

User Guide

Model AVACEN GXL



Caution: Please read the entire user guide with care prior to using the device.

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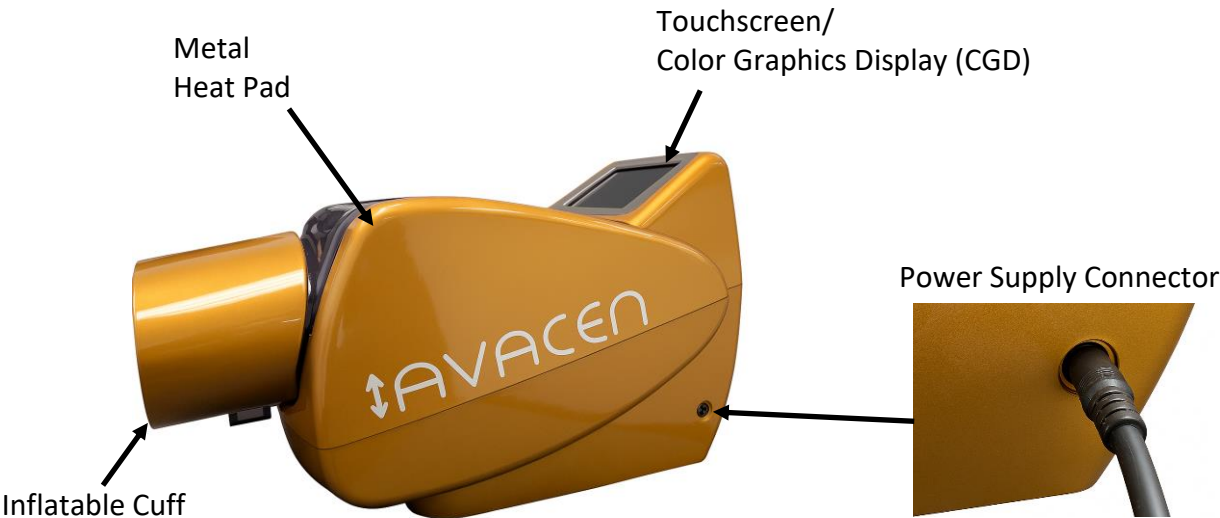
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QUICK START GUIDE IS ON BACK COVER

AVACEN GXL Device Diagram



Hand Positioning Tips: KEEP WRIST STRAIGHT AND IN THE CENTER OF THE CUFF!

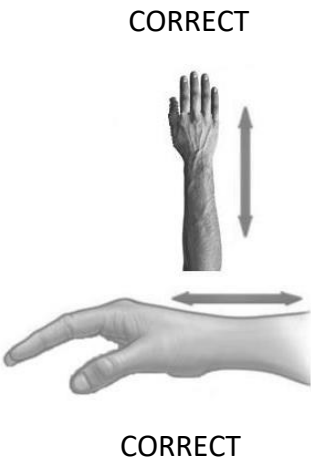


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1. DESCRIPTION

The AVACEN GXL is a Dry Heat Therapy FDA Class II Medical Device. It consists of a control panel, metal heat pad, and a Vacuum Chamber with an Inflatable Cuff. The vacuum pump and heat source are in the base of the unit. For proper function and to maintain sanitary conditions, the AVACEN device **MUST** be used with the supplied hand mitts. Extra hand mitts can be purchased by contacting AVACEN at support@avacen.com.

2. UNPACKING THE UNIT

The shipping box contains the AVACEN GXL device, power cord, power supply, mitts, and this user guide. Lift the top shipping foam piece out of the box. Then lift the AVACEN out of the box with two hands. Keep the shipping box and foam in case the AVACEN needs to be returned. Be sure to read the **What to Expect** flyer before the first use.

3. NORMAL USE

The AVACEN GXL is designed to provide dry heat therapy. Treatment time and/or number of uses per day can be increased based on professional recommendations or absence of response to treatment. Proposed use is 20 minutes first thing in the morning using the LEFT hand (hint: "Left is for day Light") and 20 minutes before bed using the RIGHT hand (hint: "Right is for Night"), healthy hand condition permitting.

Any level of major discomfort (after lowering Heat setting first) is not normal. If this happens, stop using the AVACEN GXL Device right away and report the problem to AVACEN Medical Customer Service at (888) 4-AVACEN (888-428-2236) or send an email to support@AVACEN.com.

4. INDICATIONS FOR USE

The AVACEN GXL is a heat therapy system indicated for: the temporary relief of minor muscle pain, stiffness, and the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains. The device is also used for muscular relaxation, and the temporary increase of local circulation where applied.

5. CONTRAINDICATIONS

Although there have been no issues reported, it is suggested that you contact a doctor before using the AVACEN if you are under 18 years of age, are pregnant, or have a temperature higher than 99.5°F (37.5°C). Do not use the AVACEN on a hand that has open sores or wounds.

6. WARNINGS & PRECAUTIONS



WARNINGS are used to signal potential hazards which could lead to death or serious injury. **PRECAUTIONS** are used to warn the reader of potential hazardous situations. If not avoided, these hazards may result in minor or moderate injury to the user or patient or damage to the device or other property.

Warnings

- This device **IS NOT** meant to provide ample heating where the internal body core temperature is falling uncontrollably or is lower than 95°F (35°C). In these cases, **GET MEDICAL ATTENTION FAST!**
- Making changes to this device is not allowed.
- **Do not** use the AVACEN GXL with other devices or accessories except as described in this User Guide.
- Choking hazard - contains small parts. Keep out of reach of children.
- Strangulation hazard - contains a long power cord that may cause strangulation if used improperly. Keep out of reach of small children.

Precautions

- The following cautions are guidelines only and are not meant to replace a health care professional's advice. If any harmful effect occurs while using the product, stop use and contact your health care professional.
- Use with care. May cause serious burns. **Do not** use on sensitive skin areas or in the presence of poor circulation.
- The **unattended use** of the AVACEN by children or incapacitated persons may be dangerous.
- **Do not** use with liniment, salve, essential oils or ointments - may cause skin irritation.
- **To prevent damage to the mitt and inflatable cuff, remove all jewelry (rings, bracelets, watches) from the hand that will be used for therapy.**
- **Do not** use the AVACEN on a hand that has open sores or wounds. Any level of major discomfort (after lowering temperature first) is not normal.
- Metal implants - pay attention for signs of any uncomfortable heat buildup in the treatment area. If this occurs, stop using the device.
- Stop using the AVACEN right away and report any major discomfort problems to AVACEN Medical customer support at (888) 4-AVACEN (888-428-2236) or email AVACEN Medical at support@AVACEN.com.
- To remove your hand from the Vacuum Chamber at any time, unplug the unit. The air will drain from the cuff as you slowly pull your hand out of the device.
- Although there have been no issues reported, consult your healthcare professional **before** using the AVACEN if you have any of the following:
 - Malignancy (A term for diseases in which abnormal cells divide without control and can invade nearby tissues) .
 - Pregnancy.
 - Chronically hot or swollen joint in the hand, fingers, or wrist
 - Circulatory diseases.
 - Recent acute joint injury in the hand, fingers, or wrist

7. IMPORTANT SAFETY INFORMATION


















- Read the entire AVACEN device User Guide before using this device.
- For continued protection against risk of fire and shock, use the hand unit only with the provided power supply, AVACEN part number 50-100000.
- Do not store the AVACEN device in direct sunlight. The AVACEN should be stored in a clean, well-ventilated area at room temperature. Keep out of reach of small children and pets. Optional carrying bags should be left open to allow for ventilation.
- Do not use outdoors in the rain, snow, or under water. While the device is protected against vertically dripping water, it is not water resistant, and should not be used in wet areas.
- Pressing too hard on the heat pad can cause the AVACEN to be ineffective.
- The Power Supply Connector is the main power disconnect device for the AVACEN device. If a malfunction is suspected, unplug the power supply or remove the power input from the unit.
- This device complies with Part 18 of the FCC Rules, as well as international electromagnetic compatibility requirements. Use is subject to these two conditions:
1) This device may not cause harmful interference. 2) This device must accept any interference received, including interference that may cause undesired operation.
These limits are designed to provide reasonable protection against harmful interference in a residential installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment causes problems with radio or TV reception, which can be checked by turning the equipment off and on, you are encouraged to try to correct the interference by one or more of the following measures:
 - Reorient the receiving antenna
 - Relocate the system with respect to the receiver
 - Move the system away from the receiver, and/or
 - Plug the system into a different outlet so that the system and the receiver are on different branch circuits.

Environmental Conditions		
Temperature	Operating	50°F (10°C) to 104°F (40°C)
	Storage	32°F (0°C) to 140°F (60°C)
Relative Humidity	Operating	30% to 75% rH
	Storage	10% to 95% rH
Atmospheric Pressure	Operating	700hPa to 1060hPa
	Storage	500hPa to 1060hPa
AC Input Voltage		100 - 240V~, 50-60Hz
Expected service life of equipment and accessories		5 years

8. CONTACT INFORMATION

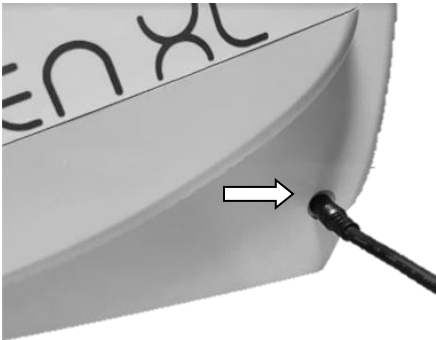
Manufacturer:	
AVACEN Medical 6451 EL Camino Real, Suite C Carlsbad, CA 92009	Phone: (888) 4-AVACEN (888-428-2236) Web: AVACEN.com Email: support@AVACEN.com

9. EXPLANATION OF SYMBOLS

Symbol	Description
	Home Icon
	Mute/Volume Icons for sound
	Start/Advance/Resume and Pause Icons
	Settings Icon
	OK/Accept/Confirm Icon
	Up / Down Adjust
	Low/Medium/High Temperature Settings
	Remove all jewelry and watch before inserting hand in the device. Do not allow your shirt sleeve to enter into the Inflatable Cuff.
	Caution: Refer to Instructions
	Read Instruction Manual
	Atmospheric Pressure Range
	Temperature Range
	Humidity Range
IP21	Protection rating for ingress of solid objects and water - protected against solid objects larger than 12.5 mm and vertically dripping
	Type BF Applied Part
	Do Not Dispose in Trash
	Identification of Manufacturer
	Complies with 47 CFR Part 18 for Industrial, Scientific, and Medical Equipment

10. OPERATING INSTRUCTIONS (NORMAL MODE OPERATION)

Connect the Power Supply Connector into the power supply jack. The power supply jack is located on the right side panel towards the lower back corner. Plug the AC power cord end from the power supply cord into the correct power source (wall plug) - GXL-240V~, 50-60Hz.



International use: When travelling internationally, care should be taken to ensure that you have the correct cord and wall plug for the country in which the AVACEN is to be used. Contact AVACEN if the wall plug on the cord does not fit.

If the device has been stored in a hot or cold area, allow it to reach normal room temperature for 1 hour before turning it on.

Turn on the AVACEN device by inserting power plug. The display will show a welcome message. Advancing beyond this welcome screen, you will see the Language selection on first power up. Please select the desired language. After the language is selected, there will be disclaimer screens (again, only on first power up). Please acknowledge that you meet the criteria by pressing “Yes” for these disclaimers. Once completed, you will arrive at the “Please Wait, Warming up” screen. This message will remain until the hand pad has reached ~98.6° F.

It is very important that the AVACEN is placed on a level surface and your hand is **NOT** inside the Vacuum Chamber when you turn the device on. If your hand is inside the vacuum chamber (resting on the heat pad) when the device is turned on, the onboard computer will not measure your hand pressure correctly. If you turn the device off (by mistake or on purpose), remove your hand from the Vacuum Chamber before turning the device back on again.

Note: The unit will go into a standby mode after 5 minutes of no use. To wake the unit up, simply press anywhere on the touch screen to resume operation. During Standby, the heat pad will remain at the preheated temperature of ~98.6° F.

When the hand pad reaches the predetermined standby temperature, the home screen will be displayed.



Note: For the most benefit , the "High" setting is preferred. Select "Med" or "Low" only in the case of major discomfort. The heat pad will feel hot during use. If a lower temperature is used, after several uses, return to the "High" mode to see if the discomfort has been reduced. These values may be adjusted by pressing the up and down arrows for the subsequent settings.

Once you have selected your desired settings for therapy and advance to the next screen, you will see a message to remove all jewelry. This is to prevent damage to the mitt and cuff membrane. **Please remove all jewelry (rings, bracelets, watches) from the hand and wrist that will be used for therapy. If you are wearing a shirt or jacket with long sleeves, pull the sleeve up your arm so that the inflatable cuff contacts bare skin on your arm.** The inflatable cuff WILL NOT seal against a watch or shirt sleeve.

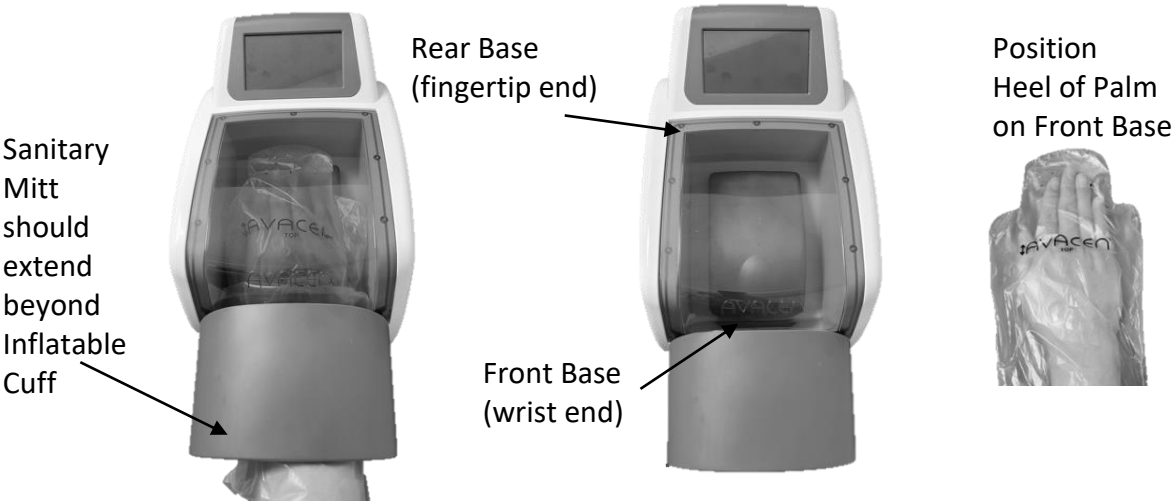


You will also be prompted to place the AVACEN mitt on the hand you plan to use for therapy. Place therapy hand in the Mitt. All 4 fingers should be placed in the body of the mitt and the thumb should be placed in the right or left thumb cavity of the mitt. **Important - Leave 1 cm (1/2 inch) in top of mitt free when placing hand inside and ensure that the pressure holes are facing up.**



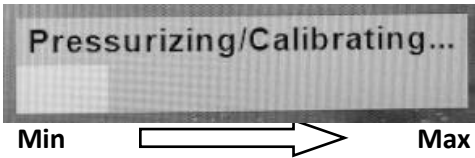
Finally, **SLOWLY** insert your hand (with mitt applied) into the Inflatable Cuff. The raised, egg-shaped portion of the heat pad should be cupped in the center of the palm. To be most effective, keep all four fingers resting on the fingertip end of the Metal heat pad. Please take care not to puncture or rip the flexible cuff, which is critical to the operation of the device. When ready, press the “Next” icon, and therapy will begin!

Metal Heat pad Diagram



11. CUFF SEALING

The "Pressurizing/Calibrating" message is displayed while the vacuum motor runs. The bar along the bottom shows the vacuum level; when the bar has fully changed color, the full vacuum has been achieved.



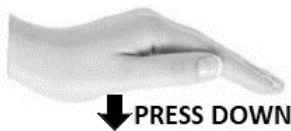
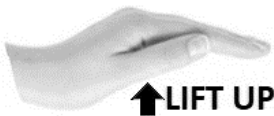
IMPORTANT NOTE: The seal on the cuff may have become dislodged during shipping and unpacking. If the seal is not properly in place, the Vacuum Chamber will not seal. Refer to the "Troubleshooting" section of this User Guide for simple ways to correct this issue.

12. HAND PRESSURE INDICATOR (HPI)


When the unit seals properly, the top of the display will show the remaining therapy time. The first few seconds after reaching the designated vacuum level is when the onboard computer measures your baseline hand weight. It is very important to have your hand in the position you would like to maintain for the entirety of the session during this time.


If, at any time during therapy, too much hand pressure is on the hand pad, an alarm will beep and the image to the right will be displayed.

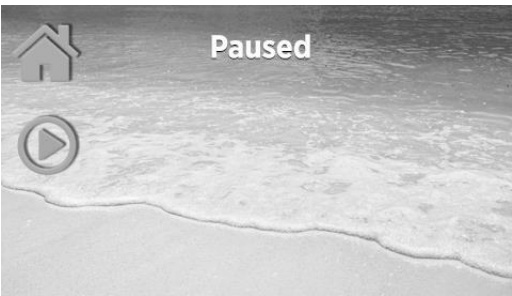
Conversely, too little hand pressure on the hand pad will also set off an alarm (beep) and display the "Press Down" message.






13. PAUSING A THERAPY SESSION

PAUSE: If the  (pause) icon on the display is pressed during treatment, the timer and Vacuum motor are paused. The cuff will depressurize and the treatment hand may be slowly removed.




Pressing the  (resume) icon will cause the timer and Vacuum Chamber sealing process to resume.



14. ADJUSTING THE THERAPY TIME

Pressing the  and  icons near the  (clock) icon on the display while running a therapy session will cause the therapy timer to increase or decrease in value.

15. ADJUSTING THE THERAPY TEMPERATURE

Pressing the  or  buttons near the  (temperature) icon on the display during therapy will switch the Temperature setting from High to Medium to Low, and back to High again.



16. END OF THERAPY

When the treatment time runs down to zero, the device will finalize the session. The cuff will begin to deflate and the "Remove Hand Slowly" message is displayed. Remove your hand from the Vacuum Chamber. Remove the Mitt and discard or retain for your own use at a later time. Therapy is now complete. The device will return to the Welcome screen for the next session.




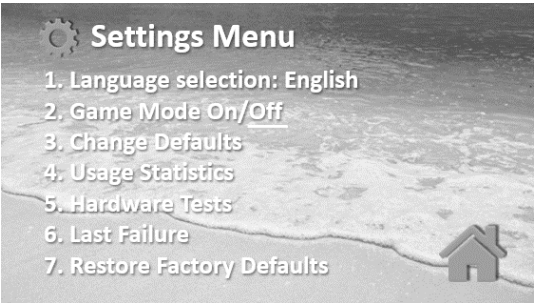
If there is a problem during operation, the device will display an error message. Please refer to the "Troubleshooting" section of this user guide for instruction.

17. STANDBY MODE OPERATION

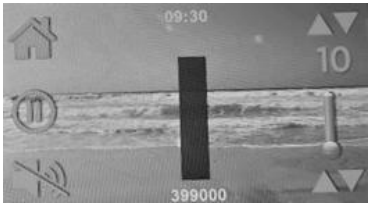
The AVACEN device will enter a standby mode after 5 minutes of inactivity. The display will turn off, and the hand pad temperature will stay at ~98.6°F. To wake the device, simply press anywhere on the display. It will resume operation from where it left off. The rest of the device functions are the same as described in the "Normal Mode Operation" section of this manual.

18. GAME MODE OPERATION

To enter Game Mode, go to the settings page  and press on "Game Mode." This will toggle the selection between "On" and "Off." Leave the setting at "On" to enable game mode. This setting will reset after the game session has completed.



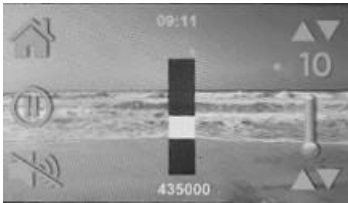
Game Mode is used to encourage the user to maintain the proper amount of pressure on the heat pad. The Hand Pressure Indicator (HPI) position in the center of the screen is used as the gauge for the game. The goal is to score the most points by keeping the HPI a solid color. If the hand is resting too lightly or heavily on the hand pad, a different color of the bar will start to appear from the center of the bar in the direction of non-compliance (up means too light, down means too heavy).



Balanced Hand Force



Slightly Light Hand Force



Slightly Heavy Hand Force

Points will be tallied during the game, positioned below the HPI. The number of points earned is based on how well the user keeps the HPI a solid color. Points are scored as long as the "Lift Up" message or the "Press down" messages are not displayed. If these messages are displayed, the user will hear an audio beep, and 5,000 points will be subtracted from the total score every second.

The highest number of points awarded is 150,000 points per minute. Therefore, the user could accumulate as many as 3,000,000 points in a 20-minute therapy session (more or fewer points depending on the length of the session). A score of half the highest possible score (e.g. 1,500,000 for a 20-minute session) would indicate that the user did a very good job of keeping their hand properly seated on the heat pad. The final score can also be used as a gauge of proper hand position during unattended patient therapy sessions.

If a new high score was earned, this will be stored and viewable in the settings tab under "Usage Statistics."

19.TROUBLESHOOTING AND FAQS

If you are having problems using the AVACEN device, review this section to see if a solution is described. If you are still having trouble, call AVACEN Medical at (888) 4-AVACEN (888-428-2236) and select "Customer Service" or email support@AVACEN.com. When you call, have your AVACEN ready and make note of the device serial number (marked on the bottom of the device).

A. How long should treatment last?

The AVACEN device is designed to comfortably and noninvasively provide dry heat therapy for a period between 10 and 60 minutes. For many conditions, 20 minutes twice daily is sufficient. Treatment time and/or use frequency can be increased to accommodate professional recommendations or absence of response to treatment. The best times for treatment are in the early morning and prior to bed. Suggested use should be: 20 minutes first thing in the morning using the LEFT hand (reminder hint: "Left is for day Light") and 20 minutes before bed using the RIGHT hand (reminder hint: "Right is for Night"). Switching hands assumes both hands are equally healthy. If not, use the healthy hand only.

Any level of major discomfort (after adjusting temperature) is not normal. Stop using the AVACEN right away and report the problem to AVACEN at (888) 4-AVACEN (888-428-2236) and select "Customer Service" or email support@AVACEN.com.

B. How important is the placement of my hand?

It is critical to make sure that the palm is completely inside the vacuum chamber and resting on the metal heat pad. The raised, egg-shaped portion of the heat pad should be cupped in the center of the palm.

C. Is it necessary to wear the AVACEN Mitt?

The AVACEN device design requires a special mitt. Without this mitt, the AVACEN may not seal properly. Using the mitt also provides a sanitary environment for multiple family members or clinic users. In addition, the mitt keeps dirt and hand oils off of the critical metal heat pad and from inside the vacuum chamber. This prolongs the efficiency and extends the useful life of the AVACEN.

D. Do I need a new a Mitt every time I have a treatment?

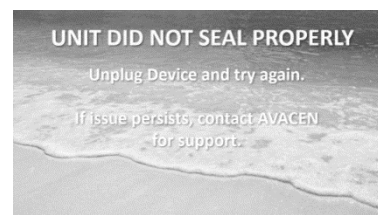
No. As long as the mitt appears to be in good repair and clean, the same person may use it for months.

E. Do I need to purchase the mitts from AVACEN?

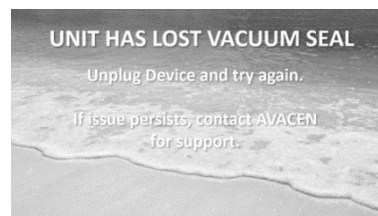
The AVACEN was developed and tested for FDA Clearance using a very specific mitt material and design. We have priced the mitts to be very affordable and therefore recommend that mitts be purchased by contacting AVACEN at support@avacen.com or visiting www.AVACEN.com and searching under accessories.

F. The AVACEN unit displays 'Did Not Seal' or 'Lost Vacuum Seal' message

If the AVACEN is not able to reach the proper vacuum level after 60 seconds, the "Unit Did Not Seal Properly" message is displayed. The user may unplug and plug the unit back in to try again or contact AVACEN if the issue persists.



If vacuum is lost during a therapy session the "Unit Has Lost Vacuum Seal" message is displayed and the user may unplug and plug the unit back in to try again or contact AVACEN if the issue persists. This can occur if:



- (i) The Inflatable Cuff is not properly sealed at the wrist.
 - See Item P: "Checking the Inflatable Cuff for leaks"
- (ii) A mitt is not being used.
 - Put on a mitt.
- (iii) The end of the mitt does not extend beyond the sealed cuff.
 - Pull the mitt on your hand and make sure the end of the mitt is outside the cuff.
- (iv) The user's hand is not properly positioned.
 - It is critical to make sure that the heel of the palm (where the palm connects to the wrist) is completely inside the vacuum chamber and touching the palm end of the metal heat pad (closest to opening).
- (v) The Inflatable Cuff is not properly positioned.
 - See section 22: " PERIODIC MAINTENANCE" for taking the Inflatable Cuff on and off.

If your skin is very dry, put a small amount of hand lotion on your wrist and rub it in to improve sealing after your hand is placed into the mitt. If you are still having trouble, call AVACEN Medical at (888) 4-AVACEN (888-428-2236) and select "Customer Service" or email support@AVACEN.com.

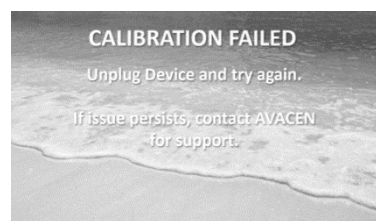
G. "Rest Palm On heat pad" message

To make sure the device calculates the proper pressure of your hand against the metal heat pad, it is important during the initial sealing and calibration process that you apply slight pressure with your palm against the heat pad. Without this base pressure, the onboard computer will not be able to properly measure the pressure of the palm against the heat pad and "Rest Palm On heat pad" message will continue to appear for 30 seconds, after which the AVACEN will go to a paused state.

It is very important that the AVACEN is placed on a level surface and your hand is NOT inside the Vacuum Chamber when you power the unit on. If your hand is inside the vacuum chamber (resting on the heat pad) when the unit is powered on, the onboard computer will not measure your hand pressure correctly. If you power down the unit (by mistake or on purpose), remove your hand from the Vacuum Chamber before turning the unit back on again.

H. "Calibration Failed" message

It is very important that the AVACEN is placed on a level surface and your hand is NOT inside the Vacuum Chamber when you power the device on. If your hand is inside the vacuum chamber (resting on the heat pad) when the device is powered on, the onboard computer will not measure your hand pressure correctly. If you remove power (by mistake or on purpose), remove your hand from the Vacuum Chamber before plugging the device back in.



To make sure that the device computes the proper weight of your hand against the metal heat pad, it is important during the initial sealing and calibration process to apply slight pressure with your palm against the heat pad. Without this base pressure, the onboard computer will not be able to properly manage the pressure of the palm against the heat pad. At that point the "Calibration Failed" message will appear and the user must unplug and plug in the device to try again or contact AVACEN if the issue persists.

After the weight of the hand is measured during the calibration phase, the onboard computer monitors if there is too much or too little palm pressure against the heat pad. A warning will appear on the display if too little or too much hand pressure has been applied. After a number of uses, it will become much easier to judge the proper pressure of your palm against the heat pad. If you are still having trouble, call AVACEN at (888) 4-AVACEN (888-428-2236) and select "Customer Service" or email support@AVACEN.com.

I. "System Error" Message

The device is always checking and adjusting the temperature of the heat pad. If for some reason it cannot measure the heat pad temperature, a warning message will be displayed. This can happen for a couple reasons:



(i) The device is very cold.

- Turn off the device and allow it to warm to room temperature before turning on.

(ii) The device has been stored somewhere very hot.

- This may have damaged the device. Unplug the unit, then plug back in and try again. If the message is displayed a second time, call AVACEN at (888) 4-AVACEN (888-428-2236) and select "Customer Service" or email support@AVACEN.com.

J. There is noise while the AVACEN device is running

There is an air pump inside the AVACEN that runs during therapy. Some motor noise is normal, and the noise will vary as the AVACEN adjusts the air pressure of the inflatable cuff and inside the vacuum chamber. This improves the comfort of the inflatable cuff.

K. The inflatable cuff is too tight

The inflatable wrist bladder is designed to work on almost any size wrist and therefore it may feel tighter to some people than others. The first inflation exerts the most pressure to assure a proper seal every time. This highest pressure will only last for less than a minute. After that the pressure will relax to a more comfortable level. If the pressure does not relax there may be a vacuum leak. Refer to Item F: "The AVACEN unit displays 'Did Not Seal' or 'Lost Vacuum Seal' message" for solutions.

L. I keep getting a "Press Down" or "Lift Up" message

It is very important that the AVACEN is placed on a level surface and your hand is NOT inside the Vacuum Chamber when you turn the device on. If your hand is inside the vacuum chamber (resting on the heat pad) when the device is turned on, the onboard computer will not measure your hand pressure correctly. If you turn the device off (by mistake or on purpose), remove your hand from the Vacuum Chamber before turning the device back on again.

To make sure that the device calculates the proper pressure of your hand against the heat pad, it is important that during the initial sealing and calibration process that you apply slight pressure with your palm against the heat pad. Without this base pressure, the onboard computer will not be able to properly manage the pressure of the palm against the heat pad and "Press Down" or "Lift up" message will continue to appear along with a beeping sound.

During treatment there is a chance the heel of your palm will be pushing too hard against the palm end of the metal heat pad (end nearest the wrist opening). This condition is not wanted and will cause the "Lift Up" message to appear along with a beeping sound. At this point just retract your hand into the cuff to its original position and the alerts will stop.

One of the top features of the device is to monitor and display too much or too little pressure of the hand on the metal heat pad. Correct hand pressure on the heat pad increases heat transfer. After the weight of the hand is calculated during the calibration phase, the onboard computer is responsible for monitoring the palm pressure. If there is too much or too little palm pressure against the heat pad, a warning message will appear. After a number of uses, it will become much easier to judge the proper pressure of your palm against the heat pad. If you are still having trouble, call AVACEN at (888) 4-AVACEN (888-428-2236) and select "Customer Service" or email support@AVACEN.com.

M. The AVACEN heat pad is too hot (or too cold)

For the most benefit "High" is recommended. Select "Med" or "Low" only in the case of major discomfort. The heat pad will feel hot during use. If a lower temperature is used, return to the "High" mode after several uses to determine if the discomfort has been reduced. If the heat does not recede to a more comfortable level RIGHT AWAY, stop using the device and call AVACEN Medical at (888) 4-AVACEN (888-428-2236) and select "Customer Service" or email support@AVACEN.com. After using the device for some time, your hand may get used to the heat pad temperature, so that it does not "feel" as hot as it used to. This is normal and does not mean there is a problem with the device.

N. The heat pad seems "loose"

For proper measurement of hand weight on the heat pad, the heat pad must be free to move up and down and side-to-side slightly. This is normal and does not mean there is a problem.

O. The Display does not illuminate after plugging in power cord

Make sure that the power cord is plugged into the unit securely and the light on the Power Supply (black box between the device plug and wall plug) is on. If the light on the Power Supply is not on, check the ends of the power cord to make sure it is plugged into both the Power Supply and the wall plug. If the Power Supply light is still not on, make sure that the wall plug is working properly. Do this by plugging in another device or lamp that you know works into the wall plug. If you are still having trouble, call AVACEN Medical at (888) 4-AVACEN (888-428-2236) and select "Customer Service" or email support@AVACEN.com.

P. Checking the Inflatable Cuff for leaks

Running a "Self Seal Test" can check the quality of the cuff and seal it achieves.

This test can be found in SETTINGS. Refer to section 20 "SETTINGS" in this Guide for details on starting the test.

Q. Excessive swelling of the hand

The AVACEN device is designed to comfortably and noninvasively provide dry heat therapy. **Any level of major discomfort is not normal. Right away stop using the AVACEN and report the problem to AVACEN Medical at (888) 4-AVACEN (888-428-2236) and select Customer Service.**

R. Red or purple spots on the hand

Red or purple spots on the hand (usually the backside) after the first couple of AVACEN device uses can be caused by a minor hemorrhage (petechia). These spots are harmless and will likely vanish within a few days. **Should they not disappear or if they are accompanied by any level of major discomfort, this is not normal. Right away stop using the AVACEN and report the problem to AVACEN Medical at (888) 4-AVACEN (888-428-2236) and select Customer Service.**

S. Hand itches or tingles

It is common and normal for the hand to slightly itch or tingle during a treatment session as circulation in the hand increases. **If this at any time becomes uncomfortable or painful, immediately stop the treatment session and call AVACEN Medical at (888) 4-AVACEN (888-428-2236) and select Customer Service.**

T. My hand is reddish-colored like it has been in hot water

This state is normal and you will likely see this on every treatment. It is due to the increased microcirculation (blood in the capillaries).

U. Sweating when using the AVACEN

The AVACEN device is designed to comfortably and noninvasively provide heat therapy. Mild sweating is not typical but seldom may occur and is not a serious indication. **Any level of major discomfort pain is not normal. Right away stop using the AVACEN and report the problem to AVACEN Medical at (888) 4-AVACEN (888-428-2236).**

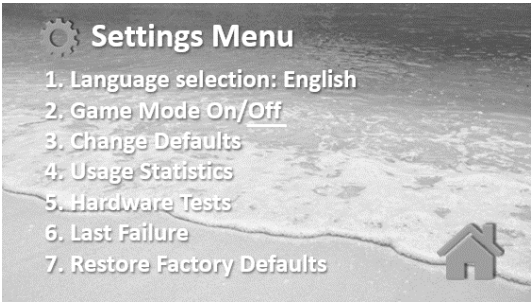
V. Discomfort in wrist or forearm during use

Raise or lower forearm or try a support cushion under the arm.

20. SETTINGS


There are some settings that can be made on the AVACEN unit that will be stored. Even if power is removed, the settings are kept. The following Settings can be made on the AVACEN:

- Language Selection
- Game Mode On/Off
- Change Default Therapy settings (Time/Temperature)
- Usage Statistics





In addition, there are some settings that can be used to help diagnose problems with the device:

- Hardware Tests
- Last Failures
- Factory Restore


All of these features are accessed in the “Settings” menu. To access “Settings”, press the  icon from the Home screen.

Moving through the different Settings is done using the touchscreen:
Touch an item to select.

Press  to go to previous menu.

Press  to return to the Home screen.

A. Language Selection




Messages can be displayed in multiple languages on some device versions. From the Settings Menu, press “Language” - the current selection is underlined. Choose the desired language, and it will become underlined. Press  “Go Back” to return to settings menu.

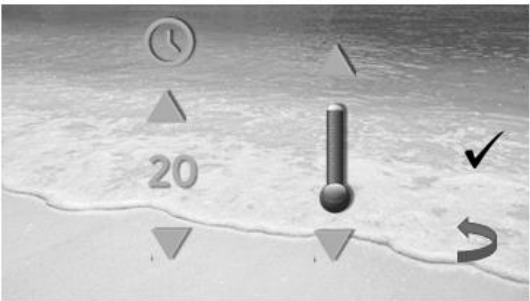


B. Game Mode On/Off

From the Settings Menu, tap the “Game Mode: On/Off” line to toggle between game mode enabled and disabled. The underline shows which mode the device is in.

C. Change Defaults

The default setting for therapy time is 20 minutes. At any time before the start of a therapy session, the therapy time may be changed from 20 minutes to 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, or 60 minutes. If you find that you are usually selecting a time other than 20 minutes for therapy, the default therapy time can be changed. From the Settings menu, press “Change Defaults.” Press  or  one or more times to choose a default therapy time setting. Press  to store the setting. Now, whenever the device is turned on, the new default therapy time will be selected. This setting will be erased with a Factory Restore.



The default setting for therapy temperature is HIGH. This is the preferred setting for maximum benefit. At any time during therapy, the temperature setting can be changed by pressing the ▲ or ▼ buttons. If you find that you are usually selecting the MEDIUM or LOW temperature setting, the default setting can be changed from HIGH to MEDIUM or LOW. From the Settings menu, select “Change Defaults,” then press ▲ or ▼ to choose a default therapy temperature setting. Press ✓ to store the setting. Now, whenever the device is turned on, the new default therapy temperature will be selected. This setting will be erased with a Factory Restore.

To exit without changing default temperature or time, press the ➡ icon.

D. Usage Statistics

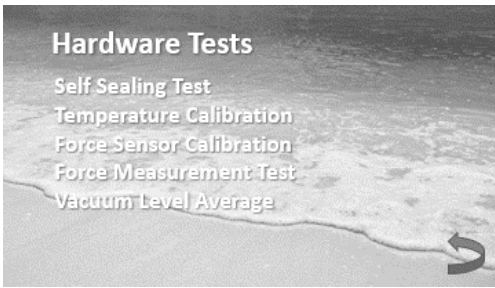
For information on number of sessions and total therapy time of the device, go the “Settings” menu and select “Usage Statistics.” From there you can view this information. Content will NOT be lost after a Factory Restore. Press ➡ icon to return to “Settings” menu.



E. Hardware Tests

If you are talking to AVACEN Customer Support, they may ask you to go to this menu for a variety of troubleshooting tests.

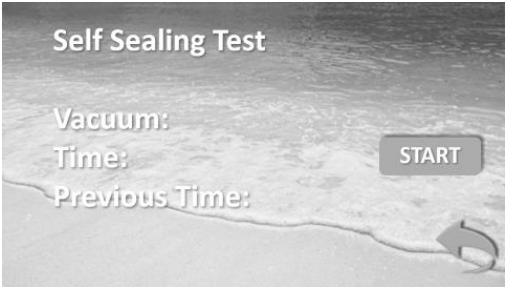
- i. Self-Sealing Test
- ii. Temperature Calibration (locked)
- iii. Force Sensor Calibration (locked)
- iv. Force Measurement Test
- v. Vacuum Level Average



i. Self-Sealing Test

The AVACEN can perform a self-test to check for air leaks. If you are talking to AVACEN customer support, they may ask you to go to this menu. This test may also be helpful when trying to see if there are any leaks in the inflatable cuff.

- To access Self Sealing Test, go to the settings (⚙️) menu and select “5. Hardware Tests”. From this menu, select the first test (Self Sealing Test).
- The screen will show the vacuum level in the chamber, the current time being measured once the “START” button is pressed (once the unit seals and begins to draw a vacuum), and the previous time it took to reach proper therapy vacuum level.
- The following are possible results:
 - Green check mark – passing.
 - Red “X” – failing to reach proper vacuum within 60 seconds.



- There can be a great deal of variation in the quality of a seal from one inflation to the next. It is recommended to run the test at least twice, back-to-back as the first seal may not be a true reflection of the quality of the cuff and ability of the unit to achieve therapy conditions.
- If the cuff does not fully inflate, or the device consistently fails the self-seal test, the cuff may have holes. To check for this, use the back of your hand to feel the inflatable cuff to see if there is any air leaking out of the cuff. This would indicate there are holes in the cuff that are leaking enough air that the cuff is not able to completely seal against itself. In this case, the Pop-on/Pop-off Cuff must be replaced. Replacements can be purchased by contacting AVACEN: support@avacen.com or by visiting www.AVACEN.com, under accessories.



ii. Temperature Calibration (locked)

iii. Force Sensor Calibration (locked)

iv. Force Measurement Test

If you are talking to AVACEN customer support, they may ask you to go to this menu. In this test, you can see the amount of force that is being put on the hand pad by your hand. To reach this menu, go to settings menu (⚙️), select “5. Hardware Tests” and press “Force Measurement Test.”



v. Vacuum Level Average

The AVACEN device can also perform a vacuum measurement test. Once the “START” button is pressed, the unit will begin to inflate the cuff. Once therapy vacuum is reached, the vacuum will be averaged for 20 seconds. At the end of the test, the customer must deflate the cuff manually.



F. Last Failure

This menu stores information about errors when the device was last used. If you are talking to AVACEN Customer Support, they may ask you to go to this menu. From the "Settings" menu, select “Last Failure” to show the last error that was recorded.

G. Factory Restore

This menu will restore the unit to the same configuration as when it left the factory – default temperature and time will revert to HIGH and 20 minutes, and game scores will be deleted. Language will need to be re-selected, and Disclaimers will again need to be verified after a Factory Restore. Usage statistics for total hours of operation and number of therapy sessions will be retained.

21. CLEANING

The outside surfaces of the AVACEN device can be wiped down with a damp cloth or a disinfectant hand wipe. Do not use any harsh cleaners or gel sanitizers as damage to the enclosure may result.

Cleaning the inside of the Vacuum Chamber is not needed between uses as long as clean mitts are used. If it is needed to disinfect the Vacuum Chamber, ensure the cuff is fully deflated and use a disinfectant hand wipe on the inside surfaces.

22. PERIODIC MAINTENANCE

If the Inflatable Cuff is too worn out or gets torn, it must be replaced. A Pop-on/Pop-off cuff replacement is available. The replacement Pop-on/Pop-off Cuff can be purchased by contacting AVACEN at support@avacen.com, or going to the website www.avacen.com and searching under accessories.

To check the Inflatable Cuff for leaks, follow the steps for the self-sealing test, which can be found in SETTINGS. Refer to section 20 "SETTINGS" in this Guide for details on starting the test.

Replacing the Inflatable Cuff

If you need to replace the inflatable cuff, begin by removing the cuff cover and setting aside for reassembly.



Next, lift up four tabs of the lock ring, circled in the images below – two on top, two on bottom. A tool has been provided to access some of the more difficult snaps. A video instruction may also be found on the AVACEN website. Note that the cuff gasket has silicone grease on the exterior.



Lower Left



Upper two

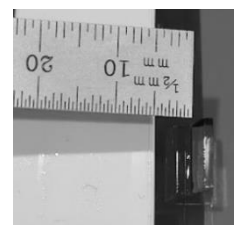


Lower Right

Gently remove the lock ring and set aside for reassembly.

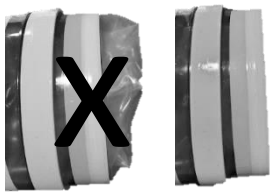


Note the location of the cuff gasket and its proximity to the tab/snaps on the device (approximately 5mm).

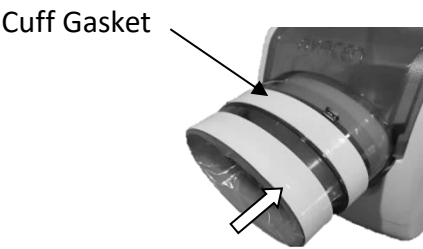


Remove old cuff.

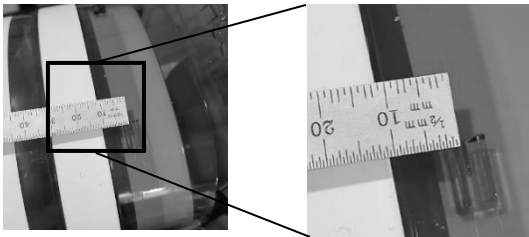
With the new cuff, ensure that the flexible portion is nested inside the rigid plastic portion.



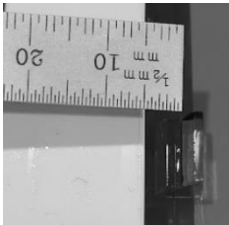
Orient the cuff with the gasket facing the product.



Gently slip the cuff into the product – ensure the gasket settles at the same distance from the tabs as the old cuff. This may require some levering of the gasket away from the cuff to fully overlap on the product side.



Need to push in more



Good

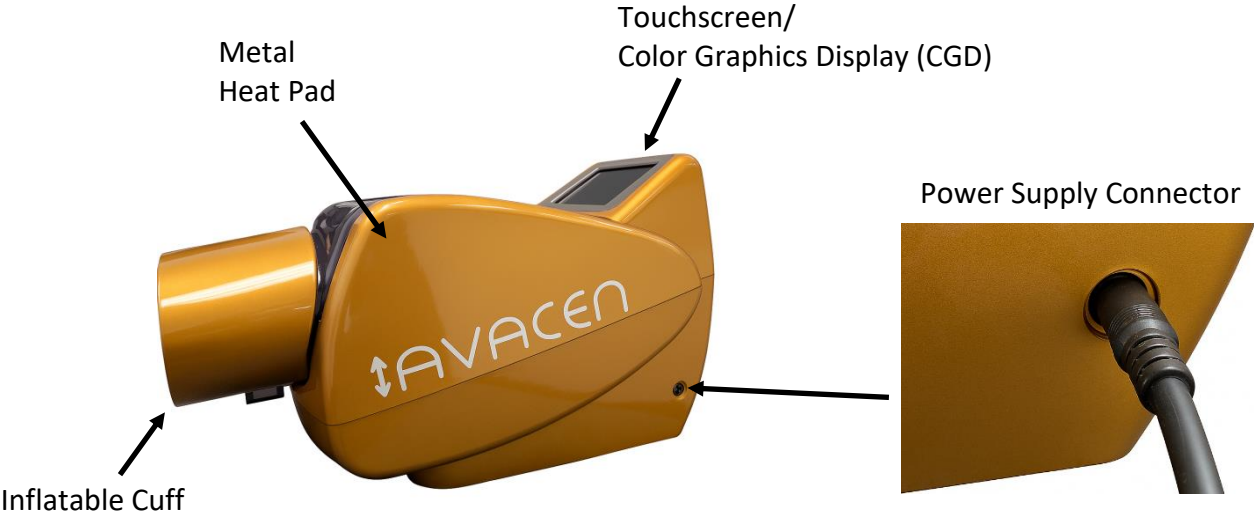
Gently slip lock ring over the cuff. Ensure four snaps are heard, one for each locking tab.



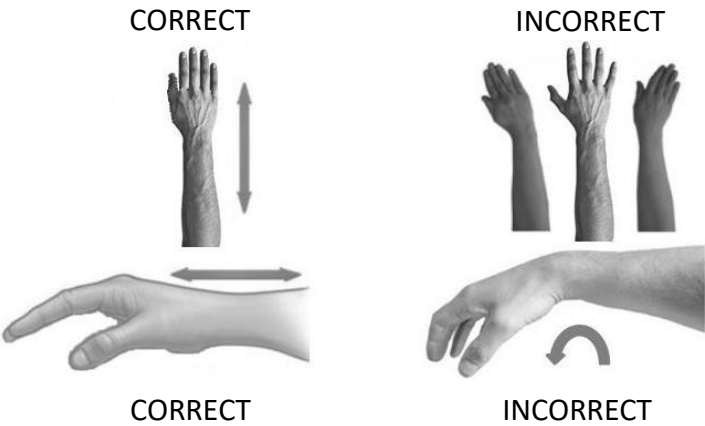
Slip the cuff cover back over the cuff.

Power the unit on and run a self-sealing test (see section 20.E.i).

AVACEN GXL Device Diagram



Hand Positioning Tips: KEEP WRIST STRAIGHT AND IN THE CENTER OF THE CUFF!






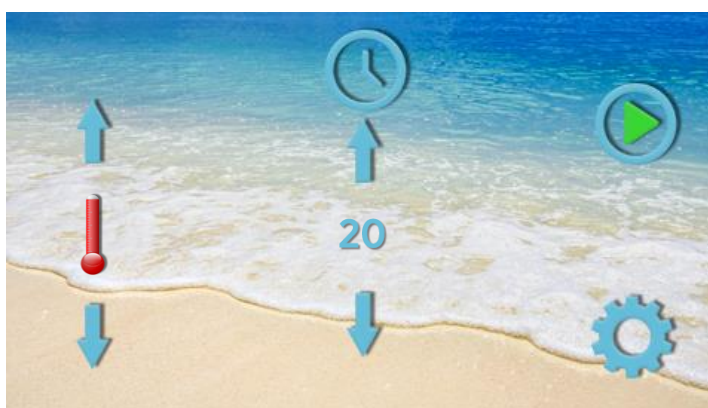
AVACEN GXL Quick Start Guide

IMPORTANT: Please read The AVACEN GXL User Guide prior to use of this device!

When you first unpack the device, run a Self Seal Test to make sure that the device was not damaged during shipping. Refer to this User Guide, section 20.E.i "Self Seal Test" for details.

To run the device normally, follow these instructions:

1. Connect the **Power Cord** to the hand unit & wall plug.
2. Accept Disclaimers.
3. Wait for Device to reach "Standby" temperature.
4. Initiate session by pressing  "Play" icon from Home screen:



Notes:

- a. **Jewelry** must be removed on treatment hand/wrist.
- b. **Default Time/Temp** is 20 Min/High.
- c. **If Temp is too hot**, select a lower temp and work back to **High** over time.



Warnings: Contact a physician before using the AVACEN if you are:

- Under 18 years of age
- Are pregnant
- Have a history of heart disease or blood circulation problems
- Have a temperature higher than 99.5°F (37.5°C)
- Have any other medical concerns

Do not use the AVACEN on a hand that has open sores or wounds. Any level of major discomfort (after changing temperature) is not normal. Stop using the AVACEN right away.

Report the problem to AVACEN Customer Support at:

(888) 4-AVACEN (888-428-2236) or email AVACEN at support@AVACEN.com

IMPORTANT: Please read The AVACEN GXL User Guide prior to use of this device!

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