

User Guide

Model AVACEN Home Device



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

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THE QUICK START GUIDE IS ON BACK COVER

AVACEN Home Device Diagram



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

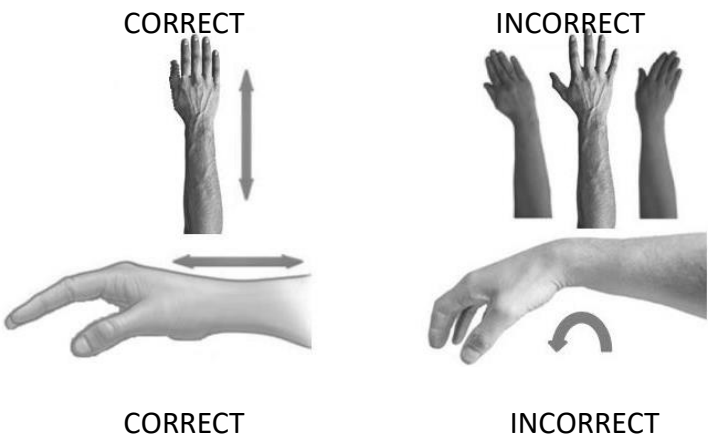


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1. DESCRIPTION

The AVACEN Home Device is a Dry Heat Therapy FDA Class II Medical Device. It consists of a control panel, metal Heatpad, 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 Home 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 Home Device, power cord, power supply, mitts, and this user guide. Lift the top shipping foam piece out of the box. Then lift the AVACEN Home Device out of the box with two hands. Keep the shipping box and foam in case the AVACEN Home Device needs to be returned. Be sure to read the **What to Expect** flyer before the first use.

3. NORMAL USE

The AVACEN 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: 15 minutes first thing in the morning using the LEFT hand (hint: "Left is for day Light") and 15 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 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 is a heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; 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 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 oversensitive 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 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, turn the unit Off. During the power down process the air will be automatically drained from the cuff so that your hand can be removed easily.
- If the unit does not turn off when the On/Off Button is pressed, 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 Home Device 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 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 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 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 Home Device. If the unit does not turn off when the On/Off Button is pressed or 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.
 - 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	700 to 1060hPa
	Storage	500 to 1060hPa
AC Input Voltage		100-240V~, 50-60Hz
Expected service life of equipment and accessories		5 years

8. CONTACT INFORMATION

Manufacturer:	
AVACEN Medical 2365 Camino Vida Roble, Suite C Carlsbad, CA 92011	Phone: (888) 4-AVACEN (888-428-2236) web: AVACEN.com Email: Support@AVACEN.com

9. EXPLANATION OF SYMBOLS

Symbol	Description
	ON/OFF Pushbutton Switch
	OK/Accept/Confirm/Select Pushbutton Switch
	Up / Down / Left / Right Function Select Pushbuttons
	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 (model AVACEN 100 only)
	Do Not Dispose in Trash
	Identification of Manufacturer
	Indicates compliance to European Directives
	Complies with 47 CFR Part 18 for Industrial, Scientific, and Medical Equipment


10. OPERATING INSTRUCTIONS (NORMAL MODE OPERATION)

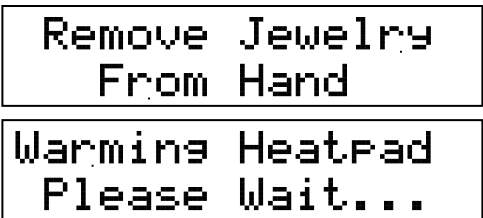
Connect the Power Supply Connector into the power supply jack. The power supply jack is located on the right side panel towards the lower back corner. Plug the AC power cord end from the power supply cord into the correct power source (wall plug): 100-240V~, 50-60Hz.

International use: When traveling 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 by pressing the  button on the left side of the control panel. The Display will show a brief welcome message and then will display: "Remove Jewelry from Hand". This is to prevent damage to the Mitt and cuff membrane. It will be followed by a "Warming Heatpad Please Wait..." message. **While waiting, 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.**



It is very important that the AVACEN Home Device 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 Heatpad) 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: If more than one person will be using the AVACEN, the device can be put into "Standby" mode so that the Heatpad stays warm in-between uses and the device does not shut down. For details on this operating mode, refer to the section of this manual below titled "Standby Mode Operation".

OPTIONAL: While the device is warming up (or at any other time), the rear feet on the bottom of the AVACEN unit can be adjusted to ensure the most comfort while using the device. Turn the feet counterclockwise to extend the feet; turn clockwise to retract the feet. This allows the user's elbow to rest on a table or other support surfaces without extreme bending at the wrist. Sessions will run from 10 to 30 minutes (user selectable), so it is recommended to adjust the feet before use.



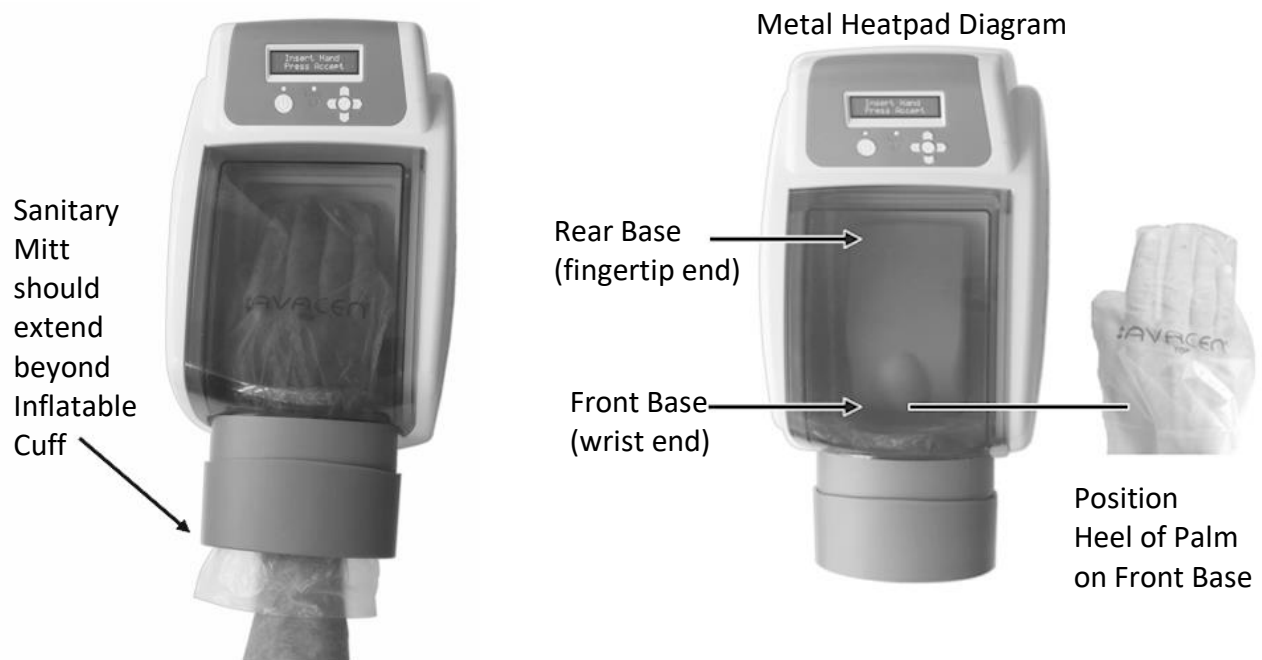
It will take about 3 minutes for the device to warm up (depending on the room temperature). Near the end of the warm-up period, the display will change to "Place Mitt on Hand".

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.**

After a few seconds, the Ready light will turn from Orange to Green ("A" on the Control Panel in the figure to the right).

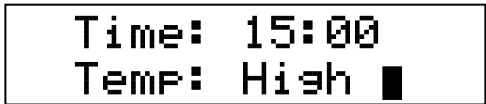
When the Heatpad has warmed up, the Display Panel will change to "Insert Hand, Press ✓" and a "beep" will sound.

SLOWLY insert the hand (with Mitt applied) into the Inflatable Cuff. The raised, egg-shaped portion of the Heatpad 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 Heatpad.



Press the ✓ button to indicate that your hand is inserted into the Mitt and Inflatable Cuff, and is properly positioned on the Metal Heatpad.
IMPORTANT: If you accidentally press the On/Off button ⏻ instead, remove your hand from the unit before turning it on again.

Set the therapy Time (10 – 30 minutes) on the Control Panel using the ▲ and ▼ buttons. Set the Temperature (High, Med, Low) by using the ◀ and ▶ buttons. OR, do nothing to accept the default of 15 minutes and High Temperature. These settings may be changed at any time during use.

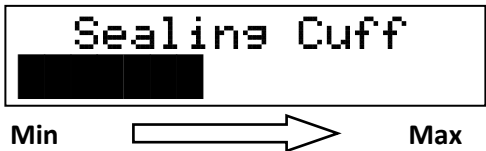


Press ✓ on the Control Panel to indicate Time and Temperature have been set or do nothing to accept default of 15 minutes and High Temperature. The Time and Temperature settings may be changed at any time during use.

Note: For the most benefit the "High" setting is preferred. Select "Med" or "Low" only in the case of major discomfort. The Heatpad 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.

11. CUFF SEALING

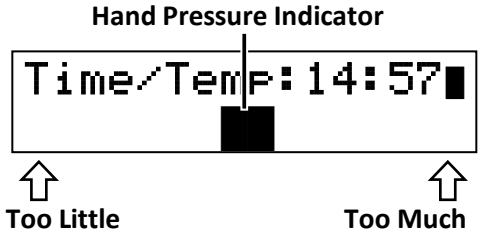
The "Sealing Cuff" message is displayed while the vacuum motor runs. The bar along the bottom shows the vacuum level; when the bar reaches the length of the Display Panel, the full vacuum has been achieved.



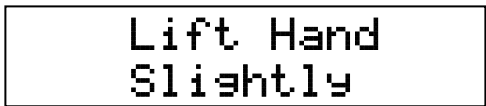
IMPORTANT NOTE: The seal on the bottom of the Vacuum Chamber may have become dislodged during shipping and unpacking. If the seal is not properly in place, the Vacuum Chamber will not seal. Refer to the "Troubleshooting" section of this User Guide for simple ways to correct this issue.

12. HAND PRESSURE INDICATOR (HPI)

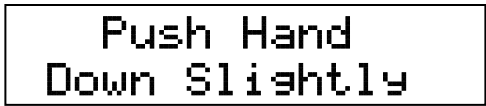
When the unit seals properly, the top line of the display will show the remaining therapy time and the temperature level indicator. The bottom line of the display will show the Hand Pressure Indicator (HPI). The HPI shows if you have the right amount of hand pressure. You are in the optimal zone when the double column indicator is near the middle.



Too much pressure will set off an alarm (beep) and display "Lift Hand Slightly".



Too little pressure will set off an alarm (beep) and display "Push Hand Down Slightly". Keeping the HPI in the middle will ensure ideal function.



13. PAUSING A THERAPY SESSION

PAUSE: If the ✓ button on the control panel is pressed during treatment, the timer and Vacuum motor are paused. Pressing ✓ again will cause the timer and Vacuum Chamber sealing process to resume.



14. ADJUSTING THE THERAPY TIME

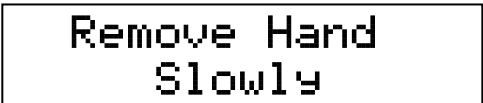
Pressing the ▲ button on the control panel while running will cause the therapy timer to increase in value and holding the ▲ button down will cause the timer to continue increasing until it reaches the initial set value. Pressing the ▼ button on the control panel while running will cause the therapy timer to decrease in value. Holding the ▼ button down will cause the timer to continue dropping until it reaches zero (00:00). Then the AVACEN will shut off.

15. ADJUSTING THE THERAPY TEMPERATURE

Pressing the ◀ or ▶ buttons during therapy will switch the Temperature setting from High to Medium to Low, and back to High again.

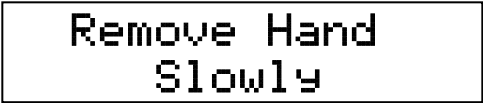
16. END OF THERAPY

When the treatment time runs down to zero, the device will begin to shut down. 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. After a few seconds, the display will change to "Powering Down", and then the device will turn off.

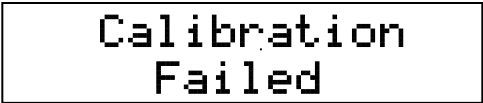


17. POWERING DOWN

If the ⏻ button is pressed the device will shut down by itself. The cuff will begin to deflate and the "Remove Hand Slowly" message is displayed. Remove your hand from the Vacuum Chamber. After a few seconds, the display will change to "Powering Down", and then the device will turn off.



If there is a problem during operation, the device will display an error message. If it cannot recover, the device will shut down. After powering down, the display will continue to show the error message.



18. STANDBY MODE OPERATION

If the AVACEN device is turned ON, turn it off by pressing the **⏻** button on the control panel and wait for the green power light to turn off. If the AVACEN is OFF or has just been turned OFF, hold down the **✓** button on the control panel and then press the **⏻ POWER** button. The Display will show "Entering Standby Mode".

The Display will then show "Remove Jewelry From Hand", "Warming Heatpad Please Wait...", and after about three minutes, the "Place Mitt on Hand" and "Insert Hand Press **✓**" message will be displayed.

Use is the same as described in the "Normal Mode Operation" section of this manual.

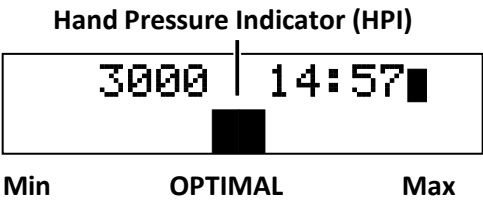
In the Standby Mode, at the end of a treatment, a "Remove Hand Slowly" message will be briefly displayed, and then the "Remaining In Standby Mode" message. In a few seconds, the startup message and the "Insert Hand" message will be displayed. The **⏻** button can be pressed anytime to turn off Standby Mode and power down the AVACEN.

The AVACEN is now ready for the next user. The rest of the device functions are the same as described in the "Normal Mode Operation" section of this manual.

19. GAME MODE OPERATION

To enter Game Mode, you must press the **▲** button when the "Insert Hand / Press **✓**" message is being displayed (after the unit is warmed up). Pressing the **▲** button while warming up has no effect. This Game Mode setting will persist even if the power is turned off or the unit is powered down (and also in Standby). Game Mode is reset to OFF when the AVACEN is unplugged. Pressing the DOWN button when the "Insert Hand / Press **✓**" message is being displayed turns Game Mode OFF.

Game Mode is used to encourage the user to maintain the proper amount of pressure on the Heatpad. The Hand Pressure Indicator (HPI) position on the bottom row of the Display Panel is used as the input for the game. The goal is to score the most points by keeping the HPI as close to the center of the screen as possible.



Entering Standby Mode

Remove Jewelry From Hand

Warming Heatpad Please Wait...

Place Mitt On Hand

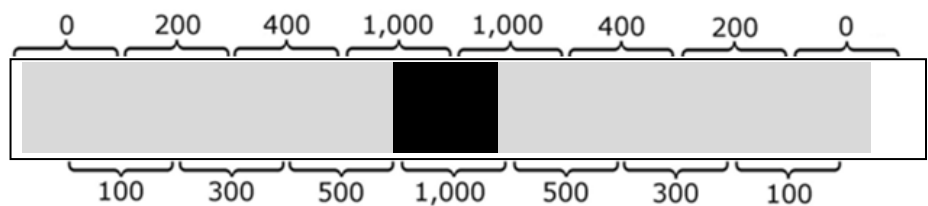
Insert Hand Press ✓

Remove Hand Slowly

Remaining In Standby Mode

Insert Hand Press ✓

An enlarged view of the bottom row of the Display Panel below shows the number of points that are awarded per second. The number of points earned is based on the position of the HPI. More points are scored by keeping the HPI in the center of the screen. If the "Lift Hand Slightly" message or the "Push Hand Down Slightly" message are displayed, the user will hear an audio beep, and 10,000 points are **subtracted** from the total score every second.



The highest number of points awarded is 60,000 points per minute. Therefore the user could accumulate as many as 1,200,000 points in a 20-minute therapy session (more or less points depending on the length of the session). A score of half the highest possible score (i.e. 600,000 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. The unit must be used for a minimum of 10 minutes in order to qualify for a high score.

At the end of the session the final score is shown, along with the current high score. If a new high score was earned, this will be shown. Pressing the ✓ button changes the display to show a random message. This message falls into one of three basic groups, that vary based on the average points per second that was scored by the user. If the average points per second is high, a "Great Job" message will be displayed. If the average points per second was in the middle (acceptable but not "high"), a "Good Job" message will be displayed. If the average number of points per second is low, a "Try Harder" message is displayed. These messages can be viewed at the end of the session (along with the final score) to see how well the user did at keeping their hand in the correct place on the hand pad during the therapy session.

"Great Job" messages:

- | | |
|---------------------------------|--------------------------------|
| "Major league performance! Wow" | "Super! That's how it's done!" |
| "You got some serious skills!" | "You did great!" |
| "Awesome Job!" | |

"Good Job" messages:

- | | |
|------------------------------------|-------------------------------------|
| "Nice! beat this score next time!" | "Well done, keep up the good work!" |
| "Next time get the high score!" | "Steady hand - good job!" |
| "You did pretty good!" | |

"Try Harder" messages:

- | | |
|-----------------------------------|-------------------------------|
| "I remember MY first time..." | "Did you actually try?" |
| "Come on! Try harder!" | "My grandma could do better!" |
| "Yay! You got the new low score!" | |

Pressing the ✓ button again causes the unit to turn off or go back into standby mode.

20. TROUBLESHOOTING AND FAQ

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 30 minutes. For many conditions 15 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: 15 minutes first thing in the morning using the LEFT hand (reminder hint: "Left is for day Light") and 15 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 Heatpad. The raised, egg-shaped portion of the Heatpad 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 Heatpad 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.

F. The AVACEN unit powers down while the 'Sealing Cuff' message or 'Lost Vacuum Seal' message is displayed

If the AVACEN is not able to reach the proper vacuum level after 60 seconds, the "Unit Did Not Seal Properly" message is displayed and the unit will automatically power down. If vacuum is lost during a therapy session the "Unit Has Lost Vacuum Seal" message is displayed and the unit will automatically power down. This can occur if:

Unit Did Not
Seal Properly

Unit Has Lost
Vacuum Seal

Powering
Down

- (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 Heatpad (closest to opening).
- (v) The Vacuum Chamber is not properly positioned.
 - See section 23: " PERIODIC MAINTENANCE" for taking the Vacuum Chamber 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 Heatpad" message

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

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 unit on. If your hand is inside the vacuum chamber (resting on the Heatpad) when the unit is turned on, the onboard computer will not measure your hand pressure correctly. If you turn the unit off (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 turn the device on. If your hand is inside the vacuum chamber (resting on the Heatpad) 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.

Calibration
Failed

Powering
Down

To make sure that the device computes the proper weight of your hand against the Metal Heatpad, it is important during the initial sealing and calibration process to apply slight pressure with your palm against the Heatpad. Without this base pressure, the onboard computer will not be able to properly manage the pressure of the palm against the Heatpad. At that point the "Calibration Failed" message will appear and the device will shut down.

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 Heatpad. This will be displayed on the Hand Pressure Indicator (HPI). After a number of uses, it will become much easier to judge the proper pressure of your palm against the Heatpad. 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 Heatpad. If for some reason it cannot measure the Heatpad temperature, a warning message will be displayed. This can happen for a few reasons:

System Error
Unplug Unit

(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 powers down while the 'Sealing Cuff' message or 'Lost Vacuum Seal' message is displayed" for solutions.

L. I keep getting a "Push Hand Down Slightly" or "Lift Hand Slightly" 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 Heatpad) 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 Heatpad it is important that during the initial sealing and calibration process that you apply slight pressure with your palm against the Heatpad. Without this base pressure, the onboard computer will not be able to properly manage the pressure of the palm against the Heatpad and "Push Hand Down Slightly" or "Lift Hand Slightly" 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 Heatpad (end nearest the wrist opening). This condition is not wanted and will cause the "Lift Hand Slightly" 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 Heatpad. Correct hand pressure on the Heatpad 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 Heatpad, it will be displayed on the Hand Pressure Indicator (HPI). After a number of uses, it will become much easier to judge the proper pressure of your palm against the Heatpad. 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 Heatpad is too hot (or too cool)

For the most benefit "High" is recommended. Select "Med" or "Low" only in the case of major discomfort. The Heatpad 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 Heatpad 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 Panel Power LED does not illuminate after pushing the ON Button

Make sure that the power cord is plugged into the unit 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

This test can be found in USER SETTINGS. Refer to section 21: "USER 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 adjust rear device feet to increase comfort.

21. USER 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 User Settings can be made on the AVACEN:

- Language Selection
- Beep Tone Style
- Default Therapy Time
- Default Therapy Temperature



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

- Display Error Messages
- Measure Hand Pad Force
- Run Self-Sealing Test

All of these features are accessed in the User Settings menu. To access User Settings, begin by turning the AVACEN device Off. Press and hold down the ▼ button while turning the device On with the ⏻ button. The display will show "User Settings".

Moving through the different User Settings is done using the front panel buttons:

- ◀ or ▶ Press to scroll back or forward through menu selections.
- ▲ or ▼ Press to scroll up or down through menus and options.
- ✓ To store the selected setting.
- ◀ Go back to the previous (higher level) menu.

After you are done making changes to any of the settings, press ◀ one or more times until the display shows "User Settings". Then press the ⏻ button to return to normal operation.

While in the "User Settings" menu, press ▶, then press ▲ or ▼ one or more times to go to the following menus:

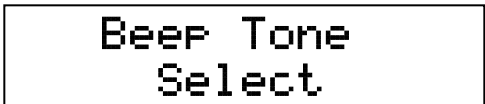
A. Language Selection

Messages can be displayed in multiple languages on some device versions. Press ▶ to enter this menu, then press ▲ or ▼ to choose the desired language. Press ✓ to select the desired language. If this menu is not available, then your device only supports English.



B. Beep Tone Style

There are two options, "Original" and "Low Tones". Press ▶ to enter this menu, then press ▲ or ▼ to choose a style of Beep Tone. A sample of the tones will sound. Press ✓ to select the desired Beep Tones.



C. Default Therapy Session Time

The default setting for therapy time is 15 minutes. At any time before the start of a therapy session, the therapy time may be changed from 15 minutes to 10, 20, 25, or 30 minutes. If you find that you are usually selecting a time other than 15 minutes for therapy, the default therapy



time can be changed. From the "Default Session Time/Temp" menu, press ► to get to the "Set Default Session Time" menu. Press ► again then 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.

D. Default Therapy Session Temperature

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 "Default Therapy Time/Temp." menu, press ►, then press ▲ or ▼ to get to the "Set Default Therapy Temp." menu. Press ► again then press ▲ or ▼ one or more times 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.

Default Session
Time/Temp.

Set Default
Temperature

E. Display Error Messages

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 "Display Last Error Message" menu, press ► to show the last error that was recorded.

Display Last
Error Message

F. Measure Hand Pad Force

If you are talking to AVACEN Customer Support, they may ask you to go to this menu. In this menu you can see the amount of force that is being put on the hand pad by your hand. From the "Hand Force Measurement" menu, press ► to display a number that shows the amount of force that is being applied to the hand pad. The number will increase or decrease as more or less weight is applied to the hand pad.

Hand Force
Measurement

G. Run 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 User Settings, begin by turning the AVACEN unit Off.
- Press and hold down the ▼ button while turning the device On with the ⏻ button. The display will show "User Settings".
- Press ► once, then the ▲ or ▼ button multiple times until the display shows "Sealing Test".
- Press ► and then ✓ to start the test.

Sealing Test

Start Test?
Press ✓

During the sealing test, the Vacuum Level will be displayed on the screen. All of the bars (or nearly all) should be lit up on the bottom row of the display. The cuff should be inflated like a balloon.



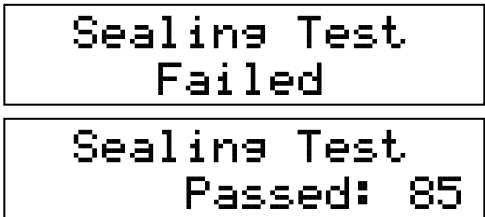
If the cuff does not fully inflate, it may have holes. In this case only a few of the bars will be displayed on the screen, indicating that the device is not making a vacuum. The cuff may not be fully inflated.



With the back of your hand, feel the inflatable cuff to see if there is any air leaking out of the cuff. This would indicate that 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 Vacuum Chamber must be replaced. If you find that the cuff has holes, replacements can be purchased by contacting AVACEN: support@avacen.com.



At the end of the test, if device was not able to maintain the vacuum inside the Vacuum Chamber, the display will show "Sealing Test Failed". If the device was able to maintain a vacuum, the display will show "Sealing Test" or "Sealing Test Passed", along with a number score. The number score is from 1 to 100. A higher number means that the seal was better than a lower number.



When you first receive and unpack the device, run the sealing test as described above. This will make sure that the device is operating well and there was no shipping damage. Write down the final score here: _____. You may want to go back from time to time and repeat the test to check that the device is still in top condition. You should not expect to get the same score every time you run the test. A cold device (or cold room) will make the cuff less flexible, resulting in a lower score. This does not mean that there is a problem with the device. If the score at the end of the test gets lower over time, this is an indication that there may be some small leaks, but the device will still operate normally. At some point, service or replacement of the Vacuum Chamber may be needed.

You can also perform the Sealing Test with your hand inside the Vacuum Chamber (be sure to use a mitt). The score at the end of the test with your hand in the Vacuum Chamber should be about the same as the score without your hand in the Chamber. If your score with your hand in the Chamber is lower, try to position your hand and wrist so that the inflatable cuff seal works better. Refer to the inside front cover of this User Guide for more details.

22. 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, remove the Vacuum Chamber (see section 23 " PERIODIC MAINTENANCE") and use a disinfectant hand wipe on the inside and outside surfaces.

The seal on the bottom side of the Vacuum Chamber is made from a high grade of silicone rubber. It is designed to provide over ten years of service when used daily. If the seal gets dirty, it can be removed and cleaned in mild soapy water. Allow the seal to dry before putting it back on the Vacuum Chamber. Do not use any oil, grease, or lube on the seal or the sealing surface - doing so will degrade performance. The seal works best when it is clean and slightly "tacky" so that it seals well to the AVACEN base enclosure. To remove and install the seal, see section 23 "PERIODIC MAINTENANCE".

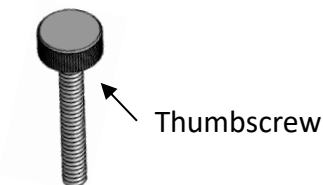
23. PERIODIC MAINTENANCE

If the Inflatable Cuff is too worn out or gets torn, it must be replaced. A "Refresh Kit" (a Vacuum Chamber and Inflatable Cuff assembly) is available. The Refresh Kit can be purchased by contacting AVACEN at: support@avacen.com.

To check the Inflatable Cuff for leaks, see Item P in section 20 "TROUBLESHOOTING AND FAQ".

Removing the Vacuum Chamber

If you need to clean inside the Vacuum Chamber, the Vacuum Chamber must be removed. The Vacuum chamber is held in place by two thumbscrews, one on each side of the Vacuum Chamber (shown by the arrows). Turn the screws by hand to remove.



To remove the Vacuum Chamber, lift the Inflatable Cuff end of the Vacuum Chamber. Then remove the air pressure line from the fitting at the front underside of the Vacuum Chamber.



Lift the Vacuum Chamber up and out. The Seal on the bottom of the Vacuum Chamber will come out with the Vacuum Chamber.



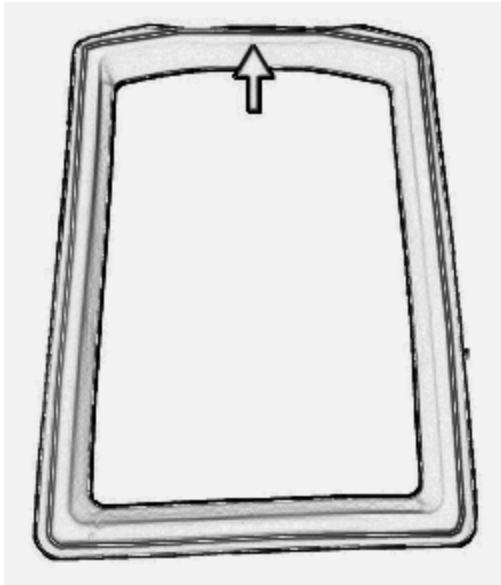
Removing the Seal

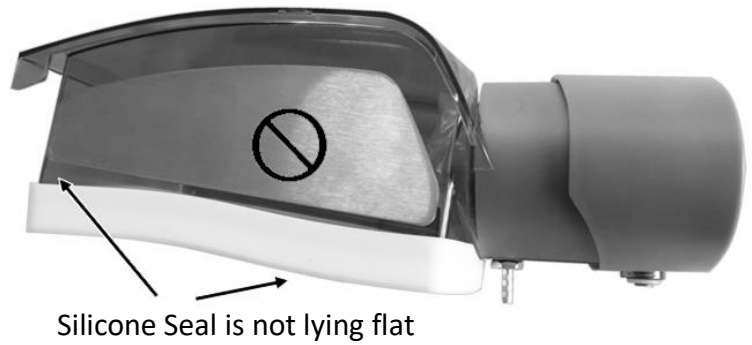
Seal Removal: Lift the Vacuum Chamber vertically away from the AVACEN unit. Remove the seal from the Vacuum Chamber by gently peeling the seal away from the Vacuum Chamber.



Installing the Seal

How to Install the Seal: The seal has a groove on one side all the way around. The bottom of the Vacuum Chamber fits into this groove. Note that the side of the seal with the groove in it has a lower area on one end. This is marked by the arrow in the photo. This is the end that fits onto the cuff end of the Vacuum Chamber (the lower area fits under the cuff). Turn the seal so that the lower part is under the cuff, and fit the groove in the seal onto the bottom of the Vacuum Chamber.





The silicone seal must also be properly positioned. Check that the silicone seal is firmly positioned against the bottom of the Vacuum Chamber.



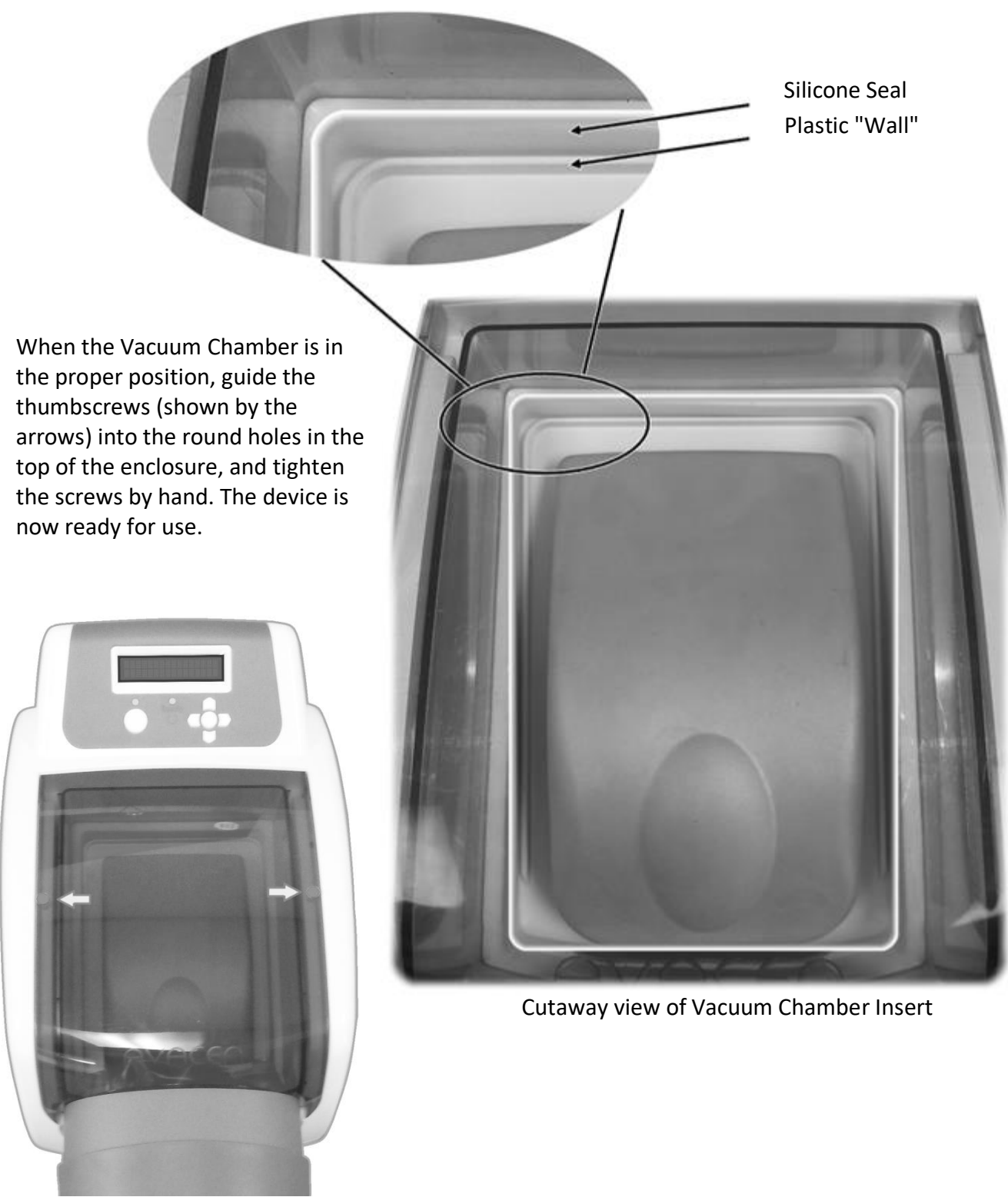
Vacuum Chamber with the Silicone Seal in the correct position

Installing the Vacuum Chamber

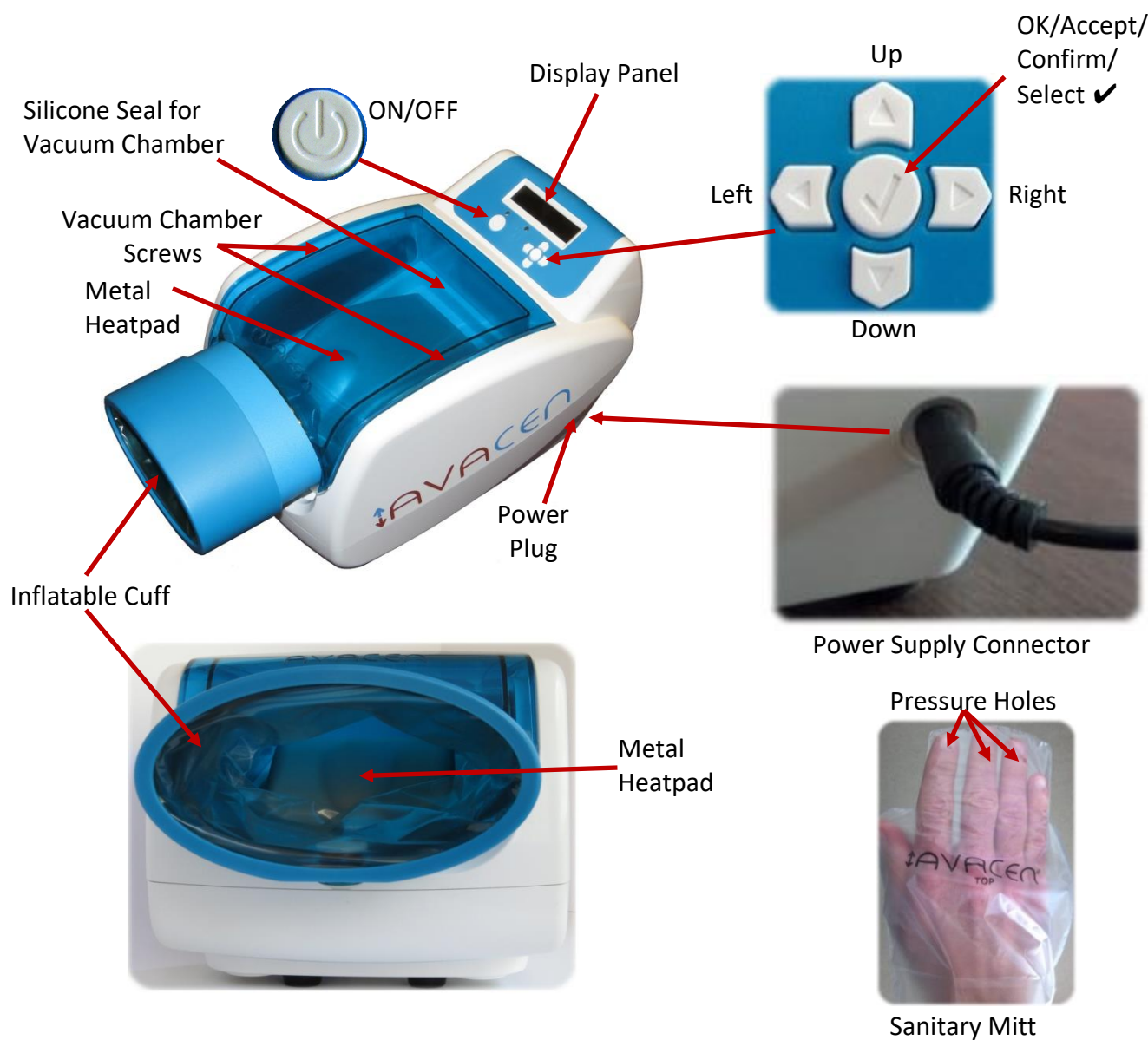
Make sure that the pressure line is re-connected to the inflatable cuff. Also ensure the pressure line is slid back into the opening inside the base of the AVACEN so that it is not kinked or obstructed. It is not needed to force the Vacuum Chamber back into position; it should go together easily.



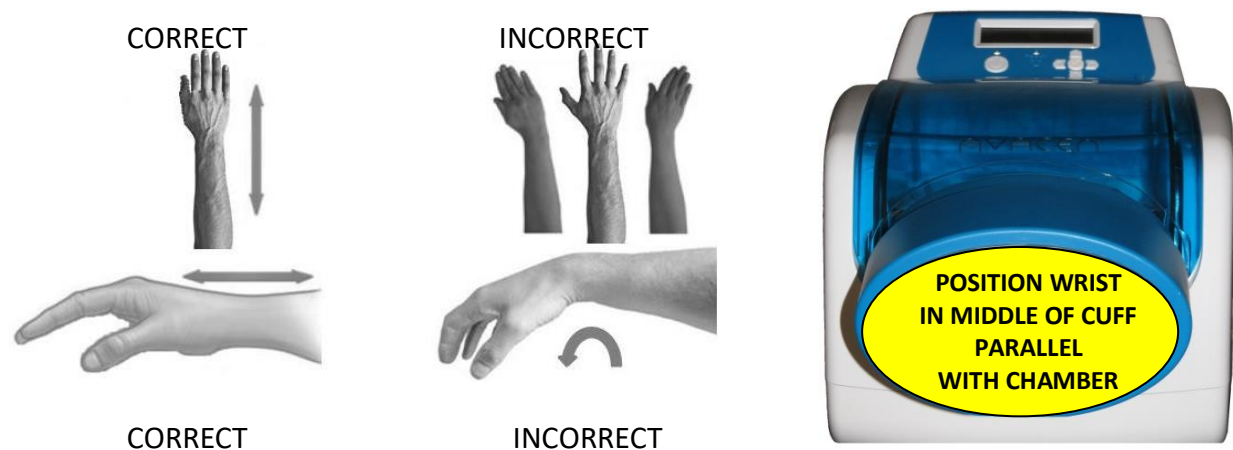
Look through the blue top cover to where the silicone seal of the Vacuum Chamber contacts the white plastic enclosure. There is a short plastic "wall" that is located in front of the silicone seal. If the silicone seal is resting on top of the "wall" then the Vacuum chamber will not seal properly.



AVACEN Device Diagram



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





AVACEN Device Quick Start Guide

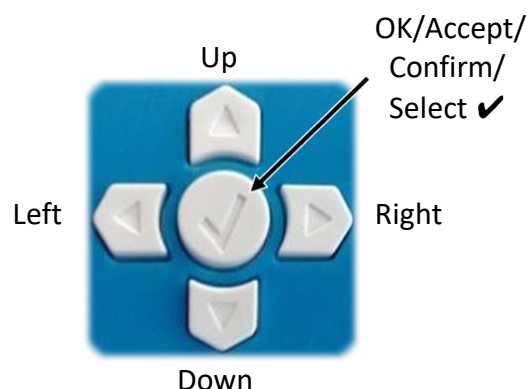
IMPORTANT: Please read The AVACEN User Guide prior to use of this device!

When you first unpack the device, run a Sealing Test to make sure that the device was not damaged during shipping. Refer to this User Guide, section 21.G "Run Self-Sealing Test" for details.

To run the device normally, follow these instructions:

1. Connect the **Power Cord** to the hand unit & wall plug.

2. Press the **On/Off Button**  on the left side of the **Control Panel** to turn **Power Light** on.



3. Follow the commands on **Display Panel**. Control buttons are as shown in the figure to the right.

Notes:

- a. **Jewelry must be removed on treatment hand/wrist.**
- b. **If Time/Temp is not modified: "15 Min/High"** will be automatically selected after 5 Seconds.
- 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.

If the unit does not turn off when the On/Off Button is pressed, please unplug the unit.

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