User Manual

NanoVi™ Devices

Eng3 Corporation

English National USA

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Life Science Technology

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NanoVi Eco™ / NanoVi Pro™ / NanoVi Exo™

User Manual

User Manual Eng3 Part Number: 4530-00

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Table of Contents

1 Device Description

The process that takes place within the NanoVi™ device occurs in four steps:

1. Creation of a continuous air stream with intake of ambient air
2. Humidification of the air stream, enriching the air stream with water droplets
3. Generation of a specific signal that is absorbed by water droplets and creates Exclusion Zone (EZ) water droplets
4. Transfers the water droplets across the humidified air stream to the user via a Flex-Arm

The NanoVi™ device is designed to assist the body's natural repair of protein damage. When this damage accumulates it is called oxidative stress damage. Repair of protein damage leads to regeneration and rejuvenation at the cellular level. Within the body, on an ongoing basis, a specific signal is emitted by certain free radicals (called Reactive Oxygen Species or ROS) and is released into the cellular water. Here it forms EZ water layers on the surface of proteins. NanoVi™ devices generate the same specific signal, emits the signal and creates EZ water droplets, which are transferred across a humid air stream to the user.

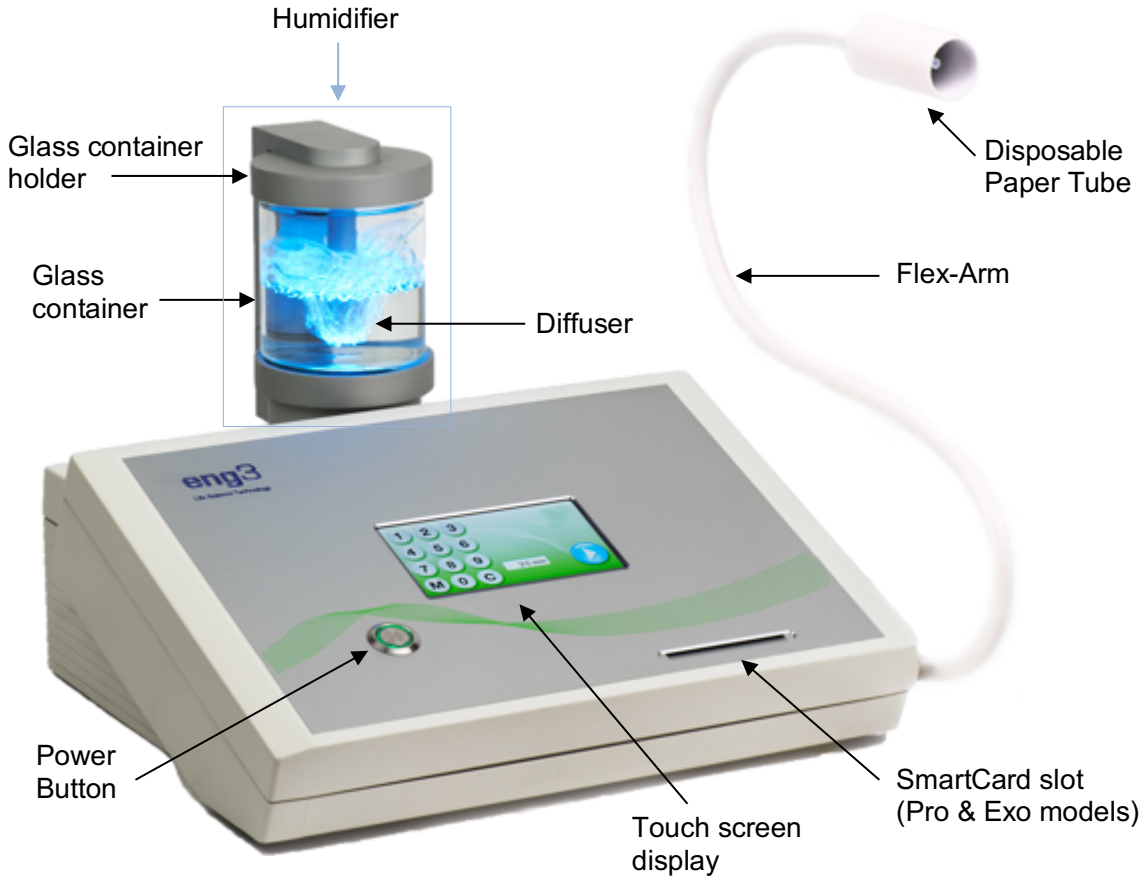


Figure 1.1: Front view of the NanoVi Exo™ device

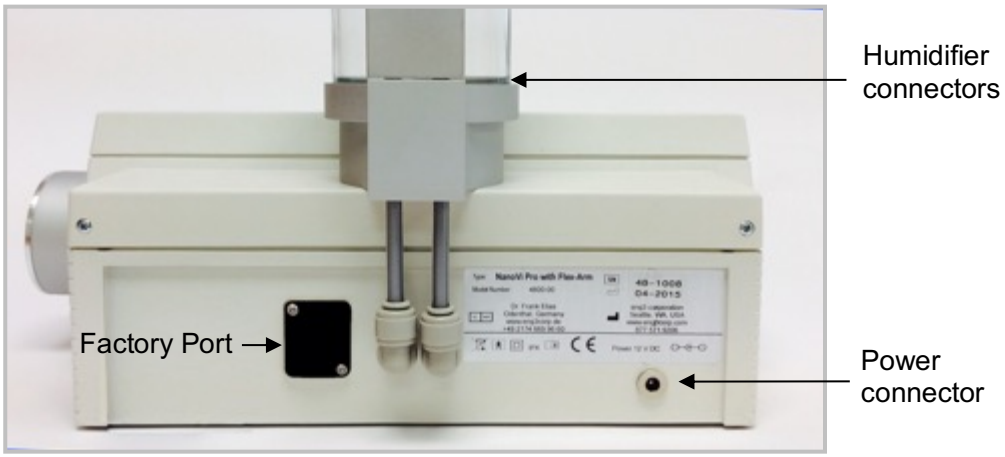


Figure 1.2: Back view of the NanoVi™ device

WARNING: Do not unscrew or remove the factory port on the back of the device (see Figure 1.2). There are no user-serviceable parts or parts required for maintenance inside. This port is for factory use only. Do not open or remove the factory port.

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

Figure 1.3: Power supply and power cord

2 Contraindications

Do not use NanoVi™ when the PATIENT is using other breathing related therapy or remedy.

Pregnant women should consult their physician before using the device.

PATIENTS must be awake and alert when using the NanoVi™. Do not use the NanoVi™ when unconscious or when under the influence of drugs or medications which interfere with alertness.

3 Possible Side Effects

The following temporary reactions have been occasionally observed when first using the NanoVi™ device. Typically, when side effects occur the body is going through an adjustment. Try shorter sessions if necessary.

- Drowsiness: Use a shorter session length for the first few sessions, Choose the time of the first session to accommodate unexpected drowsiness, which might occur after the initial application. This will disappear after several sessions.

- Insomnia: To avoid trouble falling asleep, do your session at least 4 hours before going to bed when you first start using the device.

- Dizziness and/or headaches: Dizziness and/or headaches can temporarily appear and will disappear after a short period of time. Should this occur, use shorter session times.

- Changes in stool: If unwanted changes in stool consistency appear, use shorter session times.

- Skin reactions: If skin reactions, such as reddening and itching, appear use shorter session times until skin reactions have disappeared.

4 Warnings and 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.

WARNING: This product is not designed for use on an unconscious PATIENT (unresponsive to stimuli). If the PATIENT is unresponsive to stimuli do not use this product.

WARNING: This product is not designed for use in Oxygen rich environments. Do not use in or near Oxygen rich environments.

WARNING: This product is not water or drip resistant. Do not use in wet environments or areas that may have splash or drip issues.

WARNING: Spilling water on the device may be hazardous and may damage the device. Do not spill water on the device.

WARNING: No modification of this equipment is allowed. Any changes could cause harm or increase hazard for the OPERATOR or the PATIENT. The warranty is void if any modification is made to this equipment.

WARNING: 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, PATIENT, or another person or animal, or could damage other objects or surfaces.

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

WARNING: This product is not meant to be used in temperatures below 59° F (15° C) or temperatures exceeding 97° F (36° C).

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.

If there is interference being caused by electromagnetic emissions, then the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the device.
- Increase the separation between the NanoVi™ device and the other device/s.
- Connect the NanoVi™ device into an outlet on a circuit different from that to which the other device/s are connected.
- If it is not resolved or if you have questions, contact the service department (see section 16).

4.1 Device and Accessory Warnings

WARNING: If the power cord is damaged or the casing of the power supply is cracked or damaged in any way, DO NOT USE IT.

WARNING: 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 make and model is MEAN WELL GSM60A05-P1J, which must be an IEC 60601-1 compliant power supply. Use of any other supply is prohibited.

- Only use the Salter Labs nasal cannula model 1600-1.

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 PATIENT and when they also operate the device they are considered the OPERATOR and SERVICE PERSONEL.

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

WARNING: This product is not meant to be used in temperatures below 59° F (15° C) or temperatures exceeding 97° F (36° C).

Follow these steps to set up your device:

1. Use indoors, away from wet/splash/drips, between 59°F (15°C) and 97°F (36°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.

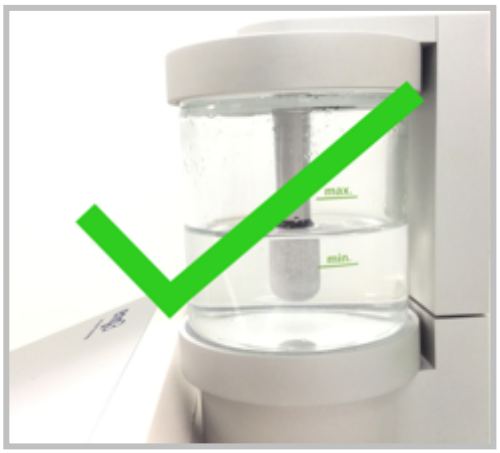


Figure 5.1: Correct water levels

Figure 5.2: Incorrect water levels

WARNING: 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)

WARNING: 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. Hand tighten glass container into the glass container holder.

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. There will be a small gap between the humidifier and the device when there is a proper connection.

Figure 5.3: Inserting humidifier into device

WARNING: 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 PATIENT or damage the device.

WARNING: Do not tip the container when inserting it into the top of the device, as water drops or water may enter the tube system or device.

Confirm that there is only a small gap between the humidifier and the device. This ensures a proper connection. (Figure 5.4).

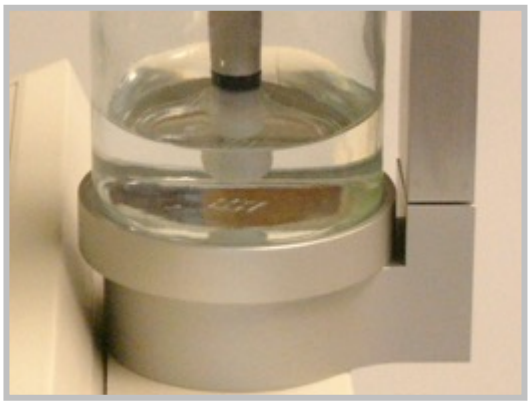


Figure 5.4: Correct insertion of humidifier

WARNING: Do not force humidifier into the device; it will fit firmly with a small gap between the two metal pieces.

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 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 PATIENT can be 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 PATIENT 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 figure 6.1. See Appendix A for proper nasal cannula use. If the PATIENT is using the device with no cannula, the Paper Tube should be positioned 1-3 inches (2.5 - 7.6 cm) away from the nose as show in in figure 6.2.

Figure 6.1: Use of Nasal Cannula

Figure 6.2: Use of Paper Tube

6.2 Use of Flex-Arm

NanoVi™ devices come with an installed Flex-Arm, as shown in Figure 6.3.

Remove the protective cap from the outlet on the Flex-Arm, if it is in place. 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 your nose, one to three inches away, as shown in Figure 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.

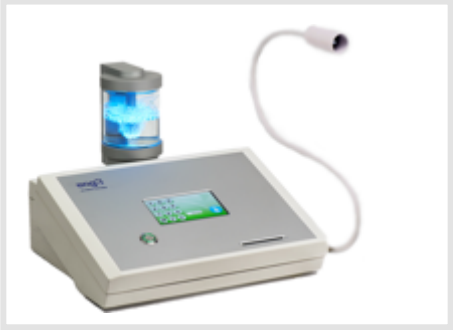


Figure 6.3: NanoVi Pro™ Device

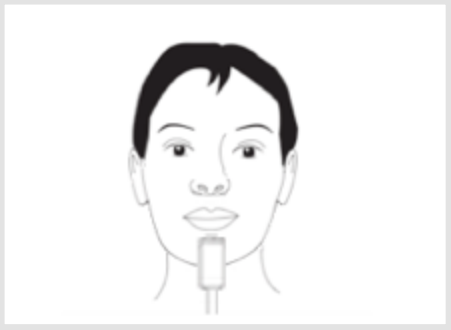


Figure 6.4: Flex-Arm use

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

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

6.3 Nasal Cannula

The NanoVi™ device can be used with a nasal cannula inserted on the outlet in the middle of the Flex-Arm attachment. 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 instead of the standard seven-foot length tubing is used. The one-foot disposable cannula is shown in Figure 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 Figure 6.6.

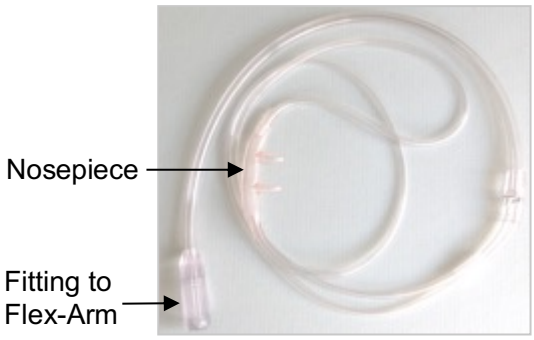


Figure 6.5: Nasal cannula

Figure 6.6: Nasal cannula use

6.4 Power On

Press the large button on the front 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 tone sounds each time you press a button, indicating that your input was registered through the touch screen.

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

6.6 Application Schedule

The session time depends on which NanoVi™ device is used. The NanoVi Exo™ device is twice as powerful as the NanoVi Pro™, and the Pro device is twice as powerful as the NanoVi Eco™. As a result, the standard session time of 15 minutes on the Exo is similar to 30 minutes on the Pro, or 60 minutes on the Eco device.

It may be necessary to build up use of the device slowly. The appropriate amount of time depends on the state of each person's health and physical condition. Although adverse reactions are experienced by only a small percentage of people, a safe approach is to start by using the NanoVi Eco™ device for only 10 minutes the first day (5 minutes for the NanoVi Pro™ or just a few minutes on the NanoVi Exo™). If you feel well and are not light headed, it is fine to do more time. Feeling light headed or uncomfortable in any way signifies that the session should be stopped for the day and time should be added gradually. If adverse reactions occur, revert to shorter session times.

It is important to start slowly to stay within your comfort zone. If you are highly sensitive and/or in need of detoxification, start with only a few minutes and keep adding time each day, as long as there are no adverse reactions. In the event of an adverse reaction, reduce the number of minutes of use until there is no reaction, then start adding minutes until the desired session time is reached.

For prevention in younger healthy people, two or three standard NanoVi™ sessions per week are adequate. Individuals that have health challenges, are older, or are performance athletes should use the device more. NanoVi™ devices can be used every day and several times a day, if desired. There is no potential to be harmed by the device so overuse is not a concern, once you are accustomed to it. The device can be used for many hours a day if desired.

6.7 Lights Illuminating the Glass Container

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

The lights illuminating the glass container are adjusted in the color selection screen. This screen is accessed by touching the color wheel icon of the splash screen, during the 10-second self-test (Figure 6.7). The color wheel does not show once the self-test is complete so it is necessary to restart the NanoVi™ device if you want to adjust the color.

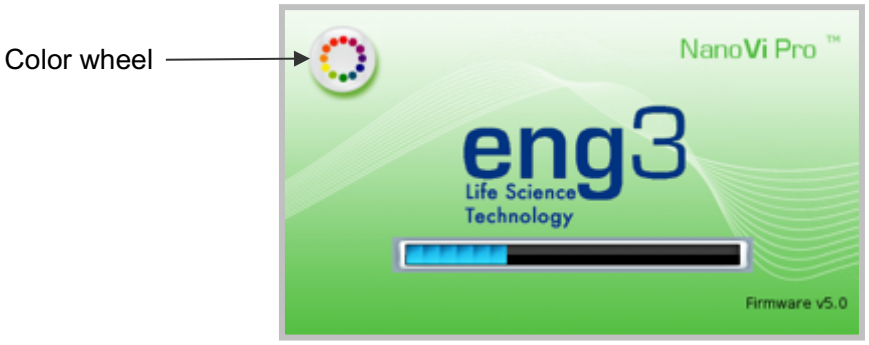


Figure 6.7: Splash screen with color wheel

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 so you can see the effect of any changes before leaving the screen. Figure 6.8 shows the color options available. Touch the 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 moon symbols. To turn the lights off, press the moon symbol until the illumination disappears. The orange bar will be all the way to the left.

The rotating color option is selected by pressing the symbols for the long or short wavelength. Pressing any part of the color transition bar will start the rotating colors. Pressing any individual color circle will stop the colors from changing.

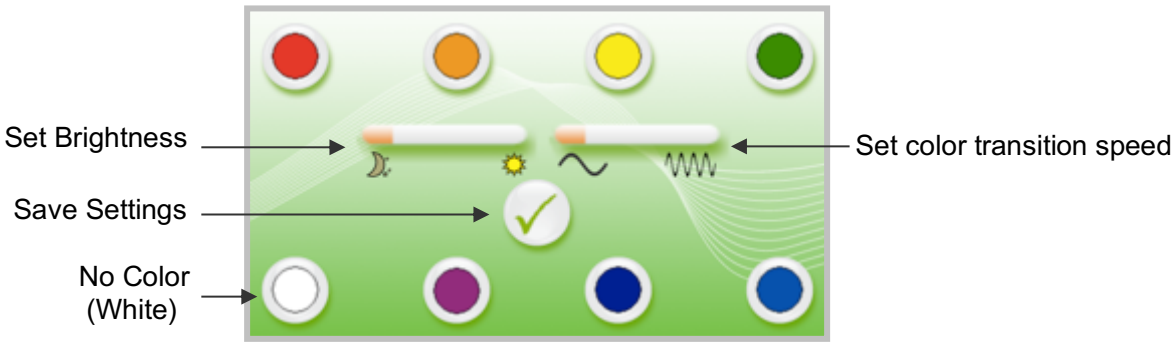


Figure 6.8: Color selection screen

Once you have selected your preferences, press the check mark button near the middle of the screen (Figure 6.8). This saves the settings and takes you back to the input 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 in Standard Mode

All three NanoVi™ devices can be operated in standard mode. Once the device is turned on, a splash screen appears. A self-test runs for 10 seconds with progress shown by the bar at the bottom of the screen. (Figure 7.1)

Figure 7.1: Initial splash screen

Upon completion of the self-test, an input screen appears allowing you to enter the amount of time for the session (Figure 7.2). Enter the desired session time by touching the appropriate numbers on the touch screen. Time is entered in minutes. The minutes entered shows in the session time indicator in the centre of the screen. Touching the “C” clears a number that has been entered, allowing you to change your input.

The “M” on the input screen lets you capture the amount of time in the memory of the device as the default session time. The amount of time most recently captured in memory will be displayed instead of “0 min” in the time indicator for all future sessions. The default time in memory can be reset to zero or to a different default time at any point, while the input screen is displayed.

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

Figure 7.2: Input screen

Figure 7.3 shows the screen when the session is in progress. The digital clock counts down the minutes and seconds remaining in the session. The rotating dots to the left indicate that a session is in progress.

The pause button allows you to interrupt a session (Figure 7.4). Pressing the start button restarts a paused session. If a session has not been restarted within 15 minutes, the device will automatically turn off.

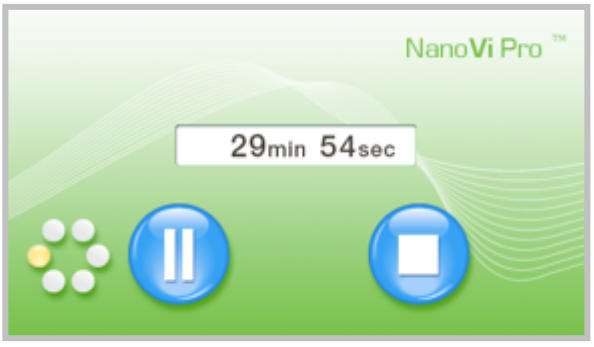


Figure 7.3: Session in progress screen

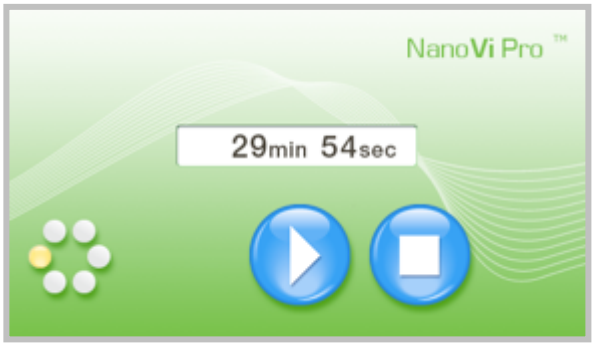


Figure 7.4: Paused session screen

Sessions can be stopped at any time by pressing the stop button. Stopping the session takes you back to the initial entry screen shown in Figure 7.2.

8 Operating in SmartCard Mode

SmartCard mode is available in the NanoVi Exo™ and NanoVi Pro™ devices, not the Eco device. Skip to section 9 if you have a NanoVi Eco™ device.

Insert SmartCards with the arrow showing on the top of the card pointing into the device. The metallic chip must be facing down for the card to work.

Two types of SmartCard are used to operate the device. The Owner Card is used to put the device in SmartCard mode, to program preferences, and to load User Cards with minutes. The User Card is used to operate the device when it is in SmartCard mode. A 4-digit code is printed on the Owner and User Cards that come with the device. This 4-digit code is unique and specific to the device it comes with. The User Cards will only work with the device that was used to program them.

8.1 Owner Card

The owner card can be inserted any time when the device is turned on. It overrides the current functions and presents the administrative screen shown in Figure 8.1. The Owner Card has three basic functions: 1) set preferences on the device, 2) set the operation mode of the device, and 3) program User Cards. Each of these functions is described below. The Owner Card administration screen also shows the rent time (number of minutes of use) and allows you to reset the rent time by pressing the circular arrow at the bottom of the screen.

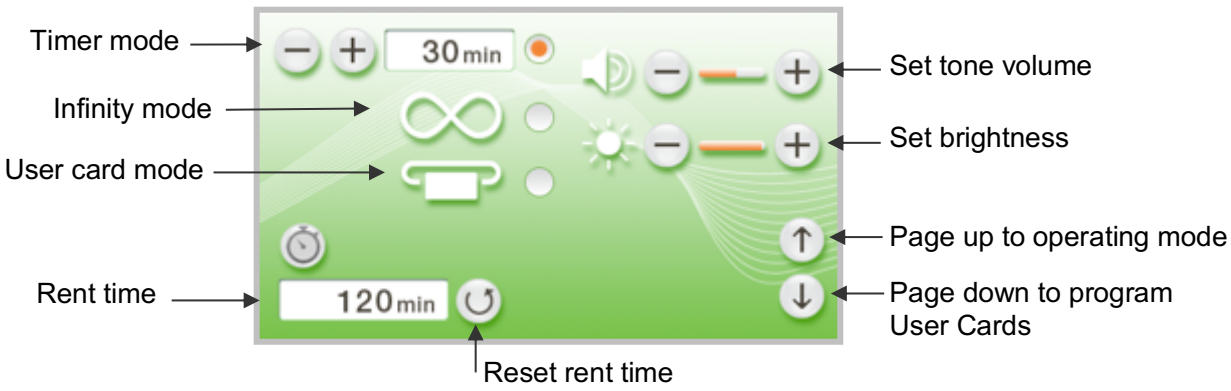


Figure 8.1: Owner Card administrative screen

1) Setting Preferences

Adjust the volume of the tone that sounds when you touch the screen by touching the + or – symbol. Repeatedly touching the – symbol will reduce the volume until the sound is turned off completely.

Adjust the brightness of the screen by touching the appropriate + or – symbols. It is not possible to turn the screen off completely.

2) Setting Operation Mode

The Owner Card administrative screen allows you to set the operation mode of the Exo or Pro device. It can be operated in four different ways: timer mode, infinity mode, User Card timer mode, and User Card session mode. These options are described below.

1. Timer mode – does not require a User Card, the device operates as described in Section 7, Operating in Standard Mode. To select this mode touch the top white button so that a dot appears, as shown to the right.

2. Infinity mode - does not require a User Card and the device remains on, as indicated by the infinity symbol. Figure 8.2 shows the start screen if the device is configured for infinity mode. Figure 8.3 shows the screen displayed during a session in infinity mode. The timer counts up instead of down in infinity mode. Touch the middle button to select infinity mode.

Figure 8.2: Infinity mode start screen

Figure 8.3: Infinity mode session screen

3. User Card timer mode – requires a User Card and allows the user to enter the session time. Select the SmartCard option by touching the bottom button.

4. User Card session mode - requires a User Card and has a predetermined session time. Select both timer mode and User Card session mode to configure the device in User Card session mode. Enter the desired session time by pressing the plus and minus arrows of timer mode. Select both the top and bottom buttons for this option.

Once you have selected one of the four operation modes listed above, press the page up arrow in the lower right corner of the Owner Card administration screen. The device goes to the operating mode that was selected and the owner card can be removed.

Selecting the page down arrow in the lower right of the Owner Card screen will take you to the screen for programming User Cards, shown below.

3) Programming User Cards

The screen shown in Figure 8.4 indicates that you should insert a User Card to be loaded with minutes. Remove the owner card and insert the first User Card to be loaded. To return to the Owner Card screen press the page up arrow on the right.

Figure 8.4: Insert User Card for Loading

When the User Card is inserted, the screen shown in Figure 8.5 is displayed. The number of minutes on the card can be seen at the top, above the SmartCard symbol. Selecting the + or – before entering the number of minutes through the touch screen, lets you add or subtract minutes on the card. Minutes that were already on the card can be reduced or eliminated. Once the desired number of minutes shows in the bottom display, press the load card button to load the User Card. Remove the User Card and insert the next one, if you are loading multiple User Cards.

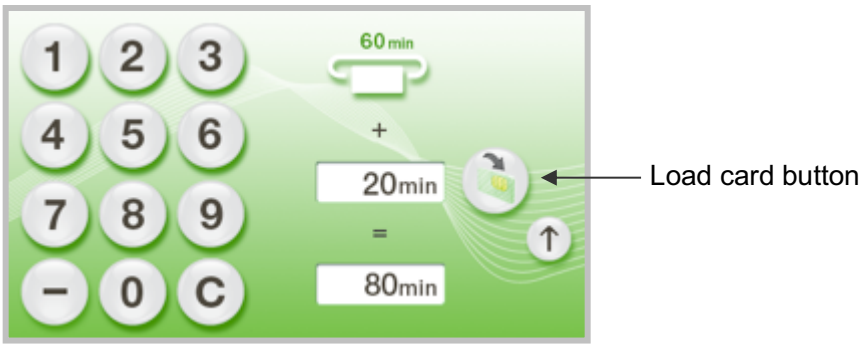


Figure 8.5: Loading User Card

After User Cards are loaded, you can press the page up arrow to return to the owner screen. Pressing the up arrow one more time will take you to the mode that was selected.

If the device has previously been set to require a User Card, the screen shown below in Figure 8.6 will appear after the initial start up screen. The Owner Card can be inserted to administer the device, or the User Card can be inserted to run the device.

8.2 User Card

The screen below is displayed when a User Card is required. A valid User Card, or an Owner Card, must be inserted to operate the device.

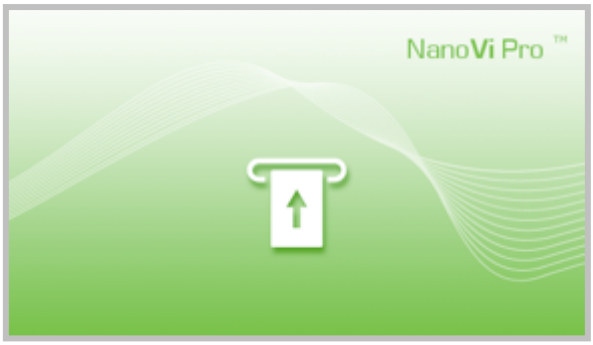


Figure 8.6: SmartCard mode

Timer Mode

The screen shown in Figure 8.7 is displayed when the NanoVi Exo™ or Pro device is configured in User Card timer mode. The SmartCard symbol shows a User Card is inserted. The card time shows the number of minutes remaining on the User Card. The session time display shows the number of minutes entered as the default session time.

Figure 8.7: User Card timer mode

The session time display shows 0 min, the desired session time must be input through the touch screen. After entering the time, press the start button. The session time will count down and minutes will be deducted from the card.

User Card sessions can be stopped at any time by pressing the stop button. Stopping the session takes you back to the initial entry screen shown in Figure 8.3. Pausing or stopping a session does not affect the number of minutes left on the card.

Session Mode

The device can be set up with a predetermined session time. In this case the session time shows and no keyboard is visible (Figure 8.8). In the example below the session time is 30 minutes and the user has 60 minutes left on their card. Although the time cannot be adjusted, it is still possible to pause or stop a session and to restart a paused session within 15 minutes of touching the pause symbol.

Figure 8.8: SmartCard with predetermined session time

If the User Card is removed at any time while the device is in SmartCard mode, the device will stop operating and display the initial SmartCard mode screen shown in Figure 8.6.

9 Use with Accessories

9.1 Transportation Case

1) The 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 the size restrictions for 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 both lids 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).

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

Weight with device and accessories: 25 lb. (11 kg)

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.

WARNING: 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.

WARNING: 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)

The humidifier must be removed from the device by pulling it straight up. The glass container is then unscrewed from the top of the humidifier.

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

WARNING: 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.

The glass container should be cleaned then rinsed with distilled, purified or osmotic water after 10 hours of use. It can be cleaned in a dishwasher but should be rinsed with distilled, purified or osmotic water. The diffuser should be rinsed with 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.

WARNING: Cleaning solution may be harmful and should not be used.

11 Maintenance

The NanoVi™ device requires no special maintenance. The PATIENT can only perform the following maintenance:

- Refresh the humidifier water.
- Replace the diffuser.
- Replace the Nasal Cannulas or Paper Tubes.
- Clean the device and its parts listed in section 10.

12 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 15 for the materials of the main components for reference for sorting parts for disposal.

13 Storage

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

1. Remove the plug from the power adapter cable.
2. Disconnect the main DC power transformer 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.
6. Place sealed box in a dry, safe place that is free from the possibility of accidentally falling.

14 Troubleshooting

14.1 Normal Operation

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

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

If the pump is 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 Figure 5.4 to see how the connection should be made.

If the pump creates little or no airflow, the effectiveness of the device is compromised. Please refer to the error codes below or contact customer support.

14.2 Errors

If an error occurs the error screen shown in Figure 13.1 is displayed. Note the error code number so that you can look it up in the table below. A telephone number is also displayed so that you can contact customer support.

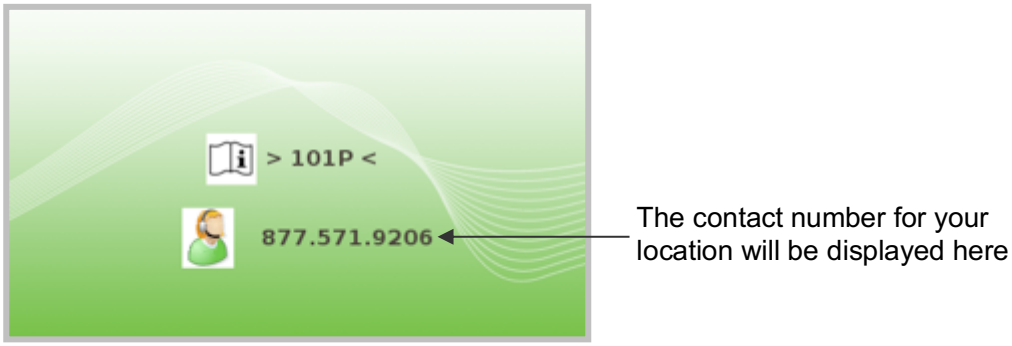


Figure 13.1 Error screen

Error codes are below and should be given to 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	Pump error
102A	Excitation unit error
103L	Lamp error
104F	Fan error

Table 13.1 Lookup table for error codes

15 Product Specifications and Registrations

15.1 Technical Specifications

	NanoVi Eco™ with Flex-Arm	NanoVi Pro™ with Flex-Arm	NanoVi Exo™
Article Number:	4650-00	4800-00	4900-00
Recommended application time per Recommended frequency of sessions:	**60 minutes** or more 3 x per week or more	**30 minutes** or more 3 x per week or more	**15 minutes** or more 3 x per week or more
Output performance:	100%	200% (Twice the output of the Eco)	400% (Twice the output of the Pro)
Minimum lifespan: Minimum # of sessions per lifespan:	10,000 hours = 600,000 minutes **10,000 sessions of 60 minutes**	10,000 hours = 600,000 minutes **20,000 sessions of 30 minutes**	10,000 hours = 600,000 minutes **40,000 sessions of 15 minutes**
Smartcard system: - **Owner Card,** pre-programmed at factory. - **User Card** programmed with device itself and only works on the device it was programmed with.	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 of 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: - Session Mode: - Infinity Mode: Option for grouping multiple devices: (With Smartcard System only)	**No** **No** **No** **No**	**Yes**, used application time gets deducted from the User Card. **Yes**, session minutes deducted from User Card. **Yes** **Yes**, User Card can be used for any device in the group.	**Yes**, used application time gets deducted from the User Card. **Yes**, session minutes deducted from User Card. **Yes** **Yes**, User Card can be used for any device in the group.
Illumination of water: Illumination effects:	7 colors, white & off Solid, variable speed transition	7 colors, white & off Solid, variable speed transition	7 colors, white & off Solid, variable speed transition
Excitation units / excitation elements: Spectral emission / max power:	1 / 6 1,100 – 1,300 nm. / 6 x 700 pW	2 / 12 1,100 – 1,300 nm. / 12 x 700 pW	4 / 24 1,100 – 1,300 nm / 24 x 700 pW
Dimensions (w x l x h): Weight:	12” x 11” x 9” (31 x 28 x 23 cm) 8.5 lb. (3.9 kg)	12” x 11” x 9” (31 x 28 x 23 cm) 9.0 lb. (4.1 kg)	12” x 11” x 9” (31 x 28 x 23 cm) 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: Check valve: Air intake and output:	2 No 0.141 CFM (4.0 liters per minute)	2 Yes 0.141 CFM (4.0 liters per minute)	2 Yes 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, cooling fan, illumination lamp	Pumps, excitation elements, cooling fan, illumination lamp	Pumps, excitation elements, cooling fan, illumination lamp
Service check: Warranty:	Not Required, self testing 2 Years	Not Required, self testing 2 Years	Not Required, self testing 2 Years

Necessary Parts

Glass Container:	Glass
Humidifier unit / holder for Glass Container:	Aluminum
Owner Smartcard for NanoVi Pro and NanoVi Exo:	Pre-programmed to choose the operation mode
User Smartcards for NanoVi Pro and NanoVi Exo:	Programmable for up to 9,999 minutes
Power Supply Input / Output:	100 - 240V AC / 12V DC, 4A
Power Cord (US, UK, EU, AUS, ITA, CHE or CHN):	6 ½ ft. (2 m)
User Manual / Concise User Manual:	Available in different languages

Consumables

Diffuser for Humidifier:	Replace once a year
Paper tube used with Flex-Arm:	White medical paper tubes
Nasal cannulas:	1 ft. (0.3 m) Latex-free material
User Smartcards for NanoVi Pro and NanoVi Exo:	Programmable for up to 9,999 minutes

15.2 Product Registrations

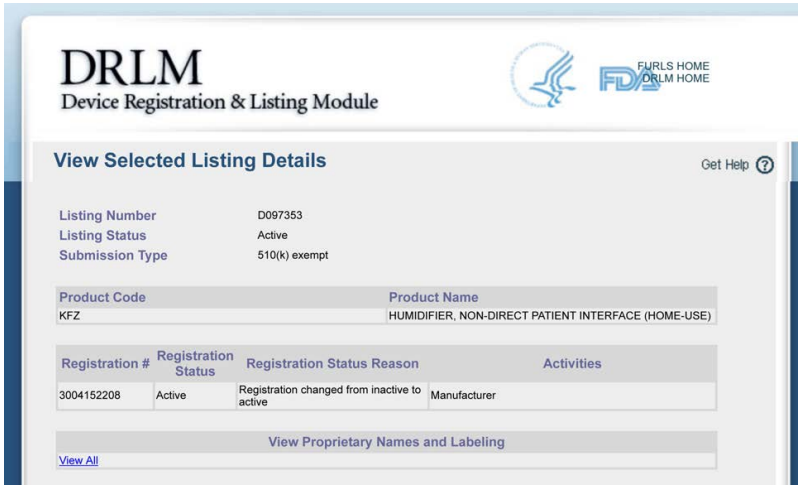
15.2.1 US FDA Registration

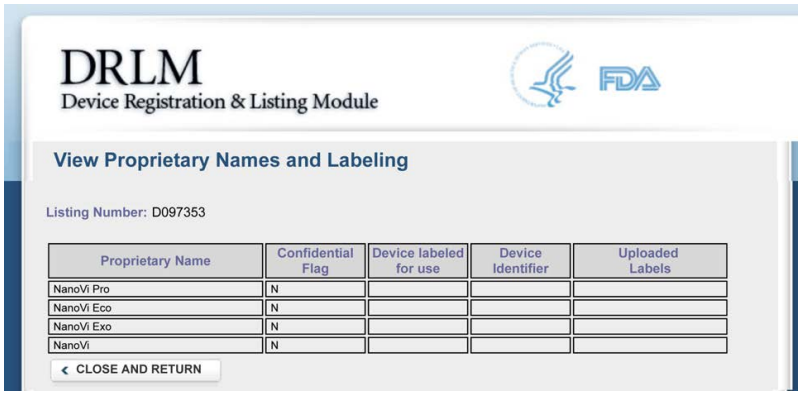
NanoVi™, NanoVi Eco™, NanoVi Pro™, and NanoVi Exo™ devices are registered with the United States Food and Drug Administration (FDA).

FDA Device Listing number: D097353

FDA Facility Registration number: 3004152208

FDA Device Listing:





15.2.2 European EC Declaration

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

eng3
Life Science Technology

EC Declaration of Conformity

We, the undersigned,

Manufacturer	Eng3 Corporation
Address, City	2234 Eastlake Ave E, Seattle, WA 98102
Country	USA
Phone number	US-206-525 0227
Fax number / e-mail	Fax: US-425-650 7171, email: customer.care@eng3corp.com
Authorized representative in Europe	See label with name and contact information on the backside of the product or visit: www.eng3corp.com/service

certify and declare under our sole responsibility that the following apparatus:

Description	**Medical Device, Class I**
Manufacturer	Eng3 Corporation, Seattle, USA
Brand	NanoVi Wellness
Identification	NanoVi, NanoVi Eco, NanoVi Pro, NanoVi Exo
Restrictive use	Professional use and Home use

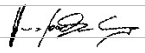
conforms with the essential requirements for CE-marking of:

Medical Devices Directive 93/42/EEC and 2007/47/EG
General Product Safety Directive
Electromagnetic Compatibility Directive (EMC)
Restriction of Hazardous Substances Directive (RoHS1) 2002/95/EC
Waste Electrical and Electronic Equipment Directive (WEEE) 2002/96/EC, currently Directive 2012/19/EU
Packaging and packaging waste directive, 94/62/EC

the following standards / specifications were applied:

IEC 60601-1:2005+AMD1:2012 General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2014 Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2013 Collateral Standard: Usability
IEC 60601-1-11:2015 Collateral Standard: Home Healthcare Environment
ISO 14971:2007(E) Medical Devices - Application of Risk Management to Medical Devices
IEC 62366-1:2015 Application of Usability Engineering to Medical Devices

and therefore, complies with the essential requirements and provisions of Medical Device , Class I.

Name	Hans J. Eng
Position of person binding	President / CEO
the manufacturer	Eng3 Corporation
Date	March 15, 2018
Signature	

CE

www.eng3corp.com | 206.525.0227 | info@eng3corp.com

16 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.

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

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

Service Department

For factory repair service call:

+1 206.525.0227

Facsimile: +1 425.650.7171

17 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 number: +1 206.525.0227 or email address: customer.care@eng3corp.com. 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.

18 Ordering Parts and Accessories

To order parts and accessories contact your local sales representative or Eng3 Corporation

at: +1 206.525.0227

Complete contact information is found below in Section 19.

19 Contact Information

MANUFACTURER

Eng3 Corporation

2234 Eastlake Avenue E. Ste. A

Seattle, WA 98102

Office phone: +1 206.525.0227

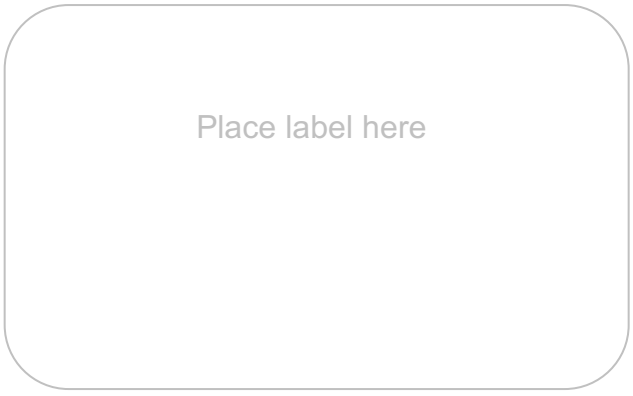
Fax: +1 425.650.7171

E-Mail: Info@eng3corp.com

URL: www.eng3corp.com

IMPORTER / REPRESENTATIVE

Contact: www.eng3corp.com/service



20 Appendix A: Accompanying Documents

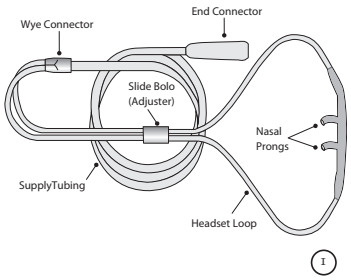
20.1 User Manual for Nasal Cannulas Model # 1600-1

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.

Who to Contact

For additional questions or comments about your Nasal Cannula, contact Salter Labs customer care at 800-421-0024, Mon–Fri 8 AM to 5 PM CST.; or email Customercare@salterlabs.com.

For questions about your home oxygen equipment, contact your local home care provider.

If your physical symptoms worsen or you experience a sudden change in your condition (e.g., increased shortness of breath, fever, dizziness), or if you develop a hypersensitivy (severe rash) to your nasal cannula, call your doctor.

If you experience severe physical problems (e.g., chest pains, cannot breath), call 911.

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(Continued on the next page)

Instructions for Use (continued)

Application

1. Wash hands. Remove nasal cannula from package.

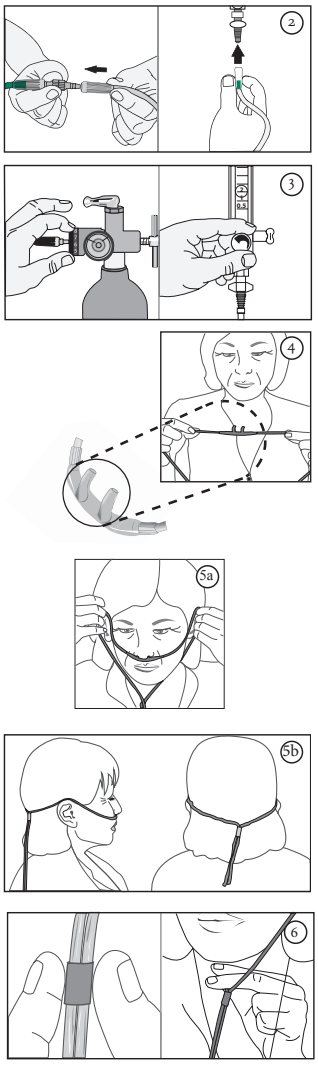
2. Attach end connector to oxygen source, e.g., oxygen extension tubing or oxygen flow control outlet.

3. Adjust flow control knob to the prescribed liter flow. Check for gas flow from the nasal prongs.

4. a–Position the nasal cannula with the nasal prongs facing upward and curved toward the face.
   b–Insert the two nasal prongs into the nostrils.

5. a–Wrap the headset loop up and over both ears.
   b–Alternative placement: Secure headset loop behind your head.

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.



Care and Cleaning Instructions

1. Once a day, use a clean damp cloth to wipe off the nasal prongs and headset tubing.

2. Do not use strong or scented detergents, degreasert, alcohol based products or lotion soaps to clean your nasal cannula.

3. Do not sterilize your nasal cannula.

4. Discard and replace your nasal cannula when it becomes soiled, discolored or the prongs become stiff. Recommend replacing nasal cannula at least once every 14 days. Do not use your nasal cannula for more than 30 days.

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(Continued on the next page)

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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.

- Do not use petroleum based products or oil-based creams and lotions in or around your nose. For example, 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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(Continued on the next page)

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.	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. Flow control valve is not turned on.	2. Set flow control to prescribed setting.
	3. Oxygen system is not functioning properly or oxygen container is empty.	3. Switch to backup oxygen source and contact your homecare provider.
	4. The nasal cannula is disconnected from oxygen device or supply tubing.	4. Reconnect oxygen tubing. Ensure all tubing connections are tight and secure.
	5. Nasal cannula or oxygen tubing kinked or blocked.	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.	1. Pour out the excess water. Ensure that the humidifer bottle is upright.
	2. Water trap is full	2. Empty water trap.
	3. High humidity environment, or sudden drop in temperature.	3. Consider adding a water trap to your oxyen supply tubing.
Nasal dryness or irritation	1. Gas flow is dry.	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. No humidifier is being used.	2. Contact your doctor or homecare provider to request humidification.
Soreness or irritation around ears	1. Headset tubing too tight.	1. Loosen headset tubing.
	2. Tubing pressing against skin.	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.	1. Contact your health care provider and/or doctor.
	2. Nasal cannula is dirty.	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. Cleaning detergent used to clean nasal cannulas may be absorbed into the plastic and can irritate the skin.	3. Replace cannula. When cleaning cannula only use a damp cloth. Do not use strong detergents, disinfectants or oil based soaps.
	4. Nasal prongs are stiff causing nasal irritation and discomfort.	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.	1. Replace your nasal cannula
	2. Alcohol based cleaners may harden the PVC material	2. Replace your nasal cannula

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20.2 User Manual for Power Supply Part # GSM60A05-P1J

User's Manual

1) The power supply shall be used and operated according to the following specification.

2) The input and output shall not exceed the rating on the label.

3) The power supply shall be operated in dry conditions.

Manufacturer: MEAN WELL USA, INC
44030 Fremont Blvd,
Fremont, CA 94538
USA
www.meanwellusa.com

60W AC-DC Reliable Green Medical Adaptor GSM60A series

(Ⅴ for 5~9V) EN60601-1 ANSI/AAMI ES60601-1 IEC60601-1

Features

- 3 pole AC inlet IEC320-C14, Class Ⅰ power unit
- Medical safety approved (2 x MOPP) accroding to ANSI/AAMI ES60601-1 and IEC/EN60601-1
- Extremely low leakage current
- No load power consumption<0.1W
- Energy efficiency level VI and meet CoC Version 5 (Except 5~9V for Level V)
- -30~+70℃ wide range working temperature
- Protections: Short circuit / Overload / Over voltage/ Over temperature
- LED indicator for power on
- Lifetime > 105 K hours
- 3 years warranty

Applications

- Mobile clinical workstation
- Oral irrigator
- Portable hemodialysis machine
- Breath Machine
- Medical computer monitor

Description

GSM60A is a highly reliable, 60W desktop style single-output green medical adaptor series. This product is a class Ⅰ power unit(with FG),equipped with a standard IEC320-C14 AC inlet and adopting the input range from 80VAC to 264VAC. The entire series supplies different models with output voltages between 5VDC and 48VDC that can satisfy the demands for various types of medical electrical devices. The circuitry design meets the international medical standards (2*MOPP), having an ultra low leakage current (<100μA), fitting the medical devices in direct electrical contact with the patients.

With the efficiency up to 91% and the extremely low no-load power consumption below 0. 1W, GSM60A is compliant with USA EISA 2007/DoE , Canada NRCan, Australia and New Zealand MEPS , EU ErP, and meet Code of Conduct(CoC) Version 5.The supreme feature allows the adaptor to save the energy when it is either under the operating mode or the standby mode. The entire series utilizes the 94V-0 flame retardant plastic case.GSM60A is certified for the international medical safety regulations.

Model Encoding

GSM60 A 05 - P1J

- P1J: DC plug type — P1J: Standard model,2.1φx5.5φx11mm,C+,tuning fork type; Other options available by customer requested (see Page 4~5)
- 05: Output voltage
- A: IEC320-C14 AC inlet
- 60: Rated wattage
- GSM: Series name

MEAN WELL 60W AC-DC Reliable Green Medical Adaptor **GSM60A series**

SPECIFICATION

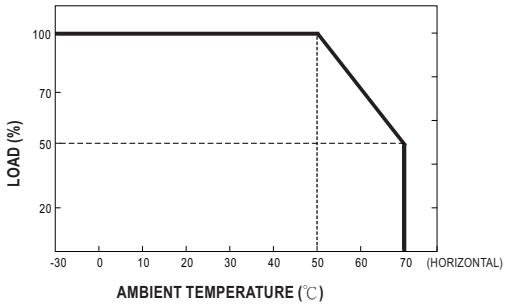
ORDER NO.		GSM60A05-P1J	GSM60A07-P1J	GSM60A09-P1J	GSM60A12-P1J	GSM60A15-P1J	GSM60A18-P1J	GSM60A24-P1J	GSM60A48-P1J
OUTPUT	SAFETY MODEL NO.	GSM60A05	GSM60A07	GSM60A09	GSM60A12	GSM60A15	GSM60A18	GSM60A24	GSM60A48
	DC VOLTAGE Note.2	5V	7.5V	9V	12V	15V	18V	24V	48V
	RATED CURRENT	6A	6A	6A	5A	4A	3.33A	2.5A	1.25A
	CURRENT RANGE	0.1 ~ 6A	0.1 ~ 6A	0.1 ~ 6A	0.1 ~ 5A	0.1 ~ 4A	0.1 ~ 3.33A	0.1 ~ 2.5A	0.1 ~ 1.25A
	RATED POWER (max.)	30W	45W	54W	60W	60W	60W	60W	60W
	RIPPLE & NOISE (max.) Note.3	80mVp-p	80mVp-p	100mVp-p	100mVp-p	100mVp-p	120mVp-p	150mVp-p	240mVp-p
	VOLTAGE TOLERANCE Note.4	±5.0%	±5.0%	±5.0%	±3.0%	±3.0%	±3.0%	±3.0%	±2.5%
	LINE REGULATION Note.5	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%
	LOAD REGULATION	±5.0%	±5.0%	±5.0%	±3.0%	±3.0%	±3.0%	±3.0%	±2.5%
	SETUP, RISE TIME Note.6	1000ms, 30ms / 230VAC 1500ms, 30ms / 115VAC at full load							
	HOLD UP TIME (Typ.)	50ms / 230VAC 18ms / 115VAC at full load							
INPUT	VOLTAGE RANGE Note.7	80 ~ 264VAC 113 ~ 370VDC							
	FREQUENCY RANGE	47 ~ 63Hz							
	EFFICIENCY (Typ.)	81.5%	86%	87.5%	88%	88.5%	89%	90.5%	91.5%
	AC CURRENT (Typ.)	1.4A / 115VAC 1A / 230VAC							
	INRUSH CURRENT (Typ.)	Cold start 30A/115VAC 60A / 230VAC							
	LEAKAGE CURRENT(max.)	Earth leakage current < 100μA/264VAC , Touch current < 100μA/264VAC							
PROTECTION	OVERLOAD	105 ~ 160% rated output power							
		Protection type : Hiccup mode, recovers automatically after fault condition is removed							
	OVER VOLTAGE	5.2 ~ 7.0V	7.8 ~ 10.2V	9.4 ~ 12.2V	12.6 ~ 16.2V	15.7 ~ 20.3V	18.9 ~ 24.3V	25.2 ~ 32.4V	50.4 ~ 64.8V
		Protection type : Shut down o/p voltage, re-power on to recover							
	OVER TEMPERATURE	Shut down o/p voltage, re-power on to recover							
ENVIRONMENT	WORKING TEMP.	-30 ~ +70℃ (Refer to "Derating Curve")							
	WORKING HUMIDITY	20% ~ 90% RH non-condensing							
	STORAGE TEMP., HUMIDITY	-40 ~ +85℃, 10 ~ 95% RH non-condensing							
	TEMP. COEFFICIENT	±0.03% / ℃ (0~40℃)							
	VIBRATION	10 ~ 500Hz, 2G 10min./1cycle, period for 60min. each along X, Y, Z axes							
	OPERATING ALTITUDE Note.8	3000 meters							
SAFETY & EMC (Note 9)	SAFETY STANDARDS	IEC60601-1, TUV EN60601-1, ANSI/AAMI ES60601-1(3.1 version), CAN/CSA-C22.2 No. 60601-1:14 - Edition 3, EAC TP TC 004 approved							
	ISOLATION LEVEL	Primary-Secondary: 2xMOPP, Primary-Earth:1xMOPP							
	WITHSTAND VOLTAGE	I/P-O/P:4KVAC I/P-FG:2KVAC O/P-FG:SHORT							
	ISOLATION RESISTANCE	I/P-O/P, I/P-FG:100M Ohms / 500VDC / 25℃ / 70% RH							
	EMC EMISSION	**Parameter**	**Standard**	**Test Level / Note**					
		Conducted emission	EN55011 (CISPR11), FCC PART 15 / CISPR22, CAN ICES-3(B)/NMB-3(B)	Class B					
		Radiated emission	EN55011 (CISPR11), FCC PART 15 / CISPR22, CAN ICES-3(B)/NMB-3(B)	Class B					
		Harmonic current	EN61000-3-2	Class A					
		Voltage flicker	EN61000-3-3	-----					
	EMC IMMUNITY	EN55024 , EN60601-1-2, EN61204-3							
		Parameter	**Standard**	**Test Level / Note**					
		ESD	EN61000-4-2	Level 4, 15KV air ; Level 4, 8KV contact					
		RF field susceptibility	EN61000-4-3	Level 3, 10V/m(80MHz~2.7GHz) Table 9, 9~28V/m(385MHz~5.78GHz)					
		EFT bursts	EN61000-4-4	Level 3, 2KV					
		Surge susceptibility	EN61000-4-5	Level 3, 1KV/Line-Line , 2KV/Line-FG					
		Conducted susceptibility	EN61000-4-6	Level 3, 10V					
		Magnetic field immunity	EN61000-4-8	Level 4, 30A/m					
		Voltage dip, interruption	EN61000-4-11	100% dip 1 periods, 30% dip 25 periods, 100% interruptions 250 periods					
OTHERS	MTBF	720K hrs min. MIL-HDBK-217F(25℃)							
	DIMENSION	125*50*31.5mm (L*W*H)							
	PACKING	0.32Kg; 40pcs/ 13.8Kg/1.05CUFT							
CONNECTOR	PLUG	See page 4~5 ; Other type available by customer requested							
	CABLE	See page 4~5 ; Other type available by customer requested							

NOTE

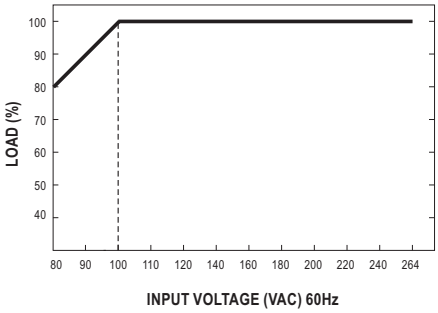
1. All parameters are specified at 230VAC input, rated load, 25℃ 70% RH ambient.
2. DC voltage: The output voltage set at point measure by plug terminal & 50% load.
3. Ripple & noise are measured at 20MHz by using a 12" twisted pair terminated with a 0.1μf & 47μf capacitor.
4. Tolerance: includes set up tolerance, line regulation, load regulation.
5. Line regulation is measured from low line to high line at rated load.
6. Length of set up time is measured at first cold start. Turning ON/OFF the power supply may lead to increase of the set up time.
7. Derating may be needed under low input voltages. Pleas check the derating curve for more details.
8. The ambient temperature derating of 3.5℃/1000m with fanless models and of 5℃/1000m with fan models for operating altitude higher than 2000m(6500ft).
9. The power supply is considered as an independent unit, but the final equipment still need to re-confirm that the whole system complies with the EMC directives. For guidance on how to perform these EMC tests, please refer to "EMI testing of component power supplies." (as available on http://www.meanwell.com)

MEAN WELL 60W AC-DC Reliable Green Medical Adaptor **GSM60A series**

■ Derating Curve

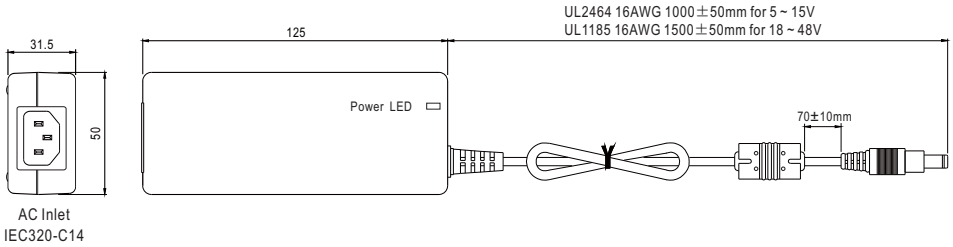


■ Static Characteristics



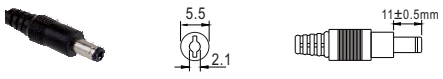
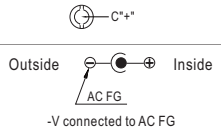
■ Mechanical Specification

Case No. GS60A Unit:mm

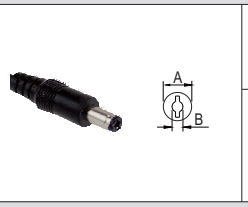


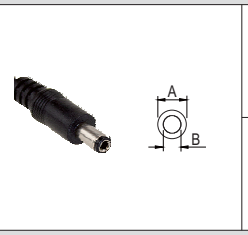
■ DC output plug

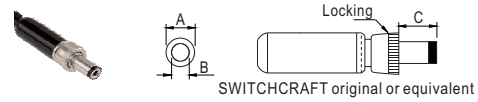
◎ Standard plug: P1J

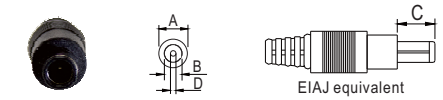
P1J	Pin Assignment
	 -V connected to AC FG

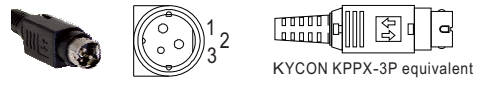
◎ Optional DC plug:

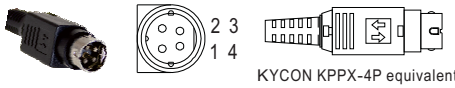
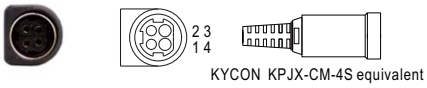
Tuning Fork Style	Type No.	A	B	C
		OD	ID	L
	P1I	5.5	2.1	9.5
	P1L	5.5	2.5	9.5
	P1M	5.5	2.5	11.0
	P1IR	5.5	2.1	9.5
	P1JR	5.5	2.1	11.0
	P1LR	5.5	2.5	9.5
	P1MR	5.5	2.5	11.0

Barrel Style	Type No.	A	B	C
		OD	ID	L
	P2I	5.5	2.1	9.5
	P2J	5.5	2.1	11.0
	P2L	5.5	2.5	9.5
	P2M	5.5	2.5	11.0
	P2IR	5.5	2.1	9.5
	P2JR	5.5	2.1	11.0
	P2LR	5.5	2.5	9.5
	P2MR	5.5	2.5	11.0

Lock Style	Type No.	A	B	C
		OD	ID	L
	P2S(S761K)	5.53	2.03	12.06
	P2K(761K)	5.53	2.54	12.06
	P2C(S760K)	5.53	2.03	9.52
	P2D(760K)	5.53	2.54	9.52

Center Pin Style	Type No.	A	B	C	D
		OD	ID	L	Center Pin
	P4A	5.5	3.4	11.0	1.0
	P4B	6.5	4.4	11.0	1.4
	P4C	7.4	5.1	11.0	0.6

Min. DIN 3 Pin with Lock (male)	Type No.	Pin Assignment	
		PIN No.	Output
	R6B	1	+Vo
		2	-Vo
		3	+Vo

Min. DIN 4 Pin with Lock (male)	Type No.	Pin Assignment	
		PIN No.	Output
 KYCON KPPX-4P equivalent	R7B	1	+Vo
		2	-Vo
		3	-Vo
		4	+Vo
Min. DIN 4 Pin with Lock (female)	**Type No.**	**Pin Assignment**	
		PIN No.	Output
 KYCON KPJX-CM-4S equivalent	R7BF	1	+Vo
		2	-Vo
		3	-Vo
		4	+Vo
DIN 5 Pin (male)	**Type No.**	**Pin Assignment**	
		PIN No.	Output
	R1B	1	-Vo
		2	-Vo
		3	+Vo
		4	-Vo
		5	+Vo
Stripped and tinned leads	**Type No.**	**Pin Assignment**	
		PIN No.	Output
 Length of Land L1 by request (MW's standard length, L: 25 mm, L1: 5 mm)	by customer	1	+Vo
		2	-Vo

■ Installation Manual

Please refer to : http://www.meanwell.com/manual.html