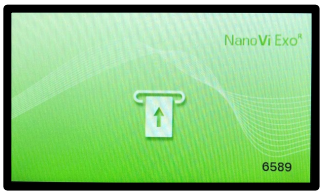


Fig. 8.11: “User Card Request”-Screen (for reference only; identical to Fig. 8.7)

Fig. 8.11.1: “Invalid User Card"-Screen (for reference only; identical to Fig. 8.7.1)

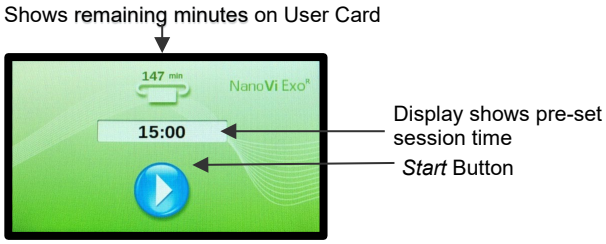


Fig. 8.12: “Start-Card”-Screen in *User-Card-“Preset”-Mode*

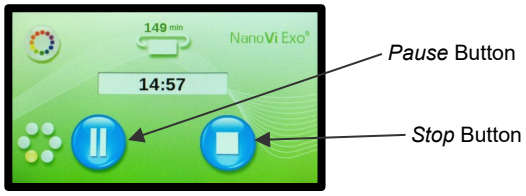


Fig. 8.13 “Card-Session in Progress”-Screen *in* User-Card-"Preset"-Mode

Fig. 8.13.1 “Card-Session in Pause”-Screen *in* User-Card-"Preset"-Mode

8.4 Programming User Cards

The Owner Card is used to program minutes onto the User Cards or delete minutes from the User Card. The Owner Card, the User Card, and the device must have the same ID#.

The maximum number of minutes a User Card can be programmed to is 9,999 minutes. The User Card can be programmed or reprogrammed as often as required.

Insert the Owner Card. The first “Administration”-Screen will appear, the “Mode setting”-Screen (Fig. 8.14).

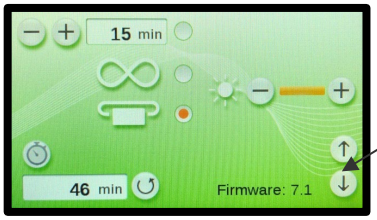


Fig. 8.14: “Mode Setting”-Screen with Owner Card (for reference only; identical to Fig. 8.1)

Press the Page down button to go to the second “Administration”-Screen, the “Switch to User Card”-Screen (Fig. 8.15).

The screen shows the input keypad and the User Card Request Indicator prompting you to enter a User Card.

If the User Card ID #, which is printed on the User Card, is not identical with the device ID#, the "Invalid User Card"-Screen (Fig. 8.15.1) will show.

Remove Owner Card and insert a valid User Card. This will bring up the third “Administration”-Screen which is the “Programming”-Screen (Fig. 8.16).

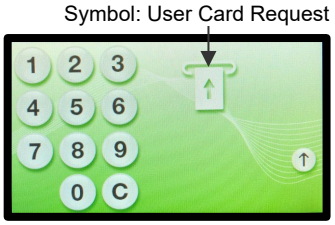


Fig. 8.15: “Switch to User Card” -Screen

Fig. 8.15.1: “Invalid User Card"-Screen (for reference only; identical to Fig. 8.11.1)

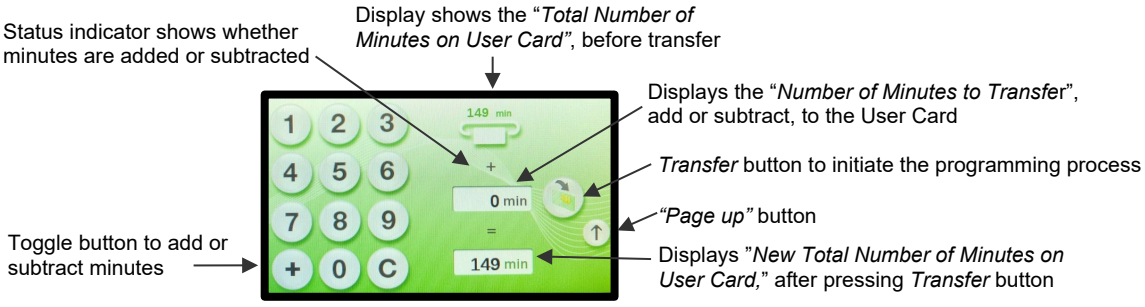


Fig. 8.16: “Programming”-Screen

The screen shows the input keypad with a “C” button to clear an entry and the “-“ or “+“ button. Pressing the *Transfer* button toggles between adding or subtracting minutes to the User Card. The toggle status of the transfer is shown below the display of the “*Total Number of Minutes on User Card*”.

The top display shows the *“Total Number of Minutes on User Card”,* before transfer, on the inserted User Card. With the keypad, choose the “*Number of Minutes to Transfer”*, by adding or subtracting to the “*Total Number of minutes on User Card*”.

The display on the bottom shows the “*New Total Number of* minutes that will be on the User Cards, after the *Transfer* button is pressed.

After pressing the *Transfer* button, the transfer is initiated, and the top display shows the updated “*Total Number of Minutes on the User Card*”.

When the transfer is complete, the “*Number of Minutes to Transfer”* is kept for repeat programming in the display. The bottom display shows the “*New Total Number of* minutes on User Card”, if the *Transfer Button* was pressed.

After removing the programmed User Card, the screen changes back to the “Switch to User Card”-Screen (Fig. 8.15).
For repeat programming, the next User Card can be inserted. If the “*Number of Minutes to Transfer”* is kept, the same number of minutes can be transferred to the next User Card right away. To change the minutes, the “C” button is used to clear the previous entry for new keypad input.

After programming the last User Card press the “Page up” button until one of the three Start Screens: for *Standard-Mode* (Fig. 7.2), for *Infinity-Mode* (Fig. 8.4) or the “User Card Request”-Screen (Fig. 8.7) for the *User Card Modes*.

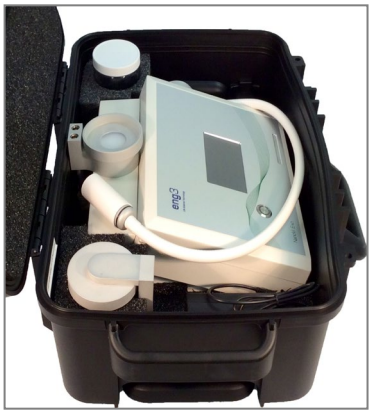
9 Use with Accessories

9.1 Transportation Case

Transportation Case for NanoVi® Device

1: The NanoVi® Transportation Case is a custom-fitted hard-shell case.

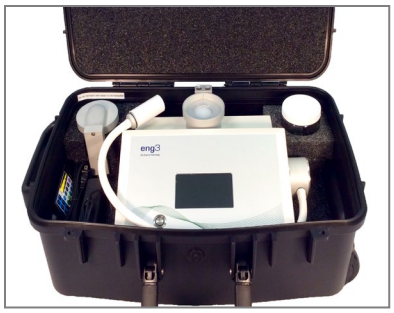
The case is suitable for checked baggage on airplanes. The outer dimension may allow it to be taken as a carry-on but this depends on size restrictions of each airline.

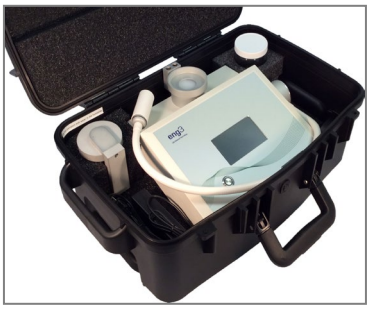


2: The NanoVi device and necessary accessories fit in custom-designed openings.

The humidifier will leak if water is left in the glass container during transportation. Simply switch the extra glass container with the container that has water and tighten the lid for transport.

The NanoVi device can remain in the transportation case during operation.





3: The case has two wheels and a pullout / retractable handle.

The case offers the possibility to be locked (lock not included).

No special handling measures are necessary for transport or storage.

Dimensions:
Length: 22.5” (57 cm)
Width: 15“ (38 cm)
Height: 9” (23 cm)

Weight with device and accessories: 25 lb. (11 kg)
(Weight varies slightly depending on numbers of cannulas you travel with)

10 Cleaning Instructions

Water in the NanoVi® device should be changed at the end of each day when used by multiple users. A single user should change the water at least once a week or every five hours of use, whichever comes first.

Do not perform cleaning, servicing, or maintenance when the device is in use. Only perform cleaning, servicing, or maintenance when the device is powered off and not in use.

Device

Clean the outside of the NanoVi® device with a moist soft cloth, never use more than a mild detergent. Multiple cleanings with this method will not affect the device.

Do not clean with solvents. Solvents are aggressive liquids that could corrode and thereby destroy the surface of the device and the touch screen display.

Humidifier (Glass Container, Glass Container Holder and Diffuser - see Section 1)

The humidifier must be removed from the device by pulling it straight up. The glass container is then unscrewed from the lid / glass container holder.

Do not attempt to unscrew the glass container while the Humidifier is still inserted in the device.

The glass container must be replaced if it is chipped or fractured. The glass container should be inspected for damage every 10 hours of use.

After 10 hours of use the glass container and the lid / glass container holder should be hand-washed then rinsed with clean, distilled, or osmotic water.

The diffuser should be rinsed with clean, distilled, purified or osmotic water. It cannot be cleaned using a dishwasher.

The diffuser must be replaced every 12 months. Additionally, if water residue (such as calcareous deposits) is detected on the diffuser, it should be replaced. Contact information for reordering can be found in Section 18.

Cleaning solution may be harmful and should not be used.

11 Maintenance

The NanoVi® device requires no special maintenance. The USER can only perform the following maintenance:

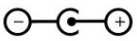
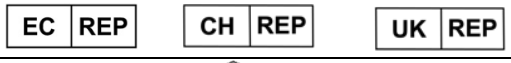
- Renew the humidifier water.
- Replace the diffuser.
- Replace the Paper Tubes or the optional Nasal Cannulas
- Clean the device and the parts listed in Section 10.

12 Storage

For long-term storage prepare the NanoVi® device as follows:

1. Pull the plug of the Power Supply out of the NanoV® device.
2. Disconnect the Power Cord from the electrical outlet.
3. Remove the humidifier from the back of the device and empty the water.
4. Clean all parts according to Section 10.
5. Place cleaned device and accessories in their original boxes (optional).
6. Place sealed box in a dry, safe place that is free from the possibility of accidentally falling.

13 Explanation of Symbols

Symbol	Title
	Direct Current Symbol
	Class II Electrical Equipment
	Type BF Applied Part
 www.eng3corp.com/eIFU	Operating Instructions available on shown website
	“ON” / ”OFF”
	Article Number
	Serial Number
	Manufacturer
	Date of Manufacture
	Keep Dry
IP20	Protected against solid foreign objects of 12,5 mm Ø and greater
	Center Pin Positive
	Owner of waste electronic equipment must recycle these separately from the unsorted municipal waste
	Recycle Packing Material
	Trash
	Symbol indicates compliance with the MDR (Medical Device Regulation 2017/745/EU
	**CE marking** is an administrative marking that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
	Certification of medical electrical equipment in Brazil with accreditation indicated by the INMETRO Mark
	Authorized Representative Service in EU, CH, UK
	Authorized Importers
	Authorized Distributors

14 Disposal of NanoVi® Device and Parts

Follow local governing ordinances and recycling plans regarding the recycling or disposal of the equipment. Refer to the Technical Specifications in Section 16 for the materials of the main components for reference for sorting parts for disposal.

Devices		Disposal
4650-00	NanoVi® Eco	
4800-00	NanoVi® Pro	
4900-00	NanoVi® Exo	
Accessories		
4300-00	Glass Container	
4370-00	Holder with Glass Container	
4340-00	Power Supply Input / Output	
4350-00	Power Cord 2-Prong, 6 ½ ft. (2 m)	
-10	Power Cord 2-Prong, 6 ½ ft. (2 m)	
-20	Power Cord 2-Prong, 6 ½ ft. (2 m)	
-30	Power Cord 2-Prong, 6 ½ ft. (2 m)	
-60	Power Cord 2-Prong, 6 ½ ft. (2 m)	
4530-00	User Manual	
4540-00	Concise User Manual	
Consumables		
4310-00	Diffuser for Humidifier	
4400-00	Paper tube	
Optional Accessories		
4200-00	Transportation Case	
Consumables		
4360-00	Nasal cannulas	
4510-00	User Smartcard	
4510-00	Owner Smartcard	
	Packing material	

15 Troubleshooting

15.1 Normal Operation

As soon as the NanoVi® device starts operation, the air pumps are switched on and the glass container is illuminated. At the same time the water starts to bubble and a humming from the air pumps can be heard.

If the pumps are not humming and the water in the humidifier is not bubbling, the air pumps are not working.

If the pumps are humming but the water in the container is not bubbling, the humidifier has not been correctly inserted into the device. Reseating the connection may resolve this problem. It is also possible that the glass container is not tightly screwed into the glass container holder. Note: Fig. 5.3 to see how the connection should be made.

If the pumps create little or no airflow, the effectiveness of the device is compromised. Refer to the error codes below or contact customer support.

15.2 Errors

If an error occurs, the “Error”-Screen (Fig. 15.1) is displayed. Note the error code number so that you can look it up in the table below. The contact number for your location will be displayed at: www.eng3corp.com/service

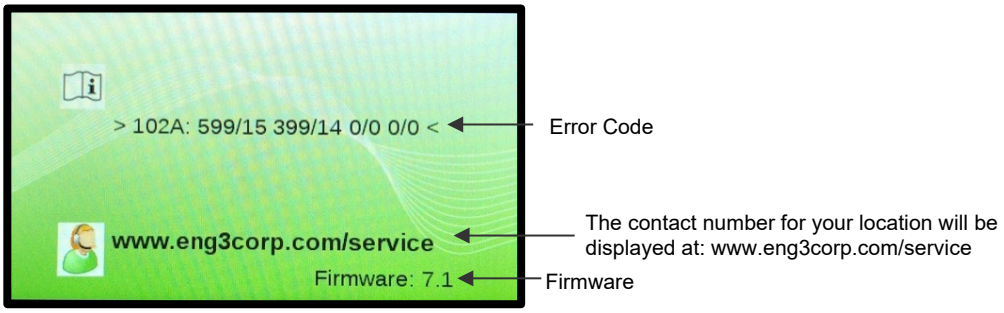


Fig. 15.1 “Error”-Screen

Error codes are below and should be given to Eng3 Customer Support when you call. Use the number of the error message screen to reach technical support for the NanoVi® device.

Code	Error Message
101P: xxx	Pump error
102A: xxx	Excitation unit LED error
103L: xxx	Lamp error

Table 15.1 Lookup table for error codes

16 Electromagnetic compatibility

16.1 Electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The NanoVi is intended for use in the electromagnetic environment specified below. The customer or the user of the NanoVi should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The NanoVi 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 NanoVi is suitable for use in all establishments, including domestic and medical 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	

16.2 Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The NanoVi is intended for use in the electromagnetic environment specified below. The customer or the user of the NanoVi 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	± 8 kV contact ± 2 kV air ± 4 kV air ± 8 kV air ± 15 kV air	± 8 kV contact ± 2 kV air ± 4 kV air ± 8 kV air ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for SIP/SOP Repetition frequency 100 kHz	± 2 kV for power supply lines Repetition frequency 100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5, 1,0 kV line(s) to line(s) ± 0,5, 1,0, 2 kV line(s) to earth	± 0,5, 1,0 kV line(s) to line(s) ± 0,5, 1,0, 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines (Blackouts, brownouts, and fluctuations of the power supply according to IEC) IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NanoVi requires continued operation during power mains interruptions, it is recommended that the NanoVi be powered from an uninterruptible supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The NanoVi is intended for use in the electromagnetic environment specified below. The customer or the user of the NanoVi should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted FR IEC 61000-4-6 Radiated RF Transient RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz 3 V/m 80 MHz to 2,7 GHz 80 % AM by 1 kHz	3 V 150 kHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz to 2,7 GHz 80 % AM by 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the NanoVi, including cables, that the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are normally. **Recommended separation distance** $dd = \frac{3,5}{3}\sqrt{PP}$ $dd = \frac{3,5}{10}\sqrt{PP}$ 80 MHz to 800 MHz $dd = \frac{7}{10}\sqrt{PP}$ 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 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 structure, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radios (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 NanoVi is used exceeds the applicable RF compliance level above, the NanoVi should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NanoVi.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

16.3 Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the NanoVi

The NanoVi is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user if the NanoVi can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NanoVi as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $dd = \frac{3,5}{3}\sqrt{PP}$	80 MHz to 800 MHz $dd = \frac{3,5}{10}\sqrt{PP}$	800 MHz to 2,5 GHz $dd = \frac{7}{10}\sqrt{PP}$
0,01	0,12	0,035	0,07
0,1	0,37	0,11	0,22
1	1,2	0,35	0,7
10	3,8	1,1	2,2
100	12	3,5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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 The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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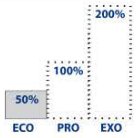
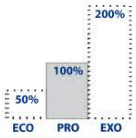
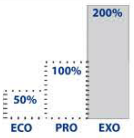
17 Product Specifications and Registrations

17.1 Technical Specifications

	NanoVi® Eco	NanoVi® Pro	NanoVi® Exo
Article Number:	4650-00	4800-00	4900-00
Output performance: NanoVi® Eco has half the output: 50% NanoVi® Pro establishes baseline output: 100% NanoVi® Exo has 2x the output: 200%			
Recommended frequency of sessions:	Optimal: Daily Ideal: 3 x per week Minimum: 1 x per week	Optimal: Daily Ideal: 3 x per week Minimum: 1 x per week	Optimal: Daily Ideal: 3 x per week Minimum: 1 x per week
Suggested session time (More is better)	**60 minutes** on the Eco =	**30 minutes** on the Pro =	**15 minutes** on the Exo
Minimum lifespan:	10,000 hours = 600,000 minutes	10,000 hours = 600,000 minutes	10,000 hours = 600,000 minutes
Minimum # of sessions per lifespan:	**10,000 sessions of 60 minutes**	**20,000 sessions of 30 minutes**	**40,000 sessions of 15 minutes**
Smartcard system: - **Owner Card** - **User Card** works on the device it was programmed for	No	Yes: - Owner Card for selecting the Operation Mode - User Card programmable for up to 9,999 minutes	Yes: - Owner Card for selecting the Operation Mode - User Card programmable for up to 9,999 minutes
Standard mode - Timer Mode:	**Yes**, enter application time in minutes on the touch screen.	**Yes**, enter application time in minutes on the touch screen.	**Yes**, enter application time in minutes on the touch screen.
Mode with Smartcard - Timer Mode:	**No**	**Yes**, used application time gets deducted from the User Card.	**Yes**, used application time gets deducted from the User Card.
- Session Mode:	**No**	**Yes**, session minutes deducted from User Card.	**Yes**, session minutes deducted from User Card.
- Infinity Mode:	**No**	**Yes**	**Yes**
Option for grouping multiple devices: (With Smartcard System only)	**No**	**Yes**, User Card can be used for any device in the group.	**Yes**, User Card can be used for any device in the group.
Lamp for Illumination of water:	16 Colors & off	16 Colors & off	16 Colors & off
Illumination effects:	Solid, flash, strobe, fade, smooth	Solid, flash, strobe, fade, smooth	Solid, flash, strobe, fade, smooth
Excitation units / - elements / max power:	1 / 6 / 6 x 700 pW	2 / 12 / 12 x 700 pW	4 / 24 / 24 x 700 pW
Spectral emission / max power:	1100–1300nm and 1500-1700nm	1100–1300nm and 1500-1700nm	1100–1300nm and 1500-1700nm
Dimensions (w x l x h):	12" x 11" x 9" (31 x 28 x 23 cm)	12" x 11" x 9" (31 x 28 x 23 cm)	12" x 11" x 9" (31 x 28 x 23 cm)
Weight:	8.5 lb. (3.9 kg)	9.0 lb. (4.1 kg)	9.5 lb. (4.3 kg)
Silver antimicrobial tubing: Amount of distilled water for operation:	Yes, after humidification unit 8.5 fl. oz. (250 ml)	Yes, after humidification unit 8.5 fl. oz. (250 ml)	Yes, after humidification unit 8.5 fl. oz. (250 ml)
Display: Volume and brightness adjustment:	Touch Screen LCD, color 1 factory setting	Touch Screen LCD, color 8 individual settings	Touch Screen LCD, color 8 individual settings
Pumps:	2	2	2
Air intake and output:	0.141 CFM (4.0 liters per minute)	0.141 CFM (4.0 liters per minute)	0.141 CFM (4.0 liters per minute)
Current Levels (A) Off	0.04	0.04	0.04
Current Levels (A) On-standby	0.10	0.10	0.10
Current Levels (A) On-running	0.30	0.32	0.36
Components automatically tested for function:	Pumps, excitation elements, lamp	Pumps, excitation elements, lamp	Pumps, excitation elements, lamp
Service check:	Not Required, self-testing	Not Required, self-testing	Not Required, self-testing
Warranty:	2 Years	2 Years	2 Years

Accessories

4300-00	Glass Container	Glass
4370-00	Holder with Glass Container	Aluminum
4340-00	Power Supply Input / Output	100 - 240V AC / 12V DC, 4A
4350-00	Power Cord 2-Prong, 6 ½ ft. (2 m)	US, CA, Mexico, Japan
-10	Power Cord 2-Prong, 6 ½ ft. (2 m)	EU, Asia, Israel, South America
-20	Power Cord 2-Prong, 6 ½ ft. (2 m)	UK, Malaysia, Singapore
-30	Power Cord 2-Prong, 6 ½ ft. (2 m)	Australia, New Zealand
-60	Power Cord 2-Prong, 6 ½ ft. (2 m)	China
4530-00	User Manual	Available in different languages
4540-00	Concise User Manual	Available in different languages
	Consumables	
4310-00	Diffuser for Humidifier	Replace once a year
4400-00	Paper tube	White paper tubes

Optional Accessories

4200-00	Transportation Case	Black with foam inserts
	Consumables	
4360-00	Nasal cannulas	1 ft. (0.3 m), Latex-free material
4510-00	User Smartcards for NanoVi® Pro and NanoVi® Exo	Programmable for up to 9,999 minutes for use in "Card Mode"
4510-00	Owner Smartcards for NanoVi® Pro and NanoVi® Exo	Required for setting "Card Mode" and for programming minutes on User Smartcards

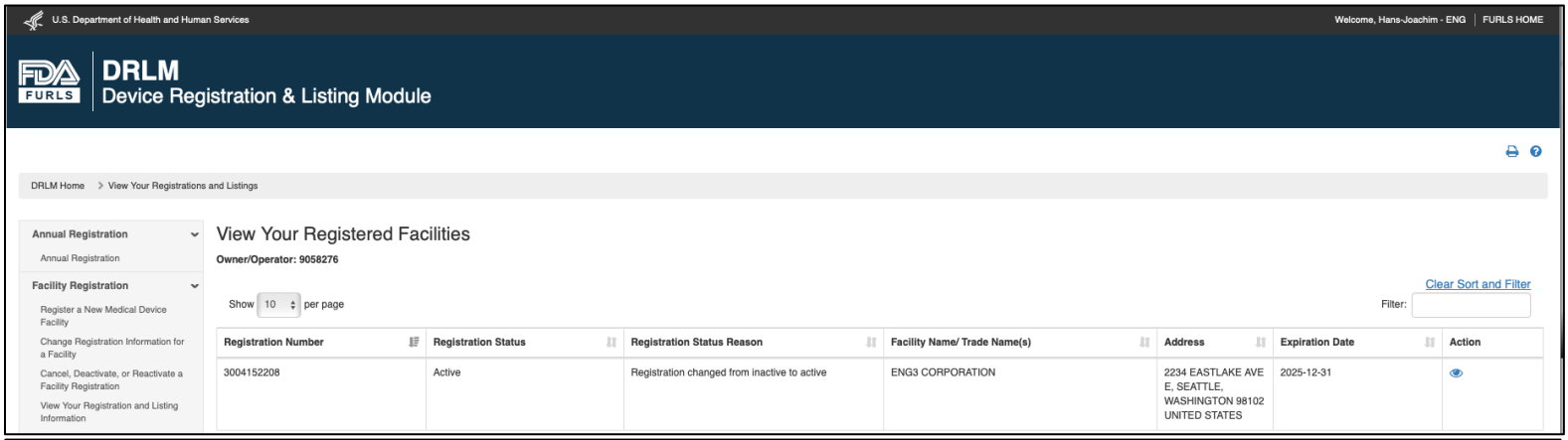
Technical specifications are subject to change without notice. Not liable for misprints.

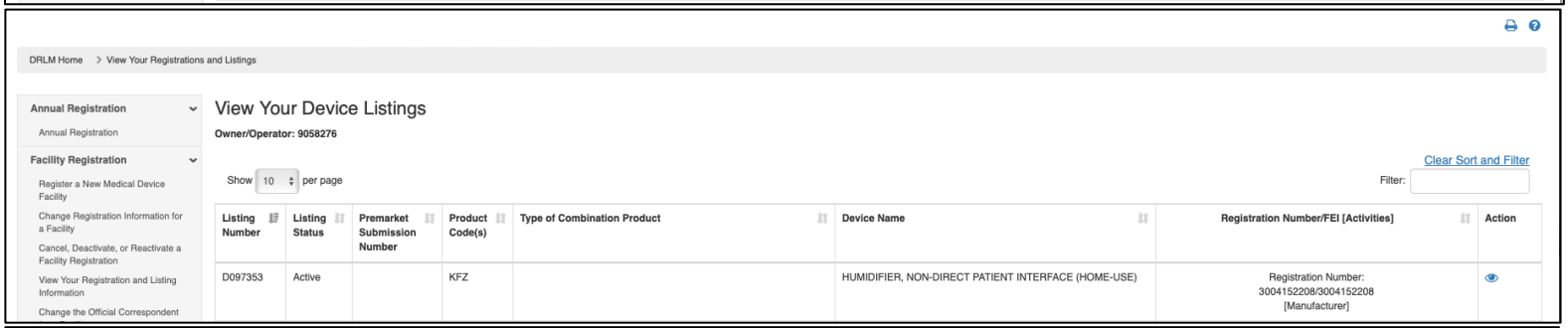
17.2 Product Registrations

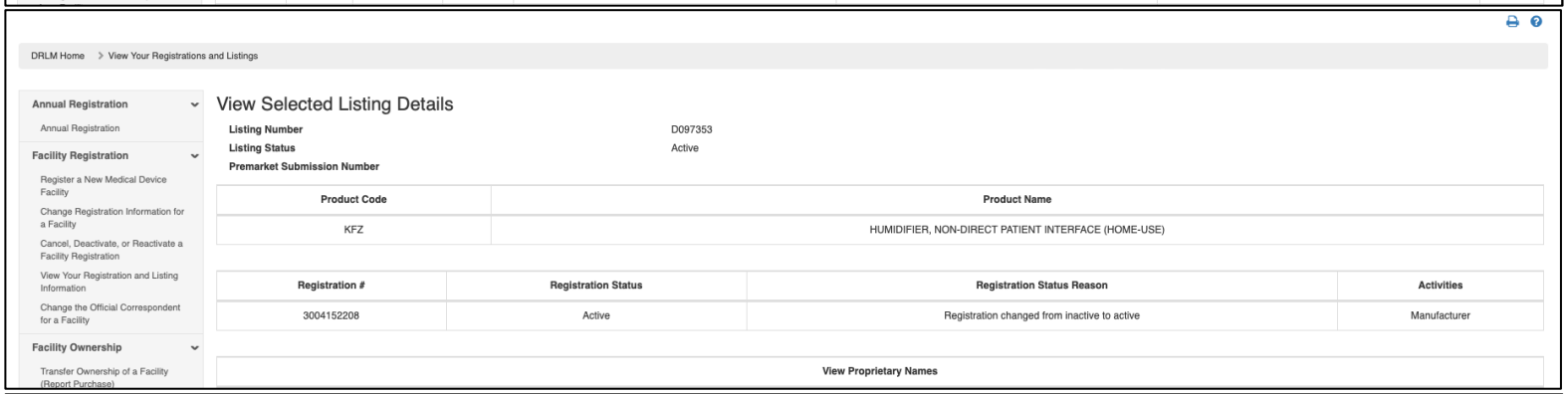
17.2.1 NanoVi® Registration: FDA

NanoVi®, NanoVi® Eco, NanoVi® Pro, and NanoVi® Exo devices are registered with the United States Food and Drug Administration (FDA).

FDA Device Listing number: D097353
FDA Facility Registration number: 3004152208







17.2.2 NanoVi® Registration: EU

All NanoVi® devices carry the CE mark represented in the declaration below.

eng3
Life Science Technology

CE

KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE
DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA

SRN-#, Name und Adresse der Firma *SRN-#,* Nom et adresse de l'entreprise *SRN-#,* Nome e indirizzo della ditta *SRN-#,* Name and address of the firm	SRN-#: Manufacturer: Street. City, Country: Phone number: E-mail:	**US-MF-000009925** **Eng3 Corporation** 2234 Eastlake Ave E, Seattle, WA 98102, USA 011-206-525 0227 info@eng3corp.com

Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto nostra responsabilità che / We declare under our sole responsibility that

das Medizinprodukt le dispositif médical il dispositivo medico the medical device	Brand: Identification: Restrictive use: HTS Code:		**NanoVi^{R}** **NanoVi^{R}, NanoVi Eco^{R}, NanoVi Pro^{R}, NanoVi Exo^{R}** Professional use and Home use 9019.20.0000
mit der Basis-UDI-DI avec la base-UDI-DI con la base-UDI-DI with the basis-UDI-DI	**0085000561401LA** **0085000561403LE** **0085000561405LJ**		
der Klasse de la classe della classe of class	**I**	***nach Anhang VIII MDR 2017/745 – Regel*** selon l'annexe VIII de la MDR 2017/745 – règle secondo l'allegato VIII della MDR 2017/745 – regola according to annex VIII of MDR 2017/745 - rule	**1 & 13**
Bestimmungsgemäße Verendung *Intended Use*	Das NanoVi®-Gerät ist für die Verwendung durch Erwachsene oder unter Aufsicht von Erwachsenen vorgesehen, um den Benutzer befeuchtete Luft ohne Erwärmung zur Inhalation bereitzustellen. Der Zustand des Wassers in der befeuchteten NanoVi®-Luft vergrößert letztlich die "Exclusion Zone", die auch als Ordnung des Wassers (geordnetes Wasser) bezeichnet wird, wenn sie sich auf Oberflächen kleiner Partikel bildet. Das NanoVi®-Gerät kann in der häuslichen Umgebung, aber auch in Büros, Spas, Sport- und Gesundheitseinrichtungen eingesetzt werden. The NanoVi® device is intended for use by adults, or under the supervision of adults, to provide humidified air without heating for inhalation by the user. The state of water in NanoVi® humidified air ultimately increases the exclusion zone, also known as the order of water (ordered water) on surfaces around small particles. The NanoVi® device may be used in a home use environment, including offices, spas, sports, and healthcare facilities.		

allen Anforderungen der MDR 2017/745 entspricht, die anwendbar sind.
remplit toutes les exigences de la MDR 2017/745 qui le concernent.
soddisfa tutte le disposizioni della MDR 2017/745 che lo riguardano.
meets all the provisions of the MDR 2017/745 which apply to it.

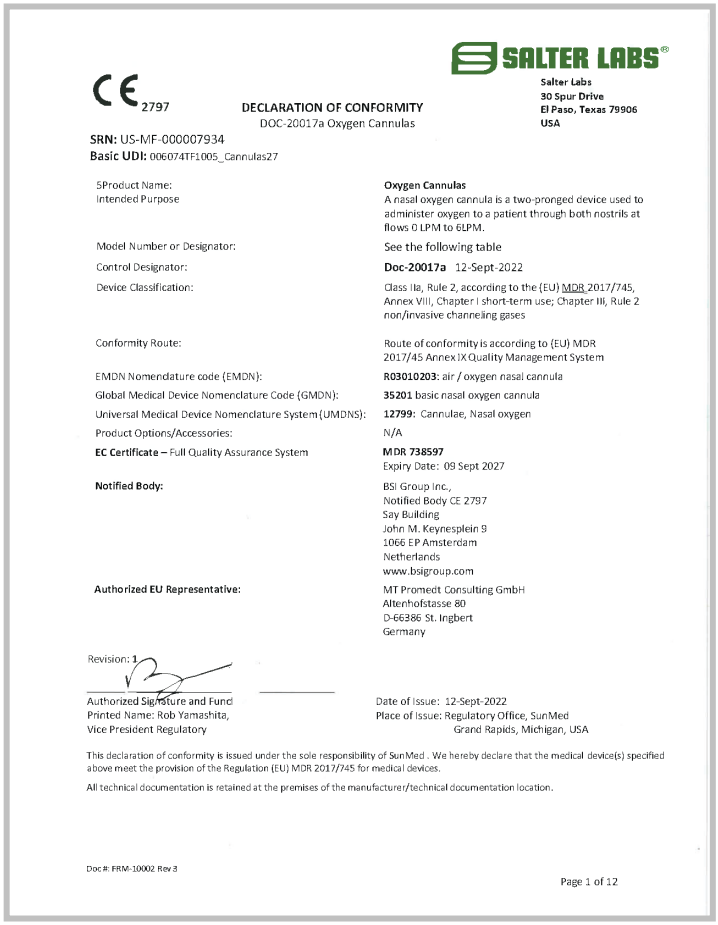
Konformitätsbewertungsverfahren Procédure d'évaluation de la conformité Procedimentodi valutazione della conformità Conformity assessment procedure		**MDR Art. 52 & Annex II, III (Klasse I)**
EC-REP:	SRN: EC-REP: Street, City, Germany: E-mail:	**DE-AR-000006764** **BEO MedConsulting Berlin GmbH** Helmholtzstraße, 2-9 10587 Berlin, Germany vigilance@beoberlin.eu
Gültigkeit der Erklärung: 1 Jahr nach Unterzeichnung oder Änderungen der technischen Dokumentation / Validité de la déclaration: 1 an après la signature ou modifications de la documentation technique / Validità della dichiarazione: 1 anno dopo la firma o modifiche alla documentazione tecnica / Declaration's validity: 1 year after signing or changes to the technical documentation.		
Weitere Registrierungen Autres inscriptions Ulteriori registrazioni Further registrations	Waste Electrical and Electronic Equipment Directive (WEEE) 2002/96/EC, currently Directive 2012/19/EU Packaging and packaging waste directive, 94/62/EC	

Seattle, WA, USA, January 03, 2025
Ort, Datum und Funktion / Lieu, date et function
Luogo, data e funzione / Place, date and function

Hans J. Eng
President / CEO
Unterschrift und Stempel / Signature and stamp
Signature et cachet / Firma e timbro

ENG3 Corporation
2234 Eastlake Ave E
WA, 98102
USA
www.eng3corp.com Phone: +206-5250227

17.2.3 NanoVi® Cannula Registration: EU



SALTER LABS®

Salter Labs
30 Spur Drive
El Paso, Texas 79906
USA

CE 2797

DECLARATION OF CONFORMITY
DOC-20017a Oxygen Cannulas

SRN: US-MF-000007934
Basic UDI: 006074TF1005_Cannulas27

5Product Name: Intended Purpose	**Oxygen Cannulas** A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through both nostrils at flows 0 LPM to 6LPM.
Model Number or Designator:	See the following table
Control Designator:	**Doc-20017a** 12-Sept-2022
Device Classification:	Class IIa, Rule 2, according to the (EU) MDR 2017/745, Annex VIII, Chapter I short-term use; Chapter III, Rule 2 non/invasive channeling gases
Conformity Route:	Route of conformity is according to (EU) MDR 2017/45 Annex IX Quality Management System
EMDN Nomendature code (EMDN):	**R03010203**: air / oxygen nasal cannula
Global Medical Device Nomenclature Code (GMDN):	**35201** basic nasal oxygen cannula
Universal Medical Device Nomenclature System (UMDNS):	**12799**: Cannulae, Nasal oxygen
Product Options/Accessories:	N/A
EC Certificate – Full Quality Assurance System	**MDR 738597** Expiry Date: 09 Sept 2027
Notified Body:	BSI Group Inc., Notified Body CE 2797 Say Building John M. Keynesplein 9 1066 EP Amsterdam Netherlands www.bsigroup.com
Authorized EU Representative:	MT Promedt Consulting GmbH Altenhofstasse 80 D-66386 St. Ingbert Germany

Revision: 1

Authorized Signature and Fund
Printed Name: Rob Yamashita,
Vice President Regulatory

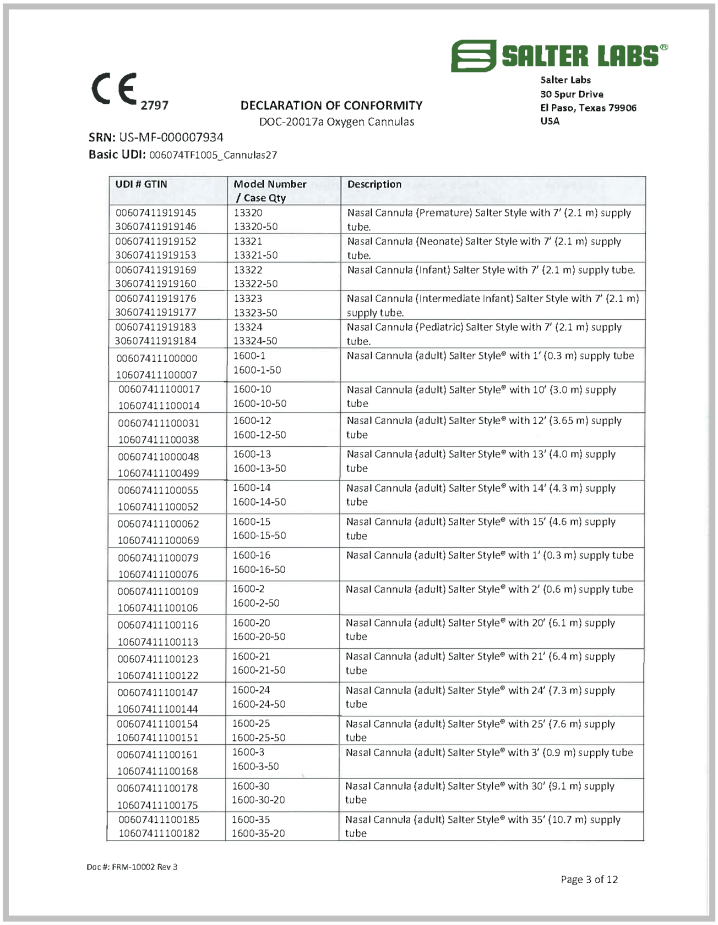
Date of Issue: 12-Sept-2022
Place of Issue: Regulatory Office, SunMed
Grand Rapids, Michigan, USA

This declaration of conformity is issued under the sole responsibility of SunMed . We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

All technical documentation is retained at the premises of the manufacturer/technical documentation location.

Doc #: FRM-10002 Rev 3

Page 1 of 12



SALTER LABS®

Salter Labs
30 Spur Drive
El Paso, Texas 79906
USA

CE 2797

DECLARATION OF CONFORMITY
DOC-20017a Oxygen Cannulas

SRN: US-MF-000007934
Basic UDI: 006074TF1005_Cannulas27

UDI # GTIN	Model Number / Case Qty	Description
00607411919145 30607411919146	13320 13320-50	Nasal Cannula (Premature) Salter Style with 7' (2.1 m) supply tube.
00607411919152 30607411919153	13321 13321-50	Nasal Cannula (Neonate) Salter Style with 7' (2.1 m) supply tube.
00607411919169 30607411919160	13322 13322-50	Nasal Cannula (Infant) Salter Style with 7' (2.1 m) supply tube.
00607411919176 30607411919177	13323 13323-50	Nasal Cannula (Intermediate Infant) Salter Style with 7' (2.1 m) supply tube.
00607411919183 30607411919184	13324 13324-50	Nasal Cannula (Pediatric) Salter Style with 7' (2.1 m) supply tube.
00607411100000 10607411100007	1600-1 1600-1-50	Nasal Cannula (adult) Salter Style® with 1' (0.3 m) supply tube
00607411100017 10607411100014	1600-10 1600-10-50	Nasal Cannula (adult) Salter Style® with 10' (3.0 m) supply tube
00607411100031 10607411100038	1600-12 1600-12-50	Nasal Cannula (adult) Salter Style® with 12' (3.65 m) supply tube
00607411000048 10607411100499	1600-13 1600-13-50	Nasal Cannula (adult) Salter Style® with 13' (4.0 m) supply tube
00607411100055 10607411100052	1600-14 1600-14-50	Nasal Cannula (adult) Salter Style® with 14' (4.3 m) supply tube
00607411100062 10607411100069	1600-15 1600-15-50	Nasal Cannula (adult) Salter Style® with 15' (4.6 m) supply tube
00607411100079 10607411100076	1600-16 1600-16-50	Nasal Cannula (adult) Salter Style® with 1' (0.3 m) supply tube
00607411100109 10607411100106	1600-2 1600-2-50	Nasal Cannula (adult) Salter Style® with 2' (0.6 m) supply tube
00607411100116 10607411100113	1600-20 1600-20-50	Nasal Cannula (adult) Salter Style® with 20' (6.1 m) supply tube
00607411100123 10607411100122	1600-21 1600-21-50	Nasal Cannula (adult) Salter Style® with 21' (6.4 m) supply tube
00607411100147 10607411100144	1600-24 1600-24-50	Nasal Cannula (adult) Salter Style® with 24' (7.3 m) supply tube
00607411100154 10607411100151	1600-25 1600-25-50	Nasal Cannula (adult) Salter Style® with 25' (7.6 m) supply tube
00607411100161 10607411100168	1600-3 1600-3-50	Nasal Cannula (adult) Salter Style® with 3' (0.9 m) supply tube
00607411100178 10607411100175	1600-30 1600-30-20	Nasal Cannula (adult) Salter Style® with 30' (9.1 m) supply tube
00607411100185 10607411100182	1600-35 1600-35-20	Nasal Cannula (adult) Salter Style® with 35' (10.7 m) supply tube

Doc #: FRM-10002 Rev 3

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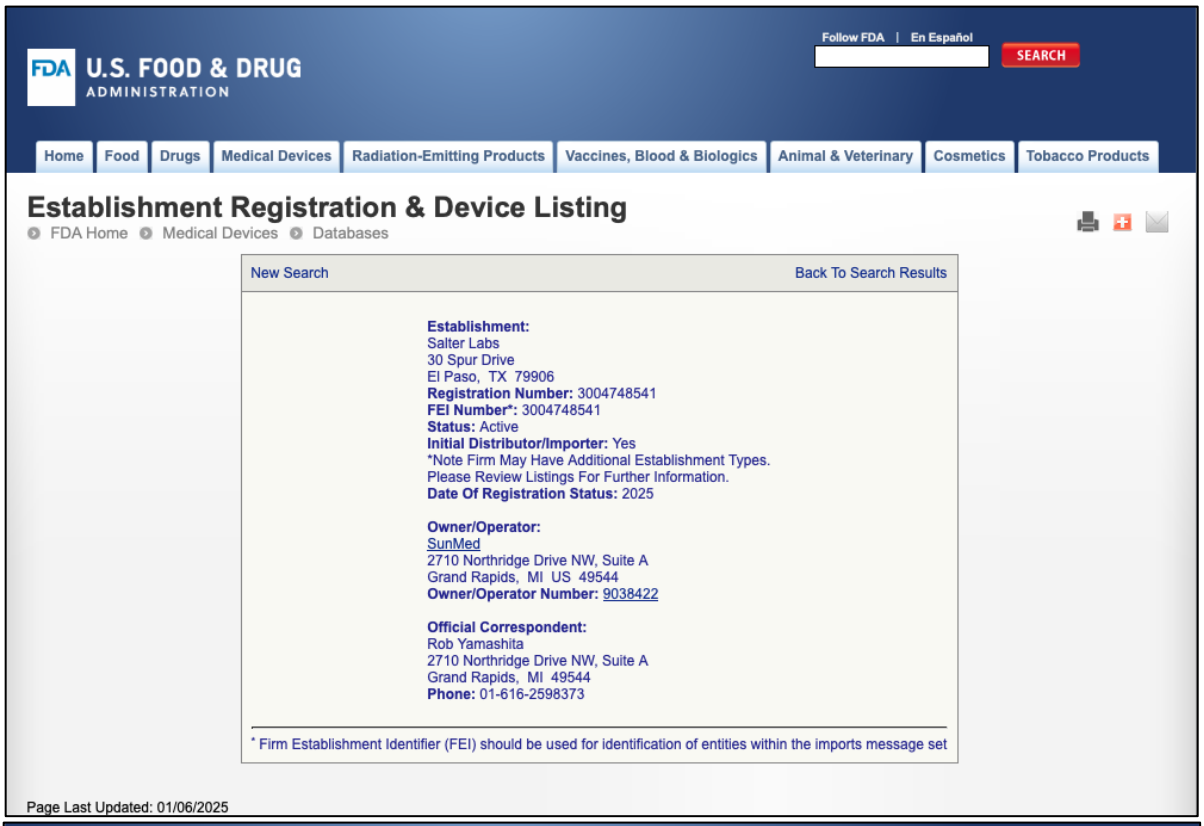
17.2.4 NanoVi® Cannula Registration: FDA



FDA U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

FDA Home ▸ Medical Devices ▸ Databases

New Search | Back To Search Results

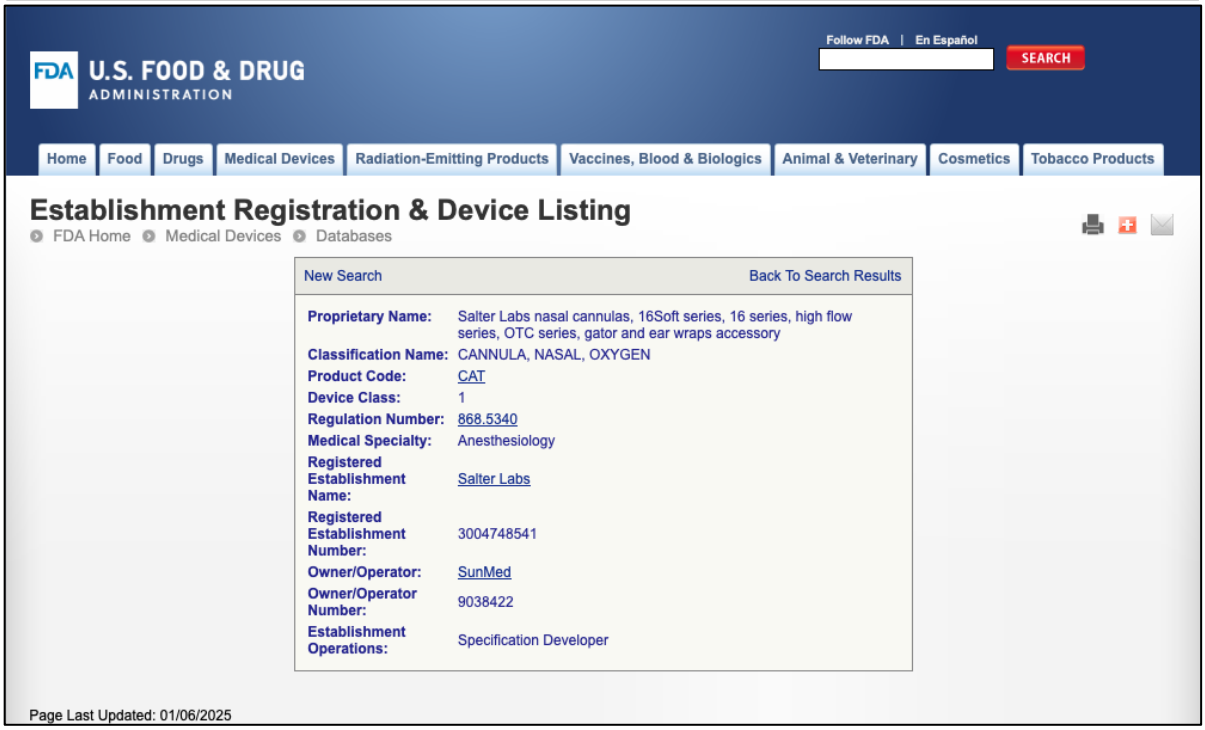
Establishment:
Salter Labs
30 Spur Drive
El Paso, TX 79906
Registration Number: 3004748541
FEI Number*: 3004748541
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2025

Owner/Operator:
SunMed
2710 Northridge Drive NW, Suite A
Grand Rapids, MI US 49544
Owner/Operator Number: 9038422

Official Correspondent:
Rob Yamashita
2710 Northridge Drive NW, Suite A
Grand Rapids, MI 49544
Phone: 01-616-2598373

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 01/06/2025



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Establishment Registration & Device Listing

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New Search | Back To Search Results

Proprietary Name:	Salter Labs nasal cannulas, 16Soft series, 16 series, high flow series, OTC series, gator and ear wraps accessory
Classification Name:	CANNULA, NASAL, OXYGEN
Product Code:	CAT
Device Class:	1
Regulation Number:	868.5340
Medical Specialty:	Anesthesiology
Registered Establishment Name:	Salter Labs
Registered Establishment Number:	3004748541
Owner/Operator:	SunMed
Owner/Operator Number:	9038422
Establishment Operations:	Specification Developer

Page Last Updated: 01/06/2025

18 Warranty

Devices manufactured or distributed by Eng3 Corporation carries a warranty, covering materials and workmanship, for a period of two years from the date of shipment, except for certain disposable products with stated warranties with different durations. Eng3 reserves the right to perform warranty service(s) at its factory, at an authorized repair station, or at the customer's facility.

Eng3's obligations under this warranty are limited to repairs, or at Eng3's option, replacement of any defective parts or of equipment without charge, if defects occur during normal usage.

Claims for damages during shipment must be filed promptly with the transportation company. All correspondence concerning the equipment must specify both the model name and number and the serial number as it appears on the device.

Improper use, mishandling, tampering with, or operation of the device without following specific operating instructions will void the warranty and release Eng3 from any further warranty obligations.

The actual warranty, outlining all terms and conditions, is included in the paperwork for the NanoVi® device.

Warranty immediately revoked if the device is opened or repaired by unauthorized personnel.

Warranty immediately revoked if any accessories other than those recommended have been used.

Service Department
For factory repair service contact through:
www.eng3corp.com/service

19 Service Policy

Eng3 Corporation will provide warranty service support to its customers within 48 hours of receiving a telephone request for technical support. This 48-hour period begins once a service request is placed through the Factory Technical Support Department in Seattle, Washington. Eng3 provides factory direct technical support to its customers through a technical support group located in Seattle, Washington. All Technical Support for Eng3 products is provided "Factory Direct".

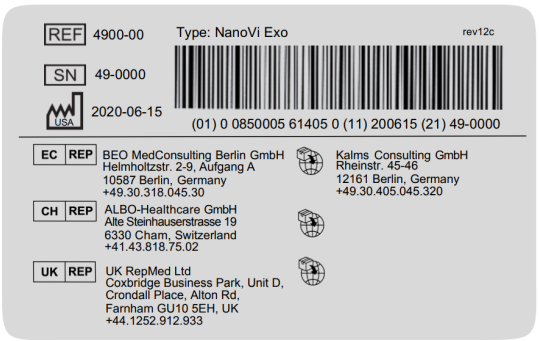
Eng3 provides technical support by telephone at the number for your location identified at www.eng3corp.com/service. It is suggested that any person calling in for technical support have the inoperative equipment available for preliminary troubleshooting as well as product identification. Eng3 reserves the right to repair or replace any product found to be defective during the warranty period. Repair may be provided in the form of replacement or exchange of parts or accessories, on-site technical repair assistance or complete system exchanges. Repairs provided due to product abuse or misuse will be considered "non-warranty" and invoiced at the prevailing service rate. Any replaced defective material should be returned to Eng3 within 10 days of being provided in order to avoid additional charges. Exchanged material should be returned promptly and directly to Eng3 using the return paperwork and shipping label(s) provided. Transferring return materials to local sales or dealer representative does not absolve the return responsibility.

20 Ordering Parts and Accessories

To order parts and accessories contact your local authorized distributor or Eng3 Corporation at: +1 206.525.0227

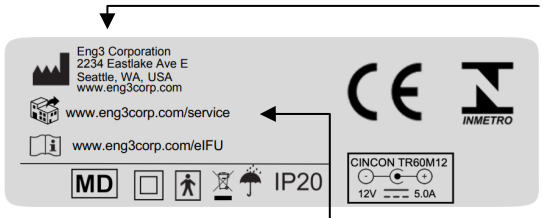
Complete overview of contact information is: www.eng3corp.com/service.

21 Contact Information



Authorized Representatives

Authorized Importers



Authorized Distributors
Overview and contact info of all distributors:
www.eng3corp.com/service

MANUFACTURER
Eng3 Corporation
2234 Eastlake Avenue E.Ste. A
Seattle, WA 98102
USA

Office phone: +1 206.525.0227
E-Mail: Info@eng3corp.com

22 Appendix A: Accompanying Documents

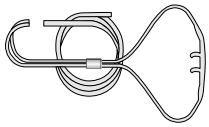
22.1 User Manual for Optional, Not-Mandatory Nasal Cannula Modell # 1600-1

Nasal Cannula

Home Oxygen Instructions for Use

Please read and follow the Instructions for Use prior to using your nasal cannula for your home oxygen therapy.

The Nasal Cannula is used to deliver supplemental oxygen to patients who have a prescription for home oxygen therapy. Prior to home use, you and/or your caregiver should receive instructions from a trained healthcare professional on how to safely use your nasal cannula while on oxygen.



Nasal Cannulas are disposable and for single-patient use.

Nasal Cannulas are intended for use in the home, outpatient, extended care, transport and hospital environments.

Nasal cannulas are available in sizes from infants to adults. The nasal cannulas are available in different styles with various lengths of supply tubing. Some styles may have liter flow limitations, which will be stated on the product label.

ysical problems (e.g., chest pains, cannot breath), call 911.

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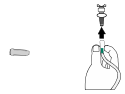
Instructions for Use (continued)

low.

Check for gas flow from the nasal prongs.

5. a–Wrap the headset loop up and over both ears.

6. a–Squeeze the sides of the bolo and glide the bolo up under your chin.
   b–Leave enough space to fit at least two fingers between the bolo and chin.



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Instructions for Use (continued)

Safety Precautions

- Oxygen is a nonflammable gas, but does support combustion. Follow your homecare provider's instructions for the care and safe operation of your oxygen delivery system (e.g., oxygen cylinder, oxygen concentrator, liquid oxygen).
- **Do not smoke or allow anyone to smoke around you.** This includes, but limited to, cigarettes, pipes, cigars, and electronic cigarettes (vapors).
- **Keep oxygen equipment at least 6 feet away from flames** or any heat source, for example, fireplaces, stoves, barbeque grills, and space heaters.

mple, don't apply Vasoline around or in your nares.

- Do not use flammable products such as aerosol sprays or cleaning products while wearing your nasal cannula or around your oxygen source.
- Avoid using electrical equipment that may cause a spark, for example, electric razor, blow-dryer or curling iron.
- Use oxygen as prescribed by your doctor.
- The total length of your nasal cannula and oxygen supply tubing should not exceed 57 feet to ensure there is enough pressure to deliver prescribed oxygen flow rate.
- Do not kink, bend or tie your oxygen tubing,
- Do not place anything on your tubing that may obstruct flow.
- Keep excess tubing loosely coiled and out of the way to prevent tripping on oxygen tubing.
- Do not place your oxygen tubing or nasal cannula under blankets, bedsheets, rugs, etc.
- Use caution to prevent your oxygen tubing from becoming entangled in your furniture.
- Keep an extra nasal cannula and other oxygen supplies available for use.
- Do not let children or pets play with your nasal cannula and oxygen equipment.
- Recommend use of swivel adapter for nasal cannula and supply tubing longer than 14 feet.
- If using humidification, add a water trap to collect excess moisture in the supply tubing.

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Instructions for Use (continued)

Troubleshooting Tips

Problem	Possible Cause	Corrective Action
No oxygen flow from nasal prongs	1. Cannot feel the airflow in your nostrils. 2. Flow control valve is not turned on. 3. Oxygen system is not functioning properly or oxygen container is empty. 4. The nasal cannula is disconnected from oxygen device or supply tubing. 5. Nasal cannula or oxygen tubing kinked or blocked.	1. Check air flow by placing prongs next to hand or place nasal prongs into a small container of clean water. Bubbles will appear if there is oxygen flow. 2. Set flow control to prescribed setting. 3. Switch to backup oxygen source and contact your homecare provider. 4. Reconnect oxygen tubing. Ensure all tubing connections are tight and secure. 5. Inspect cannula and oxygen tubing for kinks or damage. Ensure nothing is placed on top the tubing.
Water in nasal cannula or oxygen supply tubing	1. Humidifier bottle overfilled, or bottle has tipped over. 2. Water trap is full 3. High humidity environment, or sudden drop in temperature.	1. Pour out the excess water. Ensure that the humidifer bottle is upright. 2. Empty water trap. 3. Consider adding a water trap to your oxyen supply tubing.
Nasal dryness or irritation	1. Gas flow is dry. 2. No humidifier is being used.	1. Use normal saline spray or water soluble ointment, (i.e., AYR Saline Nasal Gel) to moisten the inside your nostrils. If condition worsens, contact your doctor. 2. Contact your doctor or homecare provider to request humidification.
Soreness or irritation around ears	1. Headset tubing too tight. 2. Tubing pressing against skin.	1. Loosen headset tubing. 2. Place a cotton padding or cushion (i.e., EZ- Wrap) under headset tubing.
Skin rash and/or sores caused by nasal cannula	1. Sensitivity or reaction to nasal cannula material. 2. Nasal cannula is dirty. 3. Cleaning detergent used to clean nasal cannulas may be absorbed into the plastic and can irritate the skin. 4. Nasal prongs are stiff causing nasal irritation and discomfort.	1. Contact your health care provider and/or doctor. 2. Wipe nasal cannula down with a damp cloth to remove oil and debris. If detergent is needed use a mild soap and rinse well. 3. Replace cannula. When cleaning cannula only use a damp cloth. Do not use strong detergents, disinfectants or oil based soaps. 4. Replace naasal cannula. Do not use a nasal cannula for more than 30 days.
Nasal prongs and tubing is stiff	1. Most nasal cannulas are made with a PVC material, which may harden with age and extended use. 2. Alcohol based cleaners may harden the PVC material	1. Replace your nasal cannula 2. Replace your nasal cannula

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22.2 **Power Supply (2-Prong), Part # TR60M12-01E12**

User's Manual

1) The input and output should not exceed the rating on the label.

2) The 2-prong power supply should be operated only in dry conditions.

3) Manufacturer: DongGuan Cincon Electronics Limited
Factor Address: No. 1 Jingxiang Rd. Dongcheng
Foreign Trade Industrial Park, Zhushan Dong Cheng
District, Dong Guan, Guangdong, China

4) The 2-prong power supply requires a 2-prong power cord.

5) For the 2-prong power cord, choose the correct plug for your location (see below)

4340-00		Power Supply: C8 (2-prong), 110-220V for: For Power Cord with C7 (2-Prong)  The 2-prong Power Supply is the standard power supply used with NanoVi and NanoVi Wellness devices
4350-00 4350-10 4350-20 4350-30	Power Cord C7: to 2-prong 6.5 ft. (2.0m) Type A Type C Type G Type I	 Type A (US, CA, Mexico, Japan)  Type C (EU, Asia, Israel, South America)  Type G (UK, Malaysia, Singapore)  Type I (AUS, New Zealand)
4350-60	Power Cord C7: to 2-prong 6.5 ft. (2.0m) Type A-CH	 Type A-CH (China)

V16

TR60M SERIES
60W MEDICAL SWITCHING ADAPTER

Features

* Universal Input Range 90~264VAC
* Meets EN60601-1 and EN55011 Class B
* Continuous Short Circuit Protection
* Over Voltage Protection
* Meet CEC Level Ⅳ
  (Output Cable Length≦1800mm)
  (TR60M Series meets CEC Ⅳ except TR60M05 is Non-CEC Compliant)
  (TR60M12: Output Cable Length≦1220mm 16AWG)
* Efficiency & Standby Power Meet Level Ⅴ (Option)
  (Output Cable Length≦1800mm)
  (TR60M12：Output Cable Length≦720mm 16AWG)
  (TR60M15：Output Cable Length≦1220mm 16AWG)
  (TR60M18,TR60M19：Output Cable Length≦1500mm 18AWG)
* Meets 2MOPP

	36V	1.66A	360mVp-p	±2%	±1%	±2%	87%
TR60M48	48V	1.25A	480mVp-p	±2%	±1%	±2%	87%

Specifications are subject to change without notice.

V16

Specifications

INPUT SPECIFICATIONS:

Voltage ..... 90~264Vac
Frequency ..... 47 to 63Hz
Inrush Current ..... Cold Start @25℃80A max. @240Vac
Conducted EMI ..... CISPR/FCC Class B
Leakage Current ..... 0.1mA max.

OUTPUT SPECIFICATIONS:

Holdup Time ..... 8ms typ. @115Vac
Short Circuit Protection ..... Continuous
Over Voltage Protection ..... Yes
Temperature Coefficient .....±0.05%/℃

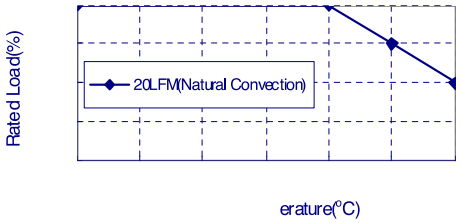
GENERAL SPECIFICATIONS:

Isolation ..... Input to output =5,656VDC
Operating Temperature ..... 0 ~ 60℃ (see derating curve)
Storage Temperature ..... -20 ~ 85℃
Humidity ..... 93% RH max. Non condensing
Cooling ..... Natural Convection
Switching Frequency ..... 100KHz Typical
MTBF ..... MIL-HDBK-217F, GB, at 25℃/115VAC ..... 200K hrs min.
Altitude 3000m
Dimensions 5.197x2.283x1.201inches (132.00x58.00x30.50mm)
Weight ..... 345g(0.76 Pounds)

SAFETY AND EMC:

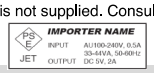
Emission and Immunity EN55011, EN60601-1-2, EN61000-3-2
EN61000-3-3
Safety ..... IEC60601-1, EN60601-1, UL ANSI/AAMI ES60601-1:2005

TR60M Series Derating Curve



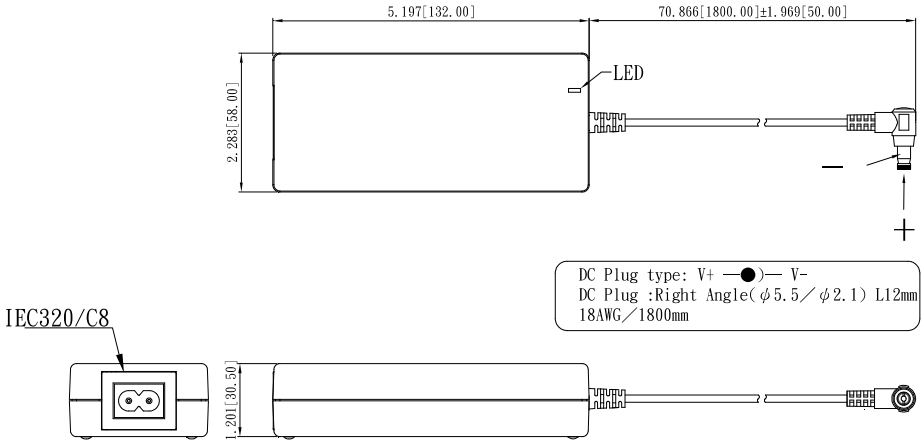
NOTE:

1. Voltage accuracy at 60% full load.
2. Add a 0.1uF ceramic capacitor and a 10uF E.L. capacitor to output for Ripple & Noise measurement @20MHz BW.
3. Line regulation measured from 100Vac to 240Vac, full load.
4. Load regulation measured from 60% to 100% full load and from 60% to 20% full load (60% +/- 40% full load).
5. Typical efficiency at 230VAC and full load at 25℃.
6. "Various TR Series adapters are PSE certified. PSE certification alone is not sufficient for importation into Japan. A valid PSE mark must contain the name of the importer as shown in the example below. If PSE mark is required, the name of the registered importer must be supplied to Cincon on order placement. Product labels will not contain PSE mark if importer name is not supplied. Consult factory or local represen tative for details".



Mechanical Specification

All Dimensions are in inches(mm)
Tolerance:Inches:X.XXX±0.02
Millimeters:X.XX±0.5



Typical at 25°C, nominal line and 75% load, unless otherwise Specified