The GentleWave® X System Console Instructions for Use

Revision Date:

SONENDO®

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Contents

1.0 Indications for Use

1.1. The Sonendo® GentleWave® X System is intended to prepare, clean, and irrigate teeth indicated for root canal therapy.

1.2. When used with the Sonendo GentleWave Molar Procedure Instrument, the System is indicated for 1st and 2nd molar teeth.

1.3. When used with the Sonendo GentleWave Anterior/Premolar Procedure Instrument, the System is indicated for anterior and premolar teeth.

1.4. When used with the Sonendo GentleWave Posterior Crossfire Procedure Instrument, the System is indicated for premolar teeth.

1.5. When used with the Sonendo GentleWave Posterior Crossfire Procedure Instrument, the System is indicated for 1st and 2nd molar teeth.

2.0 Device Description

2.1. The System is composed of the GentleWave® X Console (Console), Procedure Instrument (Handpiece) and accessories. The System is designed exclusively for use with a Sonendo GentleWave Procedure Instrument. For proper use of the Procedure Instrument with the System, consult the Sonendo GentleWave Procedure Instrument Instructions for Use.

2.2. The Console prepares and delivers procedure fluid to the Procedure Instrument (PI).

2.3. The System delivers procedure fluid into the access cavity of the tooth in such a way that it creates hydroacoustic waves within the procedure fluid accumulated inside the tooth. The procedure fluid delivered into the tooth removes organic matter from the root canals. The Console aspirates the procedure fluid and organic matter from the tooth into the Console waste canister.

2.4. The Console is designed for use with a cleaning procedure fluid of 6-10% Sodium Hypochlorite solution (NaOCl) without surfactants, 17% buffered Ethylenediaminetetraacetic acid (EDTA) and Distilled Water.

2.5. Device does not have any essential performance as defined by IEC 60601-1.

3.0 Contraindications

3.1. Refer to the specific contraindications specified in the GentleWave Procedure Instrument Instructions For Use.

3.2. Not for use with an implantable medical electronic device (e.g. pacemaker, defibrillator, etc.).

4.0 Restrictions

4.1. Federal law restricts this device to sale by or on the order of a licensed dental professional who is trained in the endodontic procedures.

4.2. This device is intended for use solely by qualified, licensed dental professionals.

4.3. This device is intended for and restricted to dental use.

4.4. For a proper procedure, it is important that the operator review the Console IFU as well as the Procedure Instrument Instructions For Use prior to use.

4.5. Prior to use the operator shall receive adequate training on the System.

5.0 Precautions

Failure to follow the following precautions may result in damage to the device, or an ineffective procedure, or harm to the patient and/or user.

5.1 In the case of device or packaging damage, deterioration, or malfunction, discontinue use immediately and contact Sonendo®.

5.2 Misuse of the Console resulting in corrosion, scratching, loosening, bending, or fracture of any or all of the components may inhibit or prevent proper function and may harm the patient and/or user.

5.3 The Console is provided non-sterile. Clean the exterior surfaces per Maintenance, Handling and Service instructions. The use of a scouring powder or an abrasive sponge will damage its surface.

5.4 Use only approved solvents or disinfectants in the fluid paths of the Console.

5.5 The System is to be used only with Sodium Hypochlorite that is regular concentrated or regular concentrated disinfecting within the 6-10% concentration range and without surfactants, scents, or additives. Sodium Hypochlorite with added surfactants, scents, or additives have additional chemicals which may disrupt the System. We do not recommend the use of the following Sodium Hypochlorite types: splashless, scented, germicidal, or performance.

5.6 The System is not intended to operate with tap water.

5.7 Proceed with caution when handling the fluid containing components as they may contain NaOCl or EDTA.

5.8 All caries must be removed prior to use of the device in order to provide adequate treatment with the System. If there is leakage of the Procedure Fluid there may be inhibition of cleaning and irrigation of the tooth.

5.9 Procedure fluids may come in contact with the patient and could cause harm to the patient.

5.10 Adequate seal of the tooth must be completed prior to use of the device in order to provide adequate treatment with the System. If there is leakage of the Procedure Fluid, there may be inhibition of cleaning and irrigation of the tooth.

6.0 Warnings

Failure to follow the following warnings may result in damage to the device, an ineffective procedure, or harm to the patient and/or user.

6.1 Ensure that the rated voltage of the power supply corresponds to the local line voltage to prevent damage to the unit. At minimum, the circuit must have a 10A breaker.

6.2 The Console must be connected to a three-pronged power outlet to ensure proper grounding.

6.3 It is recommended to power down the Console through the Shutdown Menu. In case of an emergency, it can be unplugged in order to interrupt the function of the Console without damaging the System. As such, the Console should be placed so that either end of the power cord is readily available to the operator in case of emergencies.

6.4 Check the condition of the power connection wiring prior to use. Do not connect the Console if the wiring shows signs of wear, aging, cracking, or fraying.

6.5 Not recommended for use in oxygen rich environments.

6.6 Avoid contact with patient while drawers are open.

6.7 Damage to the Console panel or other parts may expose circuitry. In such a case, do not use the Console and contact Customer Care.

6.8 Never dismantle, adjust, repair, or modify any components in a Procedure Instrument, Accessories, or the Console.

6.8.1 Console areas that may present additional hazards are not accessible to the user. These areas should only be accessed by trained service personnel with the appropriate tools.

6.9 When transporting the console, all fluid containers should be completely empty or removed from the console entirely. All accessories should be removed from console (foot pedal, power cord, Procedure Instrument) and transported separately. Ensure all lids and drawers are in secure, closed position.

6.10 Always use the designated handles when transporting the console. The front handle (underneath the display) and the rear handle (above waste door) should be the primary touch points when an operator moves the console. Using non-designated touch points to move the console (such as the touchscreen display, the PI Holder, cables (foot pedal, power), or tubing (high-pressure hose, evacuation tubing)) can lead to damage to the console.

6.11 Always check that the unit is installed in a safe and stable position. Do not position the Console in any orientation other than with the wheels locked and sitting on a stable, flat, horizontal surface.

6.12 Ensure the System has been properly flushed before and after each procedure to prevent cross-patient contamination.

6.13 Use the System for the intended purposes only. Improper use of this device and/or failure to observe manufacturer's instructions will invalidate all claims under warranty and any other claims, may result in harm to the patient and/or user, or the device being damaged, possibly beyond repair.

6.14 The Console and Procedure Instrument operate at high pressure. Incorrect operation may result in damage to the device, an ineffective procedure, or harm to the patient and/or user.

7.0 Complications and Adverse Reactions

The complications and adverse effects of this System are similar to other systems of similar design. A successful result may not be achieved in every instance of use with this device. This fact is especially true in dentistry where other patient conditions may compromise the result. Complications and adverse reactions include, but are not limited to, the following:

7.1. Bleeding

7.2. Extrusion of irrigants

7.3. Foreign material deposited in tooth

7.4. Infection

7.5. Numbness/paresthesia

7.6. Pain and/or discomfort

7.7. Reaction to materials or chemicals

7.8. Retreatment

7.9. Tooth loss

7.10. Sensitivity to hot, cold and/or pressure

7.11. Swelling or inflammation

7.12. Tissue damage

7.13. Tooth discoloration

7.14. Reaction to medication or anesthesia

7.15. Apical transportation

7.16. Crown fracture

7.17. Damaged filling

7.18. Defective or inadequate restoration

7.19. Extrusion of debris

7.20. Extrusion of foreign material

7.21. Instrument separation

7.22. Ledge formation

7.23. Perforation

7.24. Recurrent decay

7.25. Root fracture

7.26. Weakening of the tooth

8.0 Features

8.1. The Console is designed to be used only with a GentleWave Procedure Instrument. When the Procedure Instrument and Console are used together, they will be referred to as the GentleWave® X System (System).

8.2. The System is intended to prepare, irrigate and clean teeth indicated for root canal therapy. Depending on the choice of Procedure Instrument, the System may treat molar, anterior and premolar teeth.

8.3. The System is designed to simultaneously irrigate and clean the root canals of a tooth, exposing the natural surface of the dentin and maintaining tooth strength and integrity.

8.4. The System has the capability to integrate with TDO software.

9.0 Device Components

9.1. The System requires the following items in order to be operated:

GentleWave® X Console

Delivery Hose

Evacuation Tubing

Distilled Water Reservoir

NaOCl Reservoir

EDTA Reservoir

Waste Canister

Foot Pedal

Power Cord

GentleWave Molar Procedure Instrument or GentleWave Anterior / Premolar (APM) Procedure Instrument or GentleWave Posterior Crossfire Handpiece

10.0 System Specifications

Table 1. GentleWave® X Console Specifications

System Parameter	Specification
Product Name	*GentleWave® X Console*
Operating Conditions	*18°C (65°F) to 33°C (86°F) and 20% to 80% Relative Humidity, non-condensing*
Reservoir Fluids Temperature[1]	*10°C (50°F) to 40°C (104°F)*
Storage Conditions	*10°C (50°F) to 50°C (122°F) and 20% to 80% Relative Humidity, non-condensing*
Operating Atmospheric Pressure	*700 - 1060 hPa (-1000 - +10000 ft above sea level)*
Flow Pressure	*9200psi +/- 1000psi*
Flow Profile	*Continuous*
NaOCl Reservoir Volume[2]	*1300 mL*
EDTA Reservoir Volume[2]	*550 mL*
Water Reservoir Volume[2]	*2650 mL*

1 Water, EDTA and NaOCl are used as supplied, at room temperature.

2 Volumes used of water, EDTA, NaOCl, Laguna Reservoir #1 & Laguna Reservoir #2 are nominal values.

⚠ To ensure the Console and Procedure Fluids remain within the specifications the Console and Procedure Fluids should be stored in a cool location away from direct sunlight.

11.0 Using the GentleWave® X System – Primary Functions

11.1. Contact Sonendo prior to removing the Console from the packaging and prior to use, for appropriate training and unboxing support.

11.2. Unpacking and Initial Set Up

Note: in the case of device or packaging showing signs of damage, deterioration, or malfunction, discontinue use immediately and contact Sonendo.

11.2.1. Carefully unpack the Console from its packaging crate. Use caution to avoid scratching the Screen. The user must have appropriate training prior to the first use.

11.2.2. Move Console to desired location and lock in place by engaging locking casters on front two wheels. It is recommended to be near a sink for preparing the Console

11.2.3. Plug in the Power Cord to the Console and then into an outlet. Ensure the Power Safety Switch in the back of the unit is in the "On" position.

11.2.3.1. Standby button in front of console will be flashing white (**Figure 1).**

11.2.4. Turn the console on by holding down the Standby Button located in the front of the unit until the console powers on.

11.2.4.1. Standby button in front of console will turn solid blue after console powers on **(Figure 2).**

Figure 1. Standby Button – Console Ready

Figure 2. Standby Button – Console ON

11.2.5. Ensure the Foot Pedal is attached to the Console. If not, attach the Foot Pedal to the Food Pedal connection located at the lower rear of the Console.

11.2.6. Wait until the Home Screen (**Figure 9)** appears on the Screen of the unit. Each Screen will guide the user through the steps leading up to the Procedure.

Note: If using the Console for the first time, an initial system sanitization will be required. Follow the Maintenance Setup in Section 12.

Idle Mode / Backup Battery

11.2.7. The console can maintain an idle mode on a backup battery if AC/outlet power has been removed intentionally or accidently.

11.2.7.1. Console is non-operational in idle mode. No fluidic operation can occur without connection to AC/outlet power.

11.2.7.2. Standby button in front of console will flash amber (**Figure 3).**

11.2.8. Console will retain status of Prime. If console is unplugged from AC power and was previously Primed, the console will not need to re-Prime.

11.2.9. Console will retain Procedure information as well. If AC/outlet power is lost during the middle of a procedure, the console will immediately pause fluid delivery. When AC/outlet power is restored, the console will resume from the last completed checkpoint.

Figure 3. Standby Button – Console Idle

Accessing the Main Toolbar

11.2.10. The main menu toolbar (**Figure 5)** allows for navigation to high usage user functions: *Home, Maintenance, Settings, & Shutdown*

11.2.11. Access the toolbar by clicking on the circular icon (**Figure 4)** at the top of the screen, or by swiping down from the top of the screen.

11.2.12. To minimize the toolbar without making a selection, click on the upward facing arrow icon.

Figure 4. Accessing Main Toolbar

Figure 5. Main Toolbar

Figure 6. GentleWave Console

11.2 Filling the Procedure Fluid Reservoirs

11.2.1 Open the fluid housing lid by lifting on the fluid lid **(Figure 6).** Remove the Fluid Reservoirs from the fluid compartment.

Note: Do not fill bottles without removing from compartment first

11.2.2 Remove the cap on each Reservoir and fill with the respective Procedure Fluid (as labeled on the Reservoir).

11.2.3 Replace the cap and reinsert each Reservoir into its designated location in the fluid compartment (labeled with a colored sticker that matches the bottle label). Each Reservoir is shaped to fit in only one location in the fluid compartment.

11.2.4 Ensure the Waste Canister is Emptied each time Fluid Reservoirs are filled to avoid Waste Canister overflow.

Note: Ensure all Reservoirs are capped and that the fluid compartment is wiped dry and closed before proceeding to the next step.

11.2.5 Inspect bottle connectors for particulates/crystallization daily.

Note: Keeping the bottles (with some amount of procedure fluid) in the connectors overnight should help prevent crystallization

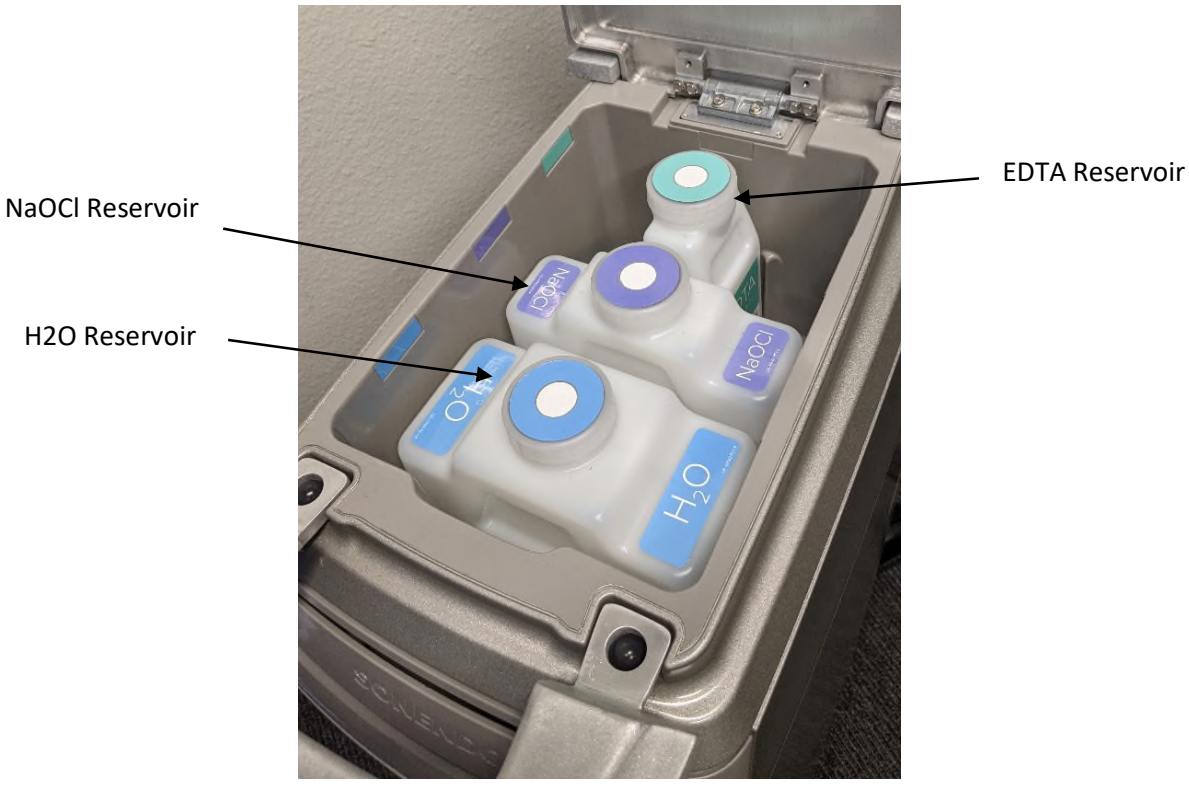


Figure 7: Filling the Procedure Fluid Reservoirs

11.2 Emptying the Waste Canister

11.3.1 Open the Waste Drawer (**Figure 8)** in the rear of the Console by firmly pushing on door until there is a clicking sound. Ensure that drawer is fully extended and there is sufficient clearance to remove canister.

11.3.2 Carefully lift Waste Canister out of housing

Note: Be mindful of the gap between the fluid compartment and its Waste Canister as this is a potential pinch point.

11.3.3 Remove cap from Waste Canister and empty contents into sink or appropriate waste receptacle through Waste Canister spout.

11.3.4 Replace cap and reinsert Waste Canister into housing.

11.3.5 Carefully close the Waste Drawer.

Figure 8. Waste Canister

11.4 Procedure Preparation – Priming System

11.4.1 Select *Prime System* on the **Home Screen** (**Figure 9**).

11.4.2 This will lead to the **Prime System Screen** (**Figure 10**).

11.4.3 Pre-Procedure Prime is only required at the beginning of the day in order to prepare the Console and Procedure Fluids for proper delivery. The steps for Pre-Procedure Prime appear on the **Prime System Screen** (**Figure 10**).

Note: Reference the troubleshooting section for mixing and concentration issues.

11.4.4 Attach the luer connection of the Evacuation Tubing to the Console's Purge Port. Check the Evacuation Tubing for any potential kinks.

Note: Ensure the check valve from a previous procedure has not been left on the Vacuum Purge Port. Doing so may result in an error message. The check valve is located on the distal end of the vacuum line attached to the Procedure Instrument.

11.4.5 Connect the distal end of the Delivery Hose to the Purge Port by attaching the Delivery Hose Connector to the Purge Port.

11.4.6 Once ready, press the Prime button on the Screen to begin Pre-Procedure Prime.

Note: Do not disconnect tubing from Purge Port during prime!

11.4.7 The Prime is complete when the progress bar shows 100%.

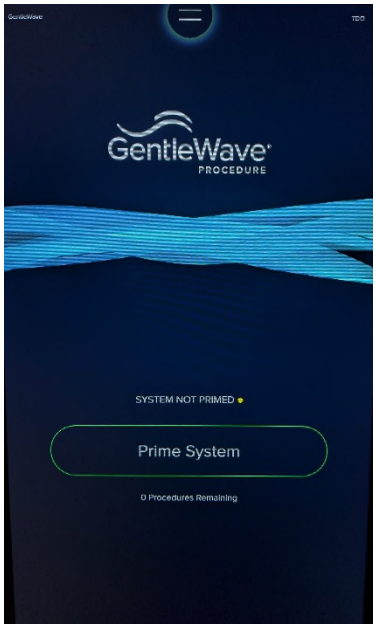


Figure 9. Home Screen

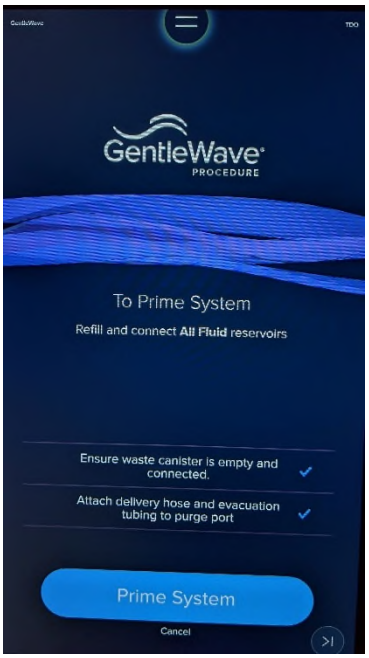
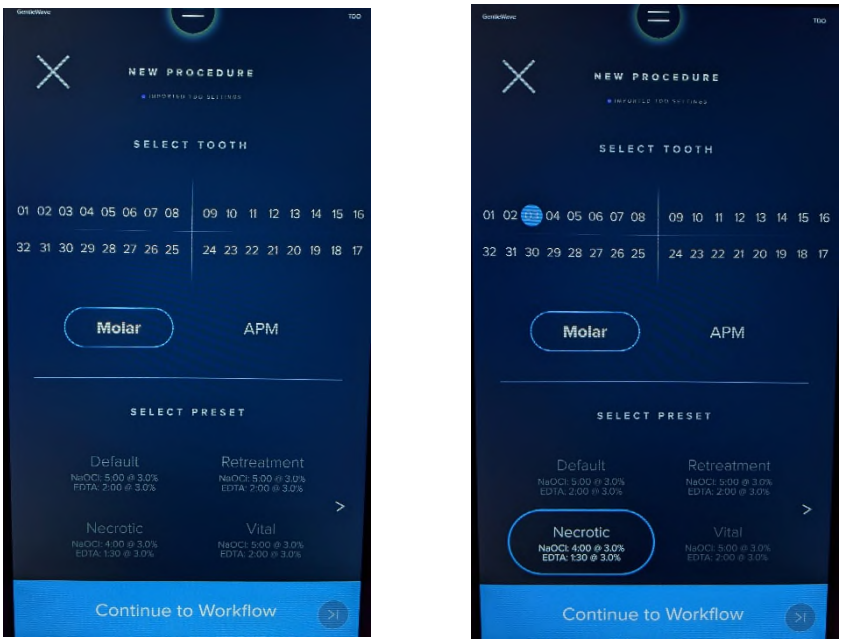


Figure 10. Prime System Screen

11.5 Procedure Preparation – Selecting Procedure

11.5.1 Once Prime is complete, select the type of tooth/Procedure Instrument and case type to be treated on the **Procedure Setup** Screen (**Figures 11**).

11.5.2 Selecting "Next" on the **Procedure Setup** screen to continue.



Figures 11. Procedure Setup Screens

11.6 Consoles Connected to TDO

11.6.1 In the TDO software under the treatment tab, select the tooth and diagnosis. At the bottom of the page select 'GentleWave Procedure', ensure the correct device is selected and select 'Start'.

11.6.2 Once Prime is complete, the tooth and diagnosis that was selected in TDO will automatically be selected under the **Procedure Setup** screens (**Figure 11**).

11.6.3 Once the procedure is complete, a log report of the GentleWave Procedure will automatically be sent to TDO software.

Note: If System Vacuum is not ready, a timer will pop up on the **Procedure Setup** Screen. A notice will appear once the Vacuum is ready on the **Procedure Setup** Screen.

Note: A screen saver will activate after 3 minutes of inactivity but not during the activation (start of leakage test) of the GentleWave Procedure. When the screen saver is activated, the Evacuation Pump is turned off to reduce the overall temperature of the Console and fluidics. During this time, the GentleWave procedure logo will be displayed and user activity is detected upon touching the screen of the touchscreen or depressing the illuminated power button. The screen will not activate when the console is in the middle of an operation (i.e. Pre-Procedure Prime or during a procedure). Upon user activity in such a case, the screen saver will close and the Evacuation Pump will turn on. A popup will display informing the user that the vacuum system is warming up. The pop-up will automatically close when the Console has reached appropriate vacuum levels and operation will subsequently resume.

11.7 Procedure Preparation – Attaching the Procedure Instrument

11.7.1 At the completion of Procedure Setup, the screen will progress to the **Attach Procedure Instrument** Screen (**Figure 12**).

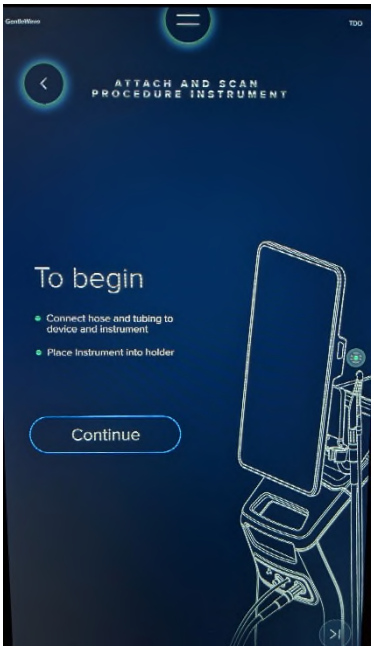


Figure 12. Attach Procedure Instrument Screen (Molar Shown)

11.7.2 Remove the Delivery Hose Connector from the Purge Port by gently rotating the Delivery Hose Connector counterclockwise.

11.7.3 Connect the Delivery Hose Connector to the new Procedure Instrument by rotating clockwise until fully threaded. Ensure the Delivery Hose and Procedure Instrument are firmly connected (**Figure 13**).

Figure 13. Connecting the Procedure Instrument

11.7.4 Connect the Evacuation Tubing of the Console to the Evacuation Tubing of the Procedure Instrument.

11.7.5 Place the Procedure Instrument fully into the Procedure Instrument holder (**Figure 14**).

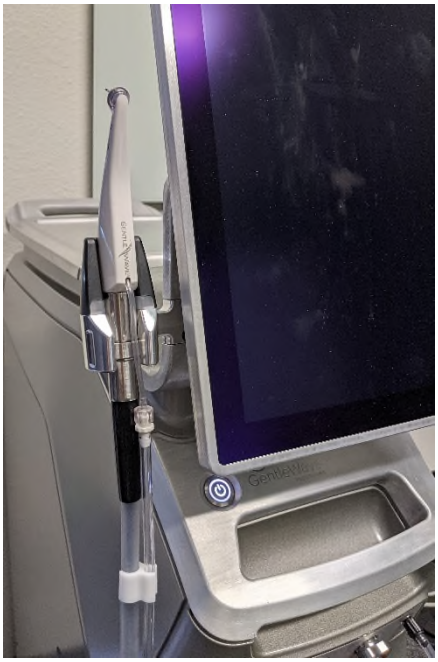


Figure 14. Procedure Instrument in the Procedure Instrument Holder

Note: An error message will be displayed if the incorrect Procedure Instrument has been scanned by the Console.

11.7.6 Once in the Procedure Instrument Holder, the new Procedure Instrument will automatically be registered. A notification will confirm that registration of the new Procedure Instrument is complete.

11.7.7 Please review the GentleWave Procedure Instrument Instructions for Use (IFU) before moving to the next section.

11.7.8 Refer to GentleWave Procedure Instrument IFU for tooth preparation.

11.7.9 When the tooth preparation steps are complete, select *Complete* to progress to the next Screen.

⚠ All caries must be removed prior to use of the device in order to provide adequate treatment with the System. If all caries are not removed, there is a potential for leakage of the procedure fluid and inhibition of cleaning and irrigation of the tooth.

11.8 Canceling Procedure

11.8.1 The procedure can be stopped at any time by selecting *Cancel* on the lower left corner of the Screen. A screen to confirm the choice to Cancel will appear. (**Figure 15**)

Note: It is important to know that canceling a procedure will consume the Procedure Instrument even if the procedure has not yet started.

11.8.2 A new Procedure Instrument will be required to restart the procedure.

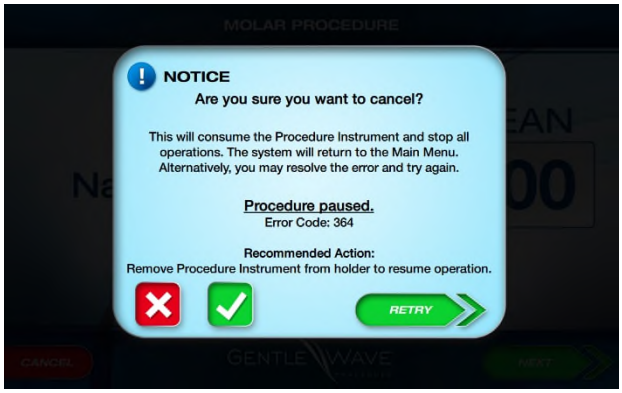


Figure 15. Confirm Cancel Screen

11.9 Leakage Test

The success of the System relies on an adequately sealed tooth. A Leakage Test is required to confirm a leak-free tooth seal and calibrate the nozzle. While performing the Leakage Test, look for large bubbles in the Sealing Cap when using the Molar Procedure Instrument or trailing bubbles in Procedure Instrument window when using the APM Procedure Instrument.

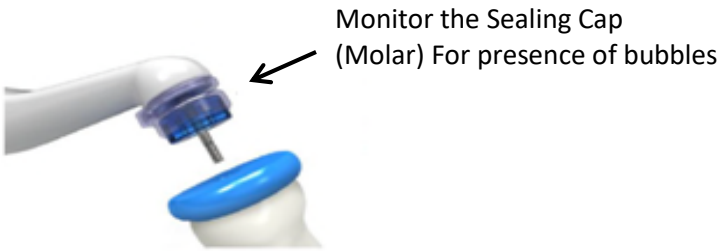


Figure 16. Monitoring the Sealing Cap for Presence of Bubbles in the Molar Procedure Instrument

11.9.1 Adequate seal of the tooth must be completed prior to use of the device in order to provide adequate Procedure with the System. If there is leakage of the Procedure Fluid, there may be inhibition of cleaning and irrigation of the tooth.

11.9.2 Continued bubbles in the Sealing Cap or the window during delivery indicate that air is being introduced in the root canal system. Bubbles may correspond to an unforeseen problem with the tooth or the tooth preparation. Do not continue with the System Procedure if bubbles are detected. Air in the procedure domain may lead to inhibition of cleaning and irrigation of the tooth.

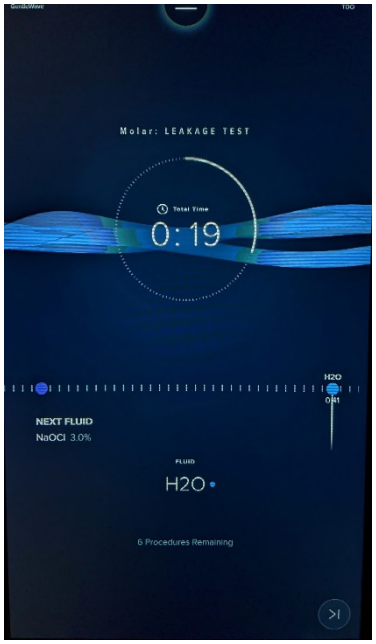


Figure 17. Leakage Test (Molar shown)

11.9.3 Begin the Leakage Test by pressing down on the foot pedal, bubbles during the initial moments after the Procedure Instrument has been placed on a tooth during the leakage test are normal.

11.9.4 When no signs of leakage or bubbles are detected during the Leakage Test, the System is ready for procedure delivery.

11.9.5 If leakage occurs, stop the Leakage Test and place the Procedure Instrument in the Procedure Instrument Holder. Rebuild the occlusal platform as instructed (refer to GentleWave Procedure Instrument IFU) and repeat the Leakage Test.

11.9.6 If leakage continues to occur, check the pulp chamber walls for any potential defects and restore the walls, if required. The tooth should be inspected for any carious lesions or old restorations which, if found, should be removed before proceeding. Check that the seal of the Procedure Instrument is not torn or damaged and is sitting firmly and evenly on the occlusal platform. Repeat the Leakage Test.

11.9.7 If leakage is still occurring, the tooth is not suitable for the Sonendo GentleWave® X System. Cancel the Procedure and provide care per traditional endodontic practices.

11.9.8 At the end of the Leakage Test the System will progress to one of the **Procedure Delivery** screen (**Figures 18a-d**).

11.10 Cleaning Procedure Delivery

11.10.1 The System will continue to run for as long as the foot pedal is depressed or until 100% of the Procedure Phase is completed. The progress of the procedure can be monitored throughout the procedure via the count up timer on one of two **Procedure Screens** (**Figures 18a-d**).

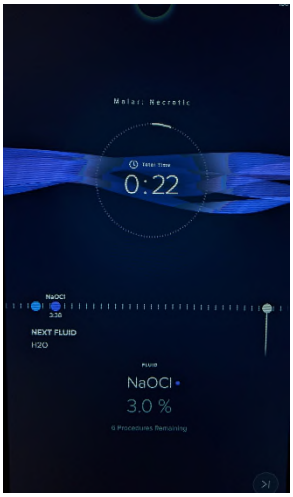


Figure 16a

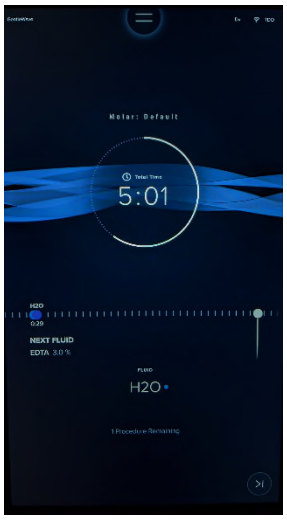


Figure 16b

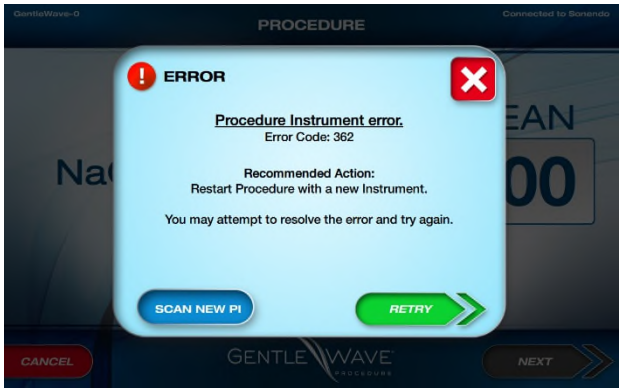
Figure 16c

Figure 16d

Figure 18a-d. Procedure Progress Screens (Molar Shown)

11.11 Swapping Procedure Instrument Mid-Procedure

11.11.1 If the user experiences a Procedure Instrument error or pauses the procedure, you will have the option to swap the Procedure Instrument mid-procedure, select *Scan New PI* (**Figure 19**). User must scan a new PI



when selecting this option. The previously used PI is no longer valid.

Figure 19. Procedure Instrument Swap

11.12 Adjusting Procedure Times

The extended (default) procedure times for the System are as follows:

- Clean (NaOCl) stage: 300 seconds
- Clean Rinse (Water) stage: 30 seconds
- Smear Removal (EDTA) stage: 120 seconds
- Smear Removal Rinse (Water) stage: 50 seconds

Note: Case specific procedure times can be found in the Appendix

11.12.1 Based on user judgement, knowledge and experience, the user may choose to continue with the current Procedure stage and deliver the default procedure fluid or may proceed to the next stage of the Procedure.

11.12.2 To advance the Clean (NaOCl) stage of the procedure, lift the foot off the Foot Pedal and select *Next* on the corresponding **Procedure** screen. This advancement may be completed at any time during the Clean (NaOCl) stage.

11.12.3 To advance the Smear Removal (EDTA) stage of the Procedure, lift the foot off the foot pedal and select *Next* on the corresponding **Procedure** screen. This advancement may be completed at any time during the Smear Removal (EDTA) stage.

11.12.4 The NaOCl and EDTA procedure times cannot be set to values greater than the default times.

11.12.5 Ensure proper Procedure Instrument positioning throughout the procedure (Refer to the GentleWave Procedure Instrument IFU). Continuously monitor the Sealing Cap or window of the Procedure Instrument and tooth during the procedure.

11.12.6 Once the Procedure time is complete, the **Procedure Complete** screen will appear (**Figure 20**).

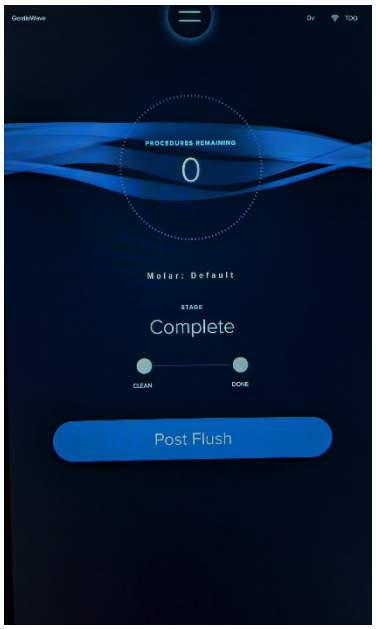


Figure 20. Procedure Complete Screen

11.12.7 Perform the Post Flush procedure by following the instructions on screen (**Figure 20).**

11.12.8 For Consoles connected to TDO, the Console will periodically update case information, informing the progress and fluid stage of the Procedure. Once the procedure is complete, a log report of the case details will be sent to TDO.

11.12.9 The tooth is now ready for root canal obturation, a coronal seal, and restoration, if applicable, per standard dental practices. The Console is now ready for another Procedure. Close the notification to return to the **Main Menu** Screen or the **Shutdown** Screen.

11.12.10 Before shutting down the Console for storage at the end of the day, perform any maintenance that may be required, as outlined in the maintenance section.

12.0 Maintenance, Handling, & Service – Secondary Functions

12.1. General Information

The outer surface of the Console (including Screen, Hoses, and Foot Pedal) can be disinfected using disinfecting towelettes (e.g. Caviwipes). The Console requires Routine Maintenance of the fluid path in order to ensure proper operation.

12.1.1. Routine Maintenance consists of sanitizing all fluid lines every month.

12.1.2. Shock Maintenance is required when a Routine Maintenance is not performed within one month of the last Routine Maintenance.

12.1.3. Manual Maintenance is used when maintenance needs to be performed on a single fluid path.

12.1.4. Daily cleaning of the procedure bottle connectors is recommended. Clean each connector thoroughly with a cotton swab to ensure all debris is removed from the bottle connectors.

12.1.5. Inspect for bottle lid cracks. Replace with provided bottle assembly spares if found cracked and discard bottle assembly with damaged lids. Contact Customer Care to request replacement spares.

12.2. Maintenance Setup

12.2.1. Select *Maintenance* from the **Main Toolbar (Figure 5).**

12.2.2. The screen will progress to the **Maintenance Type** screen **(Figure 21).**

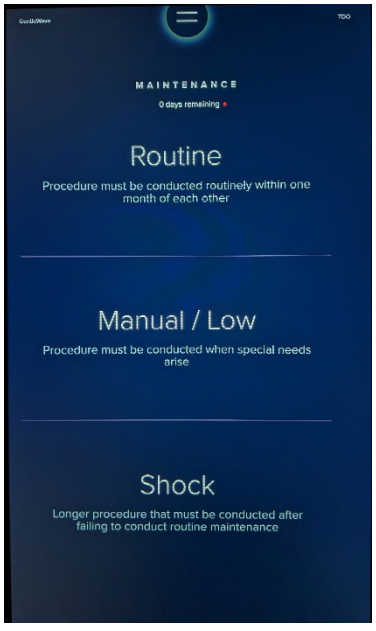


Figure 21. Maintenance Type Screen

12.2.3. Ensure Delivery Hose Connector and Evacuation Tubing are connected to the purge ports. Verify that there are no kinks. From the **Maintenance Setup** screen, select *Complete* (**Figure 22).**

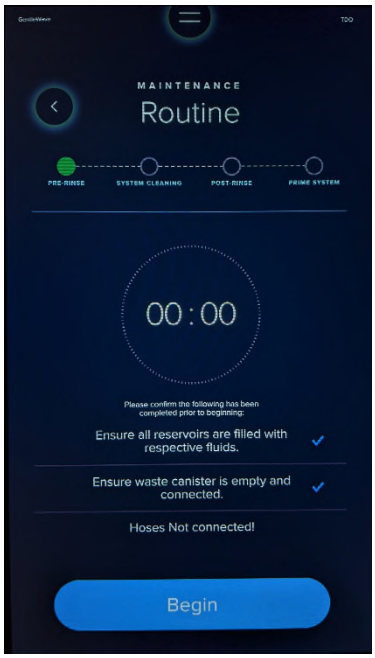


Figure 22. Maintenance Setup Screen

12.3. Routine Maintenance

The Routine maintenance procedure provides a regular sanitization of the fluid paths in the System.

From the Maintenance Type Menu, select *Routine*, as needed.

12.3.1. The Routine maintenance procedure provides a regular sanitization of the fluid paths in the System and should be performed monthly.

12.3.2. From the **Maintenance Type** screen (**Figure 21**), select *Routine* or *Shock*, as needed. The number of days remaining for Routine Maintenance are displayed at the bottom of the screen.

12.3.3. Follow the on-screen instructions to perform system Maintenance.

12.3.4. If Routine Maintenance is not carried out, the Console must be sanitized with Shock Maintenance, prior to use. Shock Maintenance is the same procedure as Routine Maintenance with the exception that it performs the System Cleaning stage a total of 3 consecutive times.

12.3.5. Maintenance Pre-Rinse

12.3.5.1. Empty each of the Reservoirs and Waste Canister.

12.3.5.2. Thoroughly rinse the Reservoirs and caps with distilled water.

12.3.5.3. Completely refill the contents of each Reservoir with distilled water.

12.3.5.4. Reconnect Reservoirs and caps to the System.

12.3.5.5. Select *Start.*

12.3.5.6. Wait for System to complete the Routine Pre-Rinse.

12.3.6. Maintenance System Cleaning

12.3.6.1. Empty each of the Reservoirs and Waste Canister.

12.3.6.2. Thoroughly rinse the Reservoirs and caps with distilled water.

12.3.6.3. Completely refill the contents of each Reservoir with NaOCl (6-10% non-diluted, regular (not splashless) and non-scented).

12.3.6.4. Reconnect Reservoirs and caps to the System.

12.3.6.5. Select *Next.*

12.3.7. Maintenance Sanitization

12.3.7.1. Upon completion of System Cleaning, the Console will begin to Sanitize, which takes up to 10 minutes.

Note: If Shock Maintenance was selected, the Console will repeat the System Cleaning stage 2 more times (for total of 3).

12.3.7.2. Upon finishing the sanitization phase, the Console is ready for Maintenance Post-Rinse.

12.3.8. Maintenance Post-Rinse

12.3.8.1. Empty each of the Reservoirs and Waste Canister.

12.3.8.2. Thoroughly rinse the Reservoirs and caps with distilled water.

12.3.8.3. Refill the contents of each Reservoir with distilled water.

12.3.8.4. Select *Next.*

12.3.8.5. Upon finishing, the Console will be ready for Priming.

12.3.9. Maintenance Post-Rinse Complete

12.3.9.1. Empty each of the Reservoirs and Waste Canister.

12.3.9.2. Refill the contents of each Reservoir with their respective fluids.

12.3.9.3. Select *Finish.*

12.3.9.4. Upon finishing, the Console will have completed the Maintenance procedure.

12.4. Manual Maintenance (**Figure 23)**

12.4.1. The Manual Maintenance provides the ability to flush each of the fluid paths in the System independently.

12.4.2. Do not flush NaOCl and EDTA consecutively. Apply a distilled water flush after NaOCl and EDTA flushes.

12.4.3. Select the Console Fluid path to Flush.

12.4.4. Use the Time Up and Down arrows to change the time to Flush.

12.4.5. Select *Start* to begin Manual Maintenance.

Figure 23. Manual Maintenance Screen

12.5. Long Term Storage Flush

12.5.1. The long-term storage flush is recommended when the Console is nonoperational for more than 4 weeks. Consoles that are not adequately flushed and left with procedure fluids may experience a failure.

12.5.2. Refill each bottle (NaOCl, H2O, EDTA) with distilled water.

12.5.3. From the Maintenance screen, select *NaOCl*, and 60 seconds. Repeat the 60 second flush for *H20* and *EDTA.*

12.5.4. When flush is complete, cover the end of the Delivery Hose with masking tape (avoid duct tape) to prevent evaporation.

12.5.5. Empty all procedure fluid bottles and leave uncapped to air dry.

12.5.6. Empty Waste Canister.

12.5.7. When ready to begin using the Console, perform *Routine Maintenance* prior to running the first procedure.

12.6. User Replaceable Parts

The following includes instructions for GentleWave users to replace parts in the GentleWave console.

12.6.1. Carbon Filter

12.6.1.1. Carbon Filter must be replaced every 6 months.

12.6.1.2. Locate the filter cover at bottom rear of the console

12.6.1.3. Remove the filter cover by unthreading four screws **(Figure 24)**

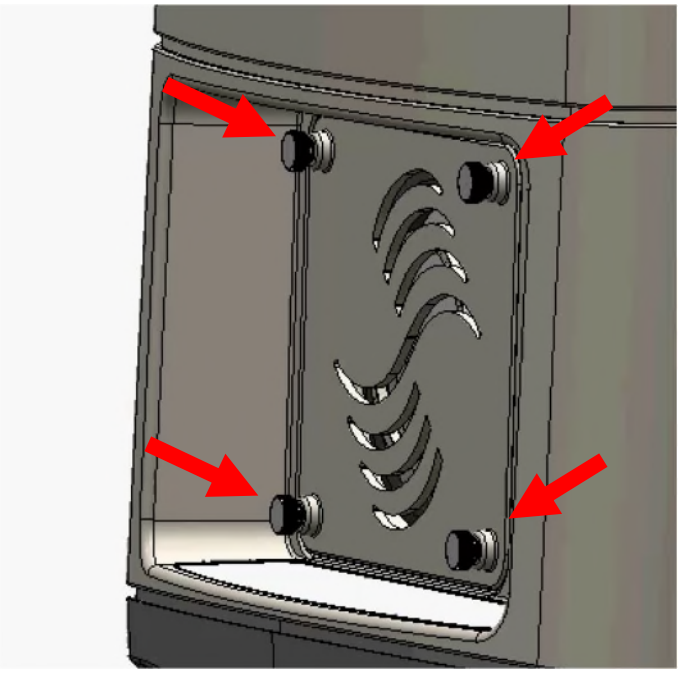


Figure 24. Carbon Filter Housing

12.6.1.4. Remove the used filter cartridge by pulling it out of the housing

12.6.1.5. Discard the used filter cartridge

12.6.1.6. Position the filter cover and tighten the four screws **(Figure 25).**

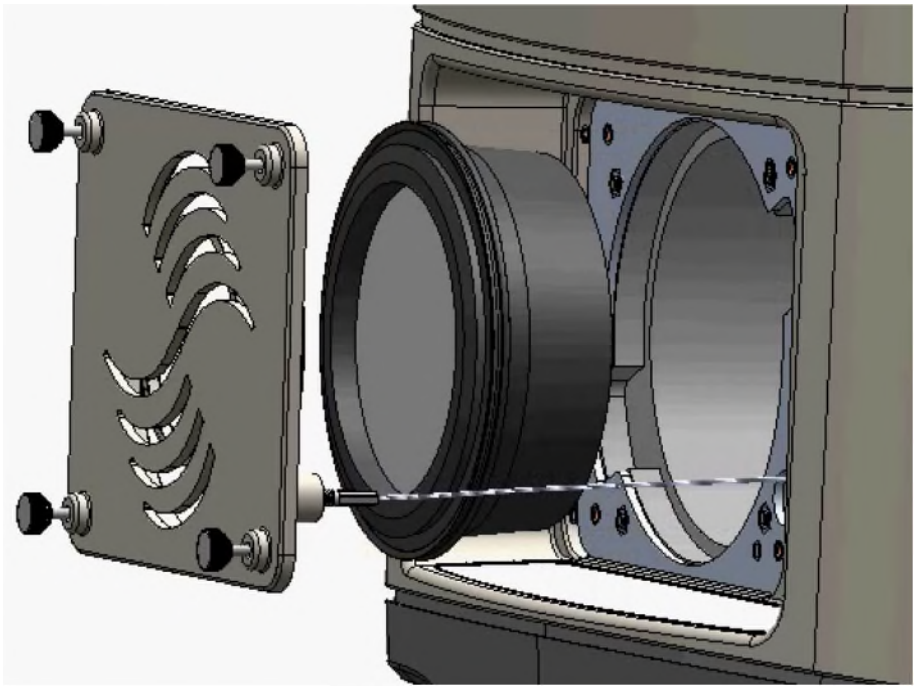


Figure 25. Carbon Filter Replacement

12.6.2. High-Pressure Hose

12.6.2.1. High-Pressure Hose must be replaced every 12 months.

12.6.2.2. With the console powered off, unthread the used high-pressure hose and discard **(Figure 26)**.

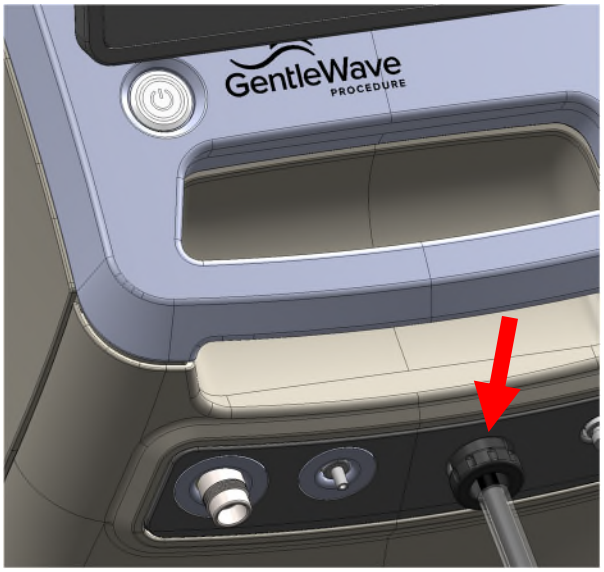


Figure 26. High-Pressure Hose Attachment

12.6.2.3. Thread the black connector of the new high-pressure hose into the same port **(Figure 27).**

Figure 27. High Pressure Hose Port

12.6.2.4. Continue to turn the threads until the thread is fully bottomed out and stops.

12.7. Shutdown Procedure

12.7.1. The Shutdown sequence can be initiated by pressing the blue power button on the front face of the Console, which will prompt **for Shutdown Selection** (**Figure 28**).

12.7.2. The Shutdown sequence can also be initiated by accessing the **Main Toolbar (Figure 5)** and selecting *Shutdown*.

12.7.3. Upon confirmation of Shutdown the application will progress to the **Shutdown Selection** screen (**Figure 28**).

12.7.4. When selecting *End of Procedure*, the application will begin the shutdown process. Place delivery hose into holder. Discard waste canister contents. Rise and clean each bottle connector.

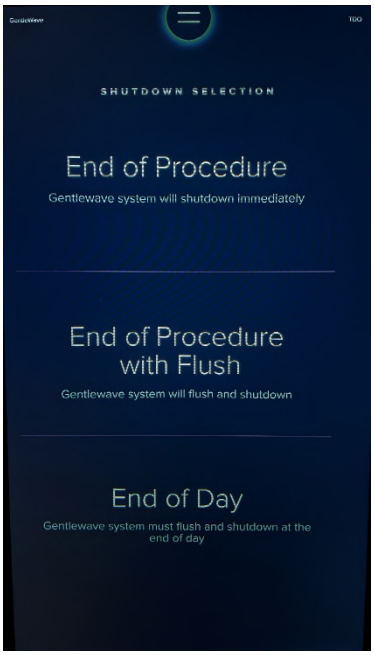


Figure 28. Shutdown Selection Screen

12.7.1. When selecting *End of Procedure with Flush*, the application with progress to **Final Flush** screen (**Figure 29**).

12.7.2. When selecting *End of Day*, the application will progress to **Final Flush** screen (**Figure 29**).

Figure 29. Shutdown Setup Screen

12.8. Final Flush

12.8.1. At the end of the day, the System requires a Final Flush (**Figure 29**). This is completed to ensure maximum longevity of the device.

12.8.2. Disconnect the Procedure Instrument from the Delivery Hose Connector on the Delivery Hose.

Note: Anterior/Premolar PI only – Ensure the check valve has not been left on the Evacuation Tubing of the Console. Doing so may result in an error message. The check valve is located on the proximal end of the Evacuation Tubing line attached to the Procedure Instrument.

12.8.3. Dispose of the Procedure Instrument and accessories as specified in the GentleWave Procedure Instrument IFU.

12.8.4. Connect the distal end of the Delivery Hose and Evacuation Tubing to the purge ports.

12.8.5. Once ready, press the *Begin* button to begin Final Flush (**Figure 29**).

Note: Do not disconnect Delivery Hose or Evacuation Tubing from Purge Port during Post-Procedure Flush.

12.8.6. When all the steps on the screen have been completed, select *Shutdown*.

12.8.7. The screen will progress to the **Shutdown** Screen (**Figure 30**).

Figure 30. Shutdown Progress Screen

12.8.8. Turn off the power using the Power Switch in the lower rear of the Console. It is recommended to remove the Power Cord when the Console is not in use.

12.8.9. The Console can now be stored until the next use.

12.9. Annual Preventive Maintenance

12.9.1. Annual Preventive Maintenance is recommended on your GentleWave® X Console to maintain its working order and verify it is functioning properly. Contact Customer Care to schedule a preventive Maintenance service visit.

12.10. Customer Replaceable Parts

12.10.1. The Evacuation Tubing can be replaced by a user if discoloration or damage occurs. Contact Customer Care to receive a replacement.

12.10.2. The High Pressure Hose can be replaced by a user.

12.11. Settings

12.11.1. Settings can be accessed in the **Main Toolbar (Figure 5)**.

12.11.2. Settings allow the user to personalize device name, procedure timer, adjust sound alerts, language, network setup, and obtain information about the Console (**Figure 31**).

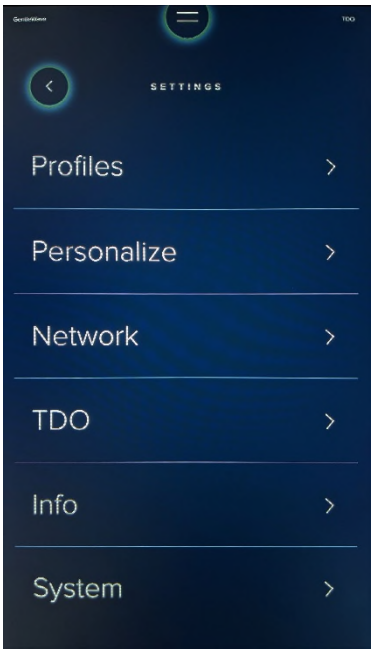


Figure 31. Settings Screen

12.12. Personalize (**Figure 32**)

12.12.1. A Device Name can be set for each individual Console. The Console name can be found when integrated with TDO software.

12.12.2. The Procedure Timer can be set to count up, count down, or display progress.

12.12.3. Adjust Sound Settings to personal preference by first selecting the type of sound (i.e. Button Press, Error/Warning, Procedure Complete) and then adjusting to the desired volume level.

12.13. Network **(Figure 33)**

12.13.1. To connect to the network, enter the WiFi name and password.

12.14. TDO Software

12.14.1. Enable the connection to TDO software. Enter the IP/Hostname address and port number of the computer that is connected to TDO software. Contact TDO support for help on locating this information.

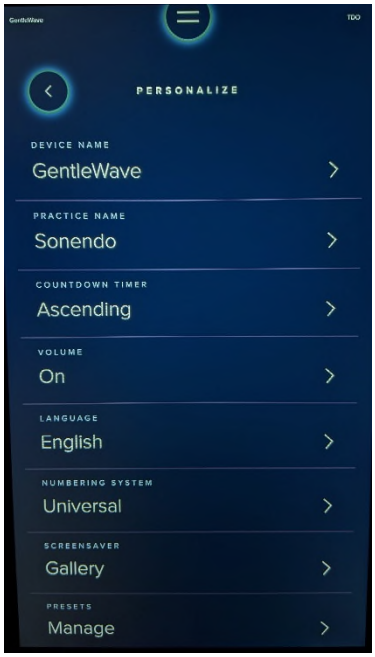


Figure 32. Personalize Settings Screen

Figure 33. Network Screen

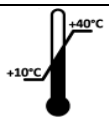
13.0 Technical Data

Table 2 Technical Data

Manufacturer	Sonendo, Inc. Laguna Hills, CA 92653
Model	GentleWave® X Laguna System REF: FG-012-00001
Classification IEC 60601-1	Class I Applied part, Type B IP 20 unit
Mode	Continuous Operation
Input Power Requirements	100VAC – 240VAC 50-60Hz 6.0A
Console	Equipment not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH NITROUS OXIDE
Console Weight	170 lbs

14.0 Symbols

Table 6. Symbols

Symbol	Manufacturer's Meaning	Symbol Standard; Reference #
	Manufacturer's Logo	No Ref #
	On	IEC 60417-5007 "ON" (power)
	Standby Power	IEC 60417-5009 Stand-by
	Off	IEC 60417-5008 "OFF" (power)
	Warning or Precaution	No Ref #
	Consult Instructions for Use (Operator's Manual)	ISO 15223-1; 5.4.3 Consult instructions for use
	Accompanying Documents must be consulted (Operator's Manual)	ISO 15223-1; 5.4.3 Read instructions for use
	Keep dry	ISO 15223-1; 5.3.4 Keep Dry
	Keep out of direct sunlight	ISO 15223-1; 5.3.2 Keep away from sunlight
	Non-ionizing Electromagnetic Radiation	IEC 60417-5140 Non-ionizing Electromagnetic Radiation
	Temperature Limits (Fluid Temperature in Reservoirs)	ISO 15223-1; 5.3.7 Temperature Limit
	Type B Applied Part	IEC 60417-5840 TYPE B APPLIED PART
	Prescription use only	21 CFR 801 Prescription Use Only

	Manufacturer	ISO 15223-1; 5.1.1 Manufacturer
Symbol	Manufacturer's Meaning	Symbol Standard; Reference #
	Input Power Requirements	IEC 60417-5034 Input
	Voltage AC	IEC 60417-5032 Alternating current
50-60 HZ	Frequency (50-60 Hertz)	No Ref #
6.0 A	Amperage (6.0 Amperes, 100-240VAC range)	No Ref #
	Do not lean	ISO 7010-P017 No pushing
	DO NOT DISPOSE IN DOMESTIC HOUSEHOLD WASTE!	WEEE Directive Annex IX Symbol for the marking of EEE
Contents	Contents of box or reservoir	No Ref #
LOT	Lot number of product	ISO 15223-1; 5.1.5 Batch Code
REF	Reference number of product	ISO 15223-1; 5.1.6 Catalogue Number
SN	Serial number of product	ISO 15223-1; 5.1.7 Serial Number

15.0 Appendix

15.1. Procedure Times

15.1.1. Molar Procedure

Case Type	3% NaOCl	H_2O	8% EDTA	H_2O
Necrotic	5 Min	20 Sec	2 Min	45 Sec
Vital, Retreatment, Extended	5 Min	20 Sec	2 Min	45 Sec

15.1.2. Anterior/Premolar Procedure

Case Type	3% NaOCl	H_2O	8% EDTA	H_2O
Necrotic, Vital, Retreatment, Extended	5 Min	20 Sec	2 Min	45 Sec

15.1.3. Posterior Procedure

Case Type	3% NaOCl	H_2O	8% EDTA	H_2O
Necrotic, Vital, Retreatment, Extended	5 Min	20 Sec	2 Min	45 Sec

16.0 Troubleshooting

16.1. Customer Care telephone number: 844-468-5928.

Table 7. Troubleshooting

Problem	Potential source	Action
System not powering on	Power cord not plugged in	Plug power cord
	System failure	Contact Customer Care
System on but screen not responding	Connection/Communication issues	Restart/Contact Customer Care

Problem	Potential source	Action
Vacuum pump not shutting off when Delivery Hose is in the Procedure Instrument Holder	Delivery Hose not completely seated in the holder	Ensure Delivery Hose is properly seated in the Procedure Instrument Holder
	Faulty Procedure Instrument Holder switch	Contact Customer Care
Vacuum errors	Stuck Procedure Instrument Holder switch	Loosen switch using fingers
	Faulty Procedure Instrument Holder switch	Refer to Error Codes (Section 18.0)
	Faulty Vacuum Pump	Contact Customer Care
Vacuum errors	Loose waste canister fittings	Firmly push and twist Waste Canister Fittings to connect to both the patient and vacuum ports
	Multiple check valves attached to evacuation tubing	Remove any check valves attached to the distal end of evacuation tubing
	Improper connections; delivery hose to purge port or evacuation tubing to purge port or procedure instrument	Ensure delivery hose and evacuation tubing are attached to purge ports during prime cycle and attached to PI during and after the Attach PI screen prompt
No response to foot switch	Waste Canister full	Empty waste canister
	One or more procedure fluid reservoirs filled to below 1 procedure level.	Fill procedure fluid reservoir to minimum level of 1 procedure
	Foot switch connection	Check foot switch connection
	Malfunction of foot switch and or System	Contact Customer Care
Procedure fluid does not flow out of hose	Procedure fluid reservoirs not connected	Connect tubing to procedure fluid reservoir
	Improper tubing connection or electrical component malfunction	Contact Customer Care
	System improperly purged	Purge System again
	Insufficient procedure fluid levels	Check procedure fluid levels and replenish if necessary
Procedure fluid does not always flow out of Delivery Hose during a cycle	Improper tubing connection, air leaks or electrical component malfunction issue	Verify tubing is connected/Contact Customer Care

Problem	Potential source	Action
System does not deliver full cycle, stops at the start of a cycle	Procedure Instrument is clogged	Attach new Procedure Instrument/check foot pedal connection/ensure Procedure Instrument is not in the holder
Progress bar not incrementing	System is not pressurizing	Contact Customer Care
Procedure fluid spills from delivery hose connections	Delivery hose might be damaged or not fully connected	Contact Customer Care
Bubbles/Air in Sealing Cap/Window	Procedure Instrument improperly seated on tooth	Remove Procedure Instrument from tooth and carefully re-apply
	Conforming resin material improperly prepared	Remove conforming resin material and reapply carefully
	System leak	Stop Procedure and contact Customer Care
	Degassing System malfunction	Stop Procedure and contact Customer Care
	Chemical line(s) not primed	Re-run pre-procedure purge.
	Kinked tubing (water or chemicals)	Check tubing at the front of the unit
	Leak on chemical injection side	Stop Procedure and contact Customer Care
Procedure fluid spilling out of Sealing Cap/Window/Vent	Evacuation tubing not connected	Connect Evacuation Tubing
	Evacuation Tubing kinked or obstructed	Check Evacuation Tubing for obstructions
	Sealing Cap/Procedure Instrument obstructed	Check Sealing Cap/Procedure Instrument for obstructions, remove obstructions and check tooth for signs of more large debris. Remove debris if necessary and continue procedure/ Restart/Contact Customer Care
	Evacuation pump not functioning correctly	Stop Procedure and contact Customer Care
System does not pressurize	High pressure pump leak	Contact Customer Care

17.0 Reminder Codes, Error Codes and Resolution

17.1. When an error is presented during a procedure or maintenance procedure, the user may either attempt to resolve the error and try again, scan a new Procedure Instrument or cancel the procedure.

17.1.1. Retry (attempt to resolve the error and try again). The user has 3 opportunities to resolve the error, at which point the procedure must be cancelled and restarted.

17.1.2. Scan a new Procedure Instrument. The user has the ability to scan a new PI and resume the existing procedure.

17.1.3. Cancel the procedure. To cancel, close the window and select Cancel.

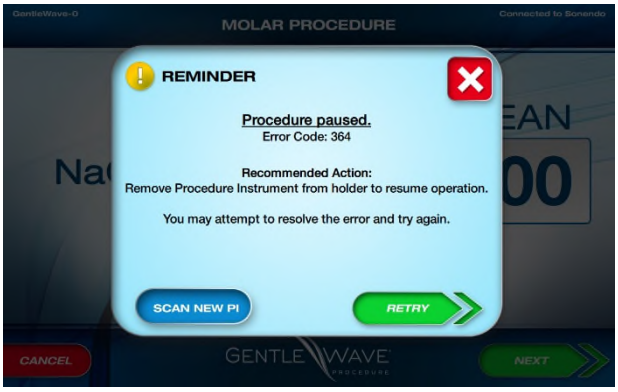


Figure 34. Error Code Recommended Action Screen

17.1.4. The user may choose to resume the procedure after closing the error message by selecting Cancel. After pressing Cancel, the user will be asked to confirm canceling by selecting the green check mark. The user may also attempt to resolve the error and resume the procedure by selecting Retry.

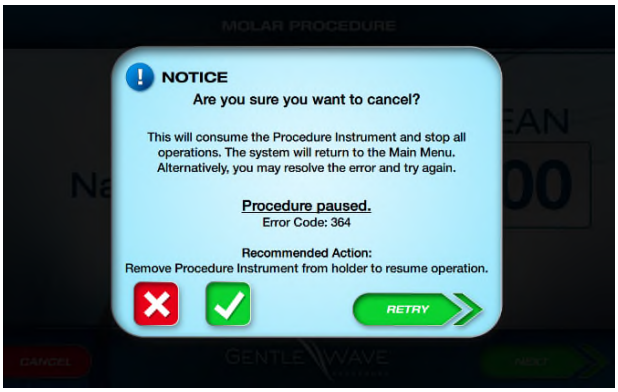


Figure 35. Cancellation/Error Code Resolution Screen

Table 8. Error/Reminder Codes

Error Code	Error Description	User Response
128	Not Ready.	Reboot Console. Contact Customer Care.
129	Null Pointer.	Reboot Console. Contact Customer Care.
130	Invalid Buffer Size.	Reboot Console. Contact Customer Care.
131	Invalid Data.	Reboot Console. Contact Customer Care.
132	Not Supported.	Reboot Console. Contact Customer Care.
133	Invalid Parameter.	Reboot Console. Contact Customer Care.
134	Device Error.	Reboot Console. Contact Customer Care.
135	Not Initialized.	Reboot Console. Contact Customer Care.
136	Communications Error.	Reboot Console. Contact Customer Care.
137	Dependent Device Error.	Reboot Console. Contact Customer Care.
138	Timeout.	Reboot Console. Contact Customer Care.
139	Not Found.	Reboot Console. Contact Customer Care.
140	Task Error.	Reboot Console. Contact Customer Care.
141	Software Error.	Reboot Console. Contact Customer Care.
142	Over Run.	Reboot Console. Contact Customer Care.
143	Out of Memory.	Reboot Console. Contact Customer Care.
144	Undefined Error.	Reboot Console. Contact Customer Care.
300	System Controller not initialized.	Reboot console. Contact Customer Care.
310	Not Enough Fluid in Distilled Water Reservoir	Refill distilled water reservoir to max fill line
311	Not Enough Fluid in EDTA Reservoir	Refill EDTA reservoir to max fill line
312	Not Enough Fluid in NaOCl Reservoir	Refill NaOCl reservoir to max fill line
313	Waste Canister Full	Empty waste canister
320	Dry Vacuum out of range.	Ensure delivery hose, evacuation tubing, foot pedal, and waste canister are securely attached.
321	Wet Vacuum out of range.	Ensure delivery hose, evacuation tubing, foot pedal, and waste canister are securely attached.
322	Purge Vacuum out of range.	Ensure delivery hose, evacuation tubing, foot pedal, and waste canister are securely attached.

Error Code	Error Description	User Response
323	Procedure Instrument Vacuum out of range.	Ensure Procedure Instrument, evacuation tubing, foot pedal, and waste canister are securely attached.
324	Degassing system malfunction.	Please contact Customer Care.
325	Dry Vacuum out of range.	Ensure delivery hose, evacuation tubing, foot pedal, and waste canister are securely attached.
326	Wet Vacuum out of range.	Ensure delivery hose, evacuation tubing, foot pedal, and waste canister are securely attached.
327	Purge Vacuum out of range.	Ensure delivery hose, evacuation tubing, foot pedal, and waste canister are securely attached.
328	Procedure Instrument Vacuum out of range.	Ensure Procedure Instrument, evacuation tubing, foot pedal, and waste canister are securely attached.
330	Prime process timeout.	Reboot Console.
331	Instrument holder should be empty.	Ensure the holder is empty during active operation.
332	Prime pressure out of range.	Ensure Procedure Instrument is disconnected from delivery hose. Please contact Customer Care.
333	Vacuum Out of Range for Level Sense	Please contact Technical Support
334	Vacuum Out of Range for Level Sense	Please contact Technical Support
341	Delivery Hose Not in Holder	Ensure delivery hose is fully seated in the holder.
342	Invalid Procedure Instrument type.	Ensure to select a procedure instrument type.
343	Invalid Treatment Mode.	Ensure to select a treatment mode.
350	Procedure Instrument error.	Ensure the correct Procedure Instrument was used. Restart Procedure with a new Instrument.
351	Unable to reach target pressure.	Ensure Procedure Instrument is securely attached to the delivery hose. If unsuccessful, restart Procedure with a new Instrument.
352	Unable to reach target pressure.	Confirm fluids are filled and fluid bottle connectors are completely seated. If unsuccessful, restart Procedure with a new Instrument.
353	Unable to reach target pressure.	Confirm fluids are filled and fluid bottle connectors are completely seated. If unsuccessful, restart Procedure with a new Instrument.
354	System flow uncharacterized.	Run Leakage Test. Restart Procedure with a new Instrument.

Error Code	Error Description	User Response
355	Unable to reach target pressure.	Ensure the correct Procedure Instrument is attached. Restart Procedure with a new Instrument.
356	Procedure Instrument error.	Ensure the correct Procedure Instrument is attached. Restart Procedure with a new Instrument.
357	Unable to reach target pressure.	Confirm fluids are filled and fluid bottle connectors are completely seated. If unsuccessful, restart Procedure with a new Instrument.
358	Inconsistent Max RPM for Target Pressure	Check high-pressure system for possible air leaks. Restart Procedure with a new PI.
360	Procedure timeout.	Reboot Console.
361	Unable to reach target pressure.	Check all fluid reservoirs for enough fluid and for potential cracks on or around the fluid bottle connector.
362	Procedure Instrument error.	Restart Procedure with a new Instrument.
364	Procedure Paused	Remove Procedure Instrument from holder to resume operation.
365	Top Hatch Opened	Close the top hatch to resume operation
366	Waste Drawer Opened	Close the waste drawer to resume operation
367	High-Pressure Hose Not Connected	Ensure High-Pressure hose is not cross-threaded and is fully engaged
400	NaOCl mixture out of range.	Confirm reservoirs are filled and fluid bottle connectors are completely seated.
401	EDTA mixture out of range.	Confirm reservoirs are filled and fluid bottle connectors are completely seated.
402	Distilled water input out of range.	Confirm distilled water reservoir is filled and the bottle connector is completely seated.
403	NaOCl input out of range.	Confirm NaOCl reservoir is filled and the bottle connector is completely seated.
404	EDTA input out of range.	Confirm EDTA reservoir is filled and the bottle connector is completely seated.
405	NaOCl fluid temperature out of range.	Please retry the operation and be sure to shutdown the console between procedures. If unsuccessful, run Manual Maintenance for NaOCl fluid.
406	EDTA fluid temperature out of range.	Please retry the operation and be sure to shutdown the console between procedures. If unsuccessful, run Manual Maintenance for EDTA fluid.
407	Distilled water temperature out of range.	Please retry the operation and be sure to shutdown the console between procedures. If unsuccessful, run Manual Maintenance for distilled water.

Error Code	Error Description	User Response
408	Mix fluid temperature out of range.	Please retry the operation and be sure to shutdown the console between procedures. If unsuccessful, run Manual Maintenance for each fluid.
409	Incorrect concentration of NaOCl detected.	Ensure NaOCl reservoir is filled and the bottle connector is completely seated. Confirm NaOCl fluid type located in System Settings is correct.
410	TEC Fluid Temperature Out of Range	Ensure fluid reservoirs are not empty and are within normal temperature range.
500	NVM primary write failure.	Reboot Console. Contact Customer Care.
501	NVM backup write failure.	Reboot Console. Contact Customer Care.
502	Invalid NVM settings, System setup required.	Please contact Customer Care.
503	Invalid NVM version, System setup required.	Please contact Customer Care.
504	Level Sensor is Not Calibrated	Please contact Customer Care.
600	Pressure Sensor not calibrated.	Please contact Customer Care.
601	No active operation to Pause.	Please contact Customer Care.
602	No paused operation to Resume.	Please contact Customer Care.
603	Board Temperature out of range.	Power off console. Reboot Console.
604	Motor Temperature out of range.	Power off console. Reboot Console.
605	Degasser Pump current sense out of range.	Reboot Console. Contact Customer Care.
606	Evac pump current sense out of range	Reboot Console. Contact Customer Care.
607	Distilled water valve current sense out of range.	Reboot Console. Contact Customer Care.
608	NaOCl valve current sense out of range.	Reboot Console. Contact Customer Care.
609	EDTA valve current sense out of range.	Reboot Console. Contact Customer Care.
610	Backflush valve current sense out of range.	Reboot Console. Contact Customer Care.
611	Sweep gas current sense out of range.	Reboot Console. Contact Customer Care.
612	AC supply power good fail.	Reboot Console. Contact Customer Care.
613	AC supply fan fail.	Reboot Console. Contact Customer Care.

Error Code	Error Description	User Response
614	Running on Battery. System cannot start fluid operations	Connect the Power Cable in order to continue. Please contact Technical support if problem persists.
615	AC supply over temp protection.	Reboot Console.
616	Motor fault condition.	Reboot Console.
617	System malfunction. Service required.	Please contact Customer Care.
618	Unable to move to next stage of operation.	Please contact Customer Care.
619	Unable to relieve pressure from delivery hose.	Disconnect Procedure Instrument over sink. Please contact Customer Care.
620	PRV out of sync	Release the Footpedal and press again to resume procedure.
621	PRV Opened - Analog	Please contact Technical Support
622	PRV Opened - Software	Please contact Technical Support
623	Barometer out of range.	Reboot Console. Contact Customer Care.
624	Vacuum sensor malfunction.	Please contact Customer Care.
625	Air Bubble Detected	Perform Manual Maintenance until fluid concentration is within range
626	Incorrect SysClock configuration.	Please contact Customer Care.
627	Slow to Relieve Pressure from Delivery Hose	Disconnect Procedure Instrument over sink. Please contact Technical Support.
628	Footpedal Not Connected	Please connect the Footpedal.
629	Footpedal Hardware Error	Please contact Technical Support
630	24 Volt Power Supply Failed System operations limited	Please contact Technical Support
631	48 Volt Power Supply Failed System operations limited	Please contact Technical Support
632	Feedback RPM Out of Range	Please contact Technical Support
633	Fluid Level Sensor Out of Range	Please contact Technical Support
634	Fan1 RPM Out of Range	Please contact Technical Support
635	Fan2 RPM Out of Range	Please contact Technical Support
636	Fan3 RPM Out of Range	Please contact Technical Support
637	Flush Pump RPM Out of Range	Please contact Technical Support

Error Code	Error Description	User Response
638	Battery is Missing	Please contact Technical Support
639	Battery is Shorted	Please contact Technical Support
640	Battery is Critically Low	Please connect the console to an AC outlet or perform a shutdown.
641	24 & 48 Volt Power Supply Failed. System Operations Limited	Please contact Technical Support
700	Unable to Communicate with Motor.	Reboot Console. Contact Customer Care.
702	Unable to Communicate with Conductivity Sensor.	Reboot Console. Contact Customer Care.
703	Unable to Communicate with TEC	Reboot Console. Contact Customer Care.
704	Unable to Communicate with Battery Monitor	Reboot Console. Contact Customer Care.
705	Unable to Communicate with Vacuum Sensor	Reboot Console. Contact Customer Care.
706	ADC DMA Communication Failure	Reboot Console. Contact Customer Care.
800	Software assertion occurred.	Reboot Console. Contact Customer Care.
1600	Failed to open SysCon COM port.	Reboot Console. Contact Customer Care.
1601	Failed to open RFID COM port.	Reboot Console. Contact Customer Care.
1605	Unexpected Shutdown	In order to avoid unplanned service calls, it is recommended to power down the console through the Shutdown Menu.
1606	PROCEDURE DISABLED.	Reboot Console. Contact Customer Care.
1607	Unsupported System Controller version.	Please contact Customer Care.
1608	Delivery Hose expired.	Contact Customer Care to have a new delivery hose installed.
1609	System Serial Number not programmed.	Please contact Customer Care.
1610	System power failure.	Reboot Console. Contact Customer Care.
1611	System fan failure.	Reboot Console. Contact Customer Care.
1612	System temperature failure.	Reboot Console. Contact Customer Care.
1613	System Controller Reset.	Reboot Console. Contact Customer Care.
1614	Real-time clock not set.	Please contact Customer Care.

Error Code	Error Description	User Response
1615	Routine maintenance recommended before use.	Perform routine maintenance.
1647	Touch Application Failure	Please contact Customer Care
1648	Sonendo Application Failure	Please contact Customer Care
1649	File System Failure	Please contact Customer Care
1650	Failed to open Python COM Port	Reboot Console. Contact Customer Care.
1651	Delivery Hose Approaching Maximum Number of Uses	Contact Customer Care regarding Preventative Maintenance
4400	RFID Reader not initialized.	Reboot Console. Contact Customer Care.
4401	Unable to Find Tag	Ensure Procedure Instrument is fully seated in the holder and try again.
4402	Unable to read tag.	Ensure Procedure Instrument is fully seated in the holder and try again.
4403	Unable to write tag	Ensure Procedure Instrument is fully seated in the holder and try again.
4404	Unable to write tag. Tag is already locked.	Discard Procedure Instrument and connect a new Procedure Instrument to continue.
4405	Invalid Address.	Please contact Customer Care.
4406	RFID Reader timeout.	Ensure Procedure Instrument is fully seated in the holder and try again.
4407	RFID CRC check failed.	Ensure Procedure Instrument is fully seated in the holder and try again.
4408	Unable to communicate with RFID Reader.	Ensure cables are properly connected and try again.
4500	RFID Reader not initialized.	Reboot console. Contact Customer Care.
4501	Used Procedure Instrument Detected	Discard used Procedure Instrument and connect a new Molar PI to continue
4502	Used Procedure Instrument Detected	Discard used Procedure Instrument and connect a new APM PI to continue
4503	Procedure Instrument not supported.	Discard Procedure Instrument and connect a new Instrument to continue.
4504	Tag revision mismatch.	Discard Procedure Instrument and connect a new Instrument to continue.
4505	Invalid Lot Number.	Discard Procedure Instrument and connect a new Instrument to continue.
4506	Invalid Part Number.	Discard Procedure Instrument and connect a new Instrument to continue.

Error Code	Error Description	User Response
4507	Invalid Procedure Instrument Type.	Discard Procedure Instrument and connect a new Instrument to continue.
4508	Invalid Start Date.	Discard Procedure Instrument and connect a new Instrument to continue.
4509	Invalid Device Serial.	Discard Procedure Instrument and connect a new Instrument to continue.
4510	Invalid UI Version.	Discard Procedure Instrument and connect a new Instrument to continue.
4511	Invalid SysCon Version.	Discard Procedure Instrument and connect a new Instrument to continue.
4512	Incorrect Procedure Instrument detected	Discard Procedure Instrument and connect a new Molar PI to continue
4513	Incorrect Procedure Instrument detected	Discard Procedure Instrument and connect a new APM PI to continue
4514	Invalid Tip Size	Discard Procedure Instrument and connect a new PI to continue
4515	Invalid token.	Discard Procedure Instrument and connect a new PI to continue.
4521	Incorrect Procedure Instrument detected	Discard Procedure Instrument and connect a new Posterior CleanFlow PI to continue.
4525	Used Procedure Instrument Detected	Discard used Procedure Instrument and connect a new Posterior CleanFlow PI to continue.
4604	SSID password is incorrect.	Ensure password is correct for SSID. Please contact Customer Care.
4605	Network port is closed.	Reboot console. Please contact Customer Care.
4606	Network request failed.	Please contact Customer Care.
4607	Network request timed out.	Please contact Customer Care.
4608	Network request aborted.	Please contact Customer Care.
4609	Network request when already in progress.	Please contact Customer Care.
4800	Failed to prepare SQL statement.	Reboot Console. Contact Customer Care.
4801	Failed to execute SQL statement.	Reboot Console. Contact Customer Care.
4802	Secondary SD Card not found.	Please contact Customer Care.
4803	Secondary SD Card out of space.	Please contact Customer Care.
4804	Failed to mount Secondary SD Card.	Please contact Customer Care.

Error Code	Error Description	User Response
4805	Database not initialized properly.	Please contact Customer Care.
4806	Database invalid console serial number.	Please contact Customer Care.
4807	Database model is out of date.	Please contact Customer Care.
5400	System Controller Upgrade .bin not found.	Please contact Customer Care.
5401	User Interface Upgrade .zip not found.	Please contact Customer Care.
5402	Upgrade config file not found.	Please contact Customer Care.
5403	Update Status file not found.	Please contact Customer Care.
5404	SysCon upgrade failed hash check.	Please contact Customer Care.
5405	UI upgrade failed hash check.	Please contact Customer Care.
5600	Unable to connect to TDO.	Ensure that GentleWave is connected to Sonendo and registered with TDO. If the problem persists, please contact Customer Care.
5601	Unable to register console with TDO	Ensure that GentleWave has been configured in the TDO Integrated Devices menu. If the problem persists, please contact Customer Care.
5602	TDO server service is not running.	Ensure that the TDO service is running. If the problem persists, Contact Customer Care.
5603	Invalid TDO api version.	Ensure that TDO is upgraded to the latest version. If the problem persists, please contact Customer Care.
5604	No TDO case found	Ensure that a TDO case has been assigned to the correct console. If the problem persists, please contact Customer Care.

18.0 Manufacturer's Declaration for the Product GentleWave X Console

18.1. Manufacturer's declaration – Electromagnetic Emission (CISPR 11 IEC 60601-1-2)

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should ensure that it is used in an electromagnetic environment as described below.

Table 9: Electromagnetic Emission

Emissions Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	The product uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

18.2. Manufacturer's declaration – Electromagnetic Immunity I (IEC 60601-1-2)

18.2.1. The product is suitable for use in a specific electromagnetic environment. The customer and /or the user of the product should assure that it is used in an electromagnetic environment a described below.

Table 10. Electromagnetic Immunity I

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floor 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/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital Environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (< 95 % dip in UT) for 0.5 cycle < 40 % UT (< 60 % dip in UT) for 5 cycles < 70 % UT (< 30 % dip in UT) for 25 cycles	< 5 % UT (< 95 % dip in UT) for 0.5 cycle < 40 % UT (< 60 % dip in UT) for 5 cycles < 70 % UT (< 30 % dip in UT) for 25 cycles	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the mains (AC) voltage before applying test levels			

18.3. Manufacturer's declaration – Electromagnetic Immunity II (IEC 60601-1-2)-for Products that are not LIFE SUPPORTING

18.3.1. The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should ensure that it is used in an electromagnetic environment as described below.

Table 11. Electromagnetic Immunity II

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 Vrms	Recommended separation distance: $d = 1.2\sqrt{P}$ for 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 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 re-commended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the symbol. 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people, and animals.

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered, if the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product should be observed, additional measures may be necessary, such as reorienting or relocating the product.

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

18.4. Manufacturer's declaration – Recommended Separation Distances Between Portable and Mobile RF- Communications Equipment and the Product – for Product that are Not LIFE SUPPORTING (IEC 60601-1-2)

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

Table 12. Separation Distance

Rated maximum output power of transmitter in watts (W)	**Separation distance according to the frequency of transmitter in meters (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	1.2	1.2	23

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 higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

19.0 FCC Notice

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.

This device complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. The equipment should be installed and operated with minimum distance of 20cm between the radiator and your body.

Caution: any changes or modifications to this device not expressly approved by Sonendo could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

20.0 ISED Notice

"This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device."

"In order to comply with ISED RF Exposure requirements, this device must be installed to provide at least 20 cm separation from the human body at all times.

"L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1. L'appareil ne doit pas produire de brouillage;

2. L’appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d’en compromettre le fonctionnement.”

“Afin de se conformer aux exigences d'exposition RF ISED, cet appareil doit être installé pour fournir au moins 20 cm de séparation du corps humain en tout temps. “

21.0 Disposal and Recycling

21.1. Dispose of unused Procedure Fluid according to applicable local and federal laws.

21.2. Empty Waste Canister according to applicable local and federal laws. Ensure caps are closed during transport.

21.3. Dispose of the Procedure Instrument and accessories according to applicable federal regulations and local laws.

21.4. This product complies with the most current revision of the WEEE Directive marking requirements as depicted below. The Console must not be discarded in domestic household waste. Disposal of the product must be in compliance with local and state laws for recycling of electronic equipment.

DO NOT DISPOSE IN DOMESTIC HOUSEHOLD WASTE!

22.0 Glossary

22.1. Sodium Hypochlorite (NaOCl) solution: Commonly known as household bleach.

22.2. Ethylenediaminetetraacetic acid (EDTA): A colorless solution used to remove the smear layer in the root canal system.

22.3. GentleWave® X System (System): Includes the GentleWave® X Console and the GentleWave Handpiece (Procedure Instrument).

22.4. GentleWave® X Console (Console): The Console that delivers procedure fluid to the Procedure Instrument and aspirates the used procedure fluid and organic matter from the root canal system.