This user’s guide and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed.

**Caution:** U.S. Federal Law restricts this device to sale to or on the order of a physician.

**Equipment covered in this User’s Guide:**

- VASER Amplifier
- VASER Pro Amplifier*
- VASER Ultrasound Footswitch
- Main Power Cord
- VASER Accessory Power Cord
- VASER Back Panel**
- VASER Power Cord Adapter**

* The VASER Pro Amplifier is provided instead of the VASER Amplifier if the System includes VASERsmooth™ Technology.

** Required if VentX Console is purchased/included.

Patent & Trademark Acknowledgements:

U.S. Patent Nos. 6,027,515; 6,129,701; 6,368,299; 6,379,326; 6,391,042; 6,540,713; 6,716,194; 6,726,698; D539,417; D548,329

Other U.S. and foreign patents pending.

The following are registered trademarks of Solta Medical, Inc.: LipoHarvester, Sound Surgical, LipoSelection, Science to Surgery, VASER, VASERlipo, VASER Hi Def, VentX, PowerX, TouchView, The Tool Behind the Talent, and VASER it.

Manufactured by:
Solta Medical, Inc.
11818 Northcreek Pkwy North,
Bothell, WA 98011 USA

For Customer Support call: 877-782-2286 (outside the U.S./Canada 1-510-786-6946)
For Technical Support call: 877-782-2286 (outside the U.S./Canada 1-510-786-6946)

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Made in USA
Printed in USA

Your local representative or authorized distributor:
European Authorized Representative

Medical Device Safety Service
Schiffgraben 41
30175 Hanover, Germany
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The VASERlipo™ System

Preface and Introduction

Solta Medical thanks you for your recent purchase of the VASER® or VASER Pro Amplifier. The VASER and VASER Pro Amplifiers create ultrasonic frequency vibration in a VASER Probe that is used to cause a surgical effect. The ultrasonic frequency vibration is created using the piezoelectric property of PZT ceramic crystals located in the VASER Handpiece. The PZT ceramic crystals expand and contract in cooperation with electrical power supplied to the VASER Handpiece by the Amplifier. The VASER and VASER Pro Amplifiers are electronic control systems that maintain vibration amplitude, maintain proper vibration frequency, and provide two modes of vibration, continuous and VASER (pulsed).

The VASERlipo™ System includes the VASER Amplifier (or VASER Pro Amplifier), and the VentX® Infiltration and Aspiration Console.

1.0 Patient and Operating Room Safety

Warnings, Cautions, Notices, and Symbols

**Warning:** Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.

**Caution:** Indicates a potentially hazardous situation that, if not avoided, could result in minor or moderate injury.

**Notice:** Indicates a potential hazard that may result in product damage.

<table>
<thead>
<tr>
<th>Table 1. VASER System Symbol Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symbol</td>
</tr>
<tr>
<td><img src="image" alt="Mains Power On" /></td>
</tr>
<tr>
<td><img src="image" alt="Mains Power Off" /></td>
</tr>
<tr>
<td><img src="image" alt="Protective Earth Ground Stud" /></td>
</tr>
<tr>
<td><img src="image" alt="General Warning" /></td>
</tr>
</tbody>
</table>
## Table 1. VASER System Symbol Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Symbol" /></td>
<td>Non-ionizing electromagnetic radiation: To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment</td>
</tr>
<tr>
<td><img src="image2" alt="Symbol" /></td>
<td>Equipotential Ground Stud: when connected together, bring the various parts of an equipment or system to the same potential Reference IEC 60601-1 for requirements for Medical Electrical systems</td>
</tr>
<tr>
<td><img src="image3" alt="Symbol" /></td>
<td>Fuse: followed by the size, rating and type</td>
</tr>
<tr>
<td><img src="image4" alt="Symbol" /></td>
<td>Serial Number: followed by the product serial number</td>
</tr>
<tr>
<td><img src="image5" alt="Symbol" /></td>
<td>Manufacturer: followed by Manufacturer name and address</td>
</tr>
<tr>
<td><img src="image6" alt="Symbol" /></td>
<td>Catalog Number: followed by the Solta Medical Part Number</td>
</tr>
<tr>
<td><img src="image7" alt="Symbol" /></td>
<td>Type BF Applied Part per EN 60601-1 The Probe is the VASER/VASER Pro Applied Part</td>
</tr>
<tr>
<td><img src="image8" alt="Symbol" /></td>
<td>AC waveform: the equipment is suitable for alternating current only, accompanied by the Voltage, Frequency and Power required for operating this equipment</td>
</tr>
<tr>
<td><img src="image9" alt="Symbol" /></td>
<td>Wheeled-bin: do not dispose of with regular trash This item must be disposed of properly. Contact your local representative or authorized distributor for disposal instructions.</td>
</tr>
</tbody>
</table>
Table 1. VASER System Symbol Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rx Only</strong></td>
<td>Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed health care practitioner</td>
</tr>
<tr>
<td></td>
<td>Consult Instructions for Use/ User’s Guide</td>
</tr>
<tr>
<td></td>
<td>Power Plug (VentX Only)</td>
</tr>
<tr>
<td></td>
<td>Foot pedal interconnect for Ultrasound Footswitch</td>
</tr>
<tr>
<td></td>
<td>Temperature Limitation: accompanied by the lower (left) and the upper (right) limits</td>
</tr>
<tr>
<td></td>
<td>Humidity Limitation: accompanied by the lower (left) and the upper (right) limits</td>
</tr>
<tr>
<td></td>
<td>Recycling Symbol: accompanied by the number or description of the recyclable material To indicate that the marked item or its material is part of a recovery or recycling process</td>
</tr>
<tr>
<td></td>
<td>Ultrasound Probe Electrosurgery Handpiece</td>
</tr>
</tbody>
</table>
### Table 1. VASER System Symbol Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Ultrasound Footswitch Connection" /></td>
<td>Ultrasound Footswitch Connection</td>
</tr>
<tr>
<td><img src="image" alt="Emitted Ultrasound Energy" /></td>
<td>Emitted Ultrasound Energy</td>
</tr>
<tr>
<td><img src="image" alt="Elapsed Time Display" /></td>
<td>Elapsed Time Display</td>
</tr>
<tr>
<td><img src="image" alt="Test Mode Switch" /></td>
<td>Test Mode Switch: indicator for starting a test run</td>
</tr>
<tr>
<td><img src="image" alt="Alarm Signal" /></td>
<td>Alarm Signal: visual indicator of an alarm condition</td>
</tr>
<tr>
<td><img src="image" alt="VASERsmooth™ Technology Label" /></td>
<td>VASERsmooth™ Technology Label: Indicates VASER Pro Amplifier includes VASERsmooth Technology</td>
</tr>
<tr>
<td><img src="image" alt="European conformity mark" /></td>
<td>European conformity mark for Class IIb medical device to 93/42/EEC as amended</td>
</tr>
<tr>
<td><img src="image" alt="Authorized representative in the European community" /></td>
<td>Authorized representative in the European community</td>
</tr>
</tbody>
</table>
Solta Medical has determined that the VASERlipo System has been shown to comply with the applicable technical standards if no unauthorized change is made in the equipment and if the equipment is properly maintained and operated. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Contraindications

Use of this device is contraindicated for patients with chronic medical conditions, such as obesity, diabetes, blood clotting disorders, heart, lung, or circulatory system disease, or vascular problems, including common circulation problems and coagulation problems associated with certain medications.

The following conditions may affect the safety or effectiveness of this device: presence of collagen, scarring, or connective tissue disorders; presence of stretch marks or potential for stretch mark formation; Lupus Erythematosus; endocrine disorders; pregnancy or the possibility of pregnancy; or other active diseases that may affect the procedure outcome or increase risk.

Operator Warnings

Warning: No modification of the equipment is allowed.

Warning: This device will not, in and of itself, produce significant weight reduction.

Warning: The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

Warning: The VASERlipo System is intended for use by healthcare professionals only.

Warning: The VASERlipo System may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the VASERlipo System or shielding the location.

Warning: Use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Solta Medical, as replacement parts, may result in increased RF Emissions and/or decreased Immunity to RF energy of the VASERlipo System.

Warning: The VASERlipo System should not be used adjacent to or stacked with other (non-Solta Medical) equipment. If adjacent or stacked use is necessary, the VASERlipo System should be observed to verify normal operation in the configuration in which it will be used.

Warning: Do not block or cover the ventilation openings on the VASERlipo System. Overheating could occur, causing decreased functionality of the system.

Warning: To avoid risk of electric shock, this equipment must be connected to a supply mains with protective earth.
Operator Cautions

**Caution:** The safe and effective use of this medical device depends to a large degree on factors solely under the control of the operator. It is important that all operators of this surgical system read, understand, and follow the operating instructions supplied with this equipment.

**Caution:** U.S. Federal Law restricts this device to sale to or on the order of a physician.

**Caution:** This device complies with the electromagnetic compatibility standard IEC EN60601-1-2. It is possible that this device may interfere with or be disturbed by other electrical devices.

**Caution:** This device is designed to contour the body by removing localized deposits of excess fat through small incisions.

**Caution:** If harvested fat is to be reimplanted, the harvested fat is only to be used without any additional manipulation.

**Caution:** Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.

**Caution:** Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.

**Caution:** The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.

**Caution:** All reusable components of the device must be sterilized and all disposable components replaced before using the device on another patient.

**Note:** The VASERlipo System has been tested and found to comply with the limits for a Class A digital device, pursuant to CISPR 11. These limits are designed to provide reasonable protection against harmful interference. However, portable and mobile RF communications equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the manufacturer's instructions, may cause harmful interference to the VASERlipo System, there is no guarantee that interference will not occur in a particular installation. If this equipment receives harmful interference from RF communications, which can be determined by turning the RF communications equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the VASERlipo System.
- Increase the separation between the VASERlipo System and the RF communications equipment.
- Connect the VASERlipo System into an outlet on a circuit different from that to which the RF communications equipment is connected.
- Consult Solta Medical Technical Support for help.
Indications for Use

The VASER Amplifier is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring (modification of the anatomy).

The VASERlipo System is intended for the fragmentation, emulsification and aspiration of subcutaneous fatty tissue for aesthetic body contouring (modification of the anatomy). The VASERlipo System is also indicated for use in the following surgical specialties for the fragmentation, emulsification and aspiration of soft tissues:

- √ Neurosurgery
- √ Gastrointestinal and Affiliated Organ Surgery
- √ Urologic Surgery
- √ Plastic and Reconstructive Surgery
- √ General Surgery
- √ Orthopedic Surgery
- √ Gynecologic Surgery
- √ Thoracic Surgery
- √ Laparoscopic Surgery

Alarm Conditions

The VASER and VASER Pro Amplifiers are equipped with audible and visual indicators (alarms) for a fault condition. The audible alarm is an Urgent Alarm (high priority) tone. Two conditions exist whereby an audible alarm will occur:

1. When the VASERsmooth™ Handpiece is connected to the VASER Pro Amplifier. The System will sound with 4 audible tones to indicate that the System detects the Handpiece (VASER Pro Amplifier only). Please reference the VASERsmooth Procedure Suggestions (240 0432) for additional information on using the VASERsmooth Handpiece and Probes with the VASER Pro Amplifier.

2. For a fault condition in which the visual indicator (a red ‘']): will also be displayed. The fault indicators will be triggered if:

   a) The Footswitch has been depressed and ultrasonic vibration has not been initiated within about one second. See Troubleshooting Section.

   b) Ultrasonic vibration has been initiated and a stall condition is encountered lasting longer than about one second. See Troubleshooting Section.

   c) Excessive VASER Probe loading is encountered. The VASER Amplifier senses the loading present on the vibrating probe. If the VASER Probe loading is excessive, as might occur with overly fibrous tissue for a selected VASER Probe or from ‘torquing’ of the VASER Handpiece, an alarm will sound. If there is a failure of the equipment, such as a faulty or disconnected Handpiece, an alarm will sound. See Troubleshooting Section for more details.
2.0 Equipment Description

Equipment List

The VASER and VASER Pro Amplifiers are composed of the following main components to include multiple controls, indicators and receptacles.

Figure 1. Front View

1. Amplitude Control
2. Amplitude Display
3. VASER (V) Mode Indicator
4. Mode Selection Button*
5. Continuous (C) Mode Indicator
6. Timer Reset Button
7. Ultrasound Vibration Time Indicator
8. Ultrasound Vibration Active Indicator - 
9. Alarm Signal Indicator - *

* Press and hold to put Amplifier in Standby Mode
The VASERlipo™ System

Figure 2. Rear View

1. VASER Footswitch Receptacle
2. AC Power I/O Switch
3. Power Entry Module

Figure 3. Right Side View

1. VASER Handpiece Receptacle
2. VASER Test Switch
Using the VASER or VASER Pro Amplifier with the VentX Console

The VASER or VASER Pro Amplifier may be combined with the VentX Console. See the VentX Console and Accessories User’s Guide for connection instructions.

3.0 Using the VASER Amplifier

This section describes the day of surgery set-up and use of the VASER Amplifier.

Before Surgery

1. Connect VASER Amplifier to a source of AC power.
2. Ensure the VASER Footswitch cord is connected to the Amplifier.
3. Turn on the VASER Amplifier. (the ‘C’ and ‘V’ Mode Indicators should be flashing/in Standby Mode)
4. Test VASER Amplifier with the VASER Test Switch. (See Troubleshooting Section for details.)
5. In the sterile field pass the connector of the VASER Handpiece out of the sterile field and connect the VASER Handpiece to the VASER Handpiece Receptacle on the VASER Amplifier.

During Surgery

Caution: Do not lay the VASER Handpiece on the patient when not in use.
Notice: Do not activate ultrasonic vibration with the VASER Probe in free air. Probe damage is likely to occur.

1. Select mode of operation using the Mode Selection Button (C or V).
2. Adjust the vibration amplitude using the Amplitude Control on the VASER Amplifier.
3. Activate ultrasonic vibration by depressing the VASER Footswitch.
4. Reset VASER Timer using Timer Reset Button as needed.
5. In the sterile field, attach and detach different VASER Probes as needed.

After Surgery

1. Turn off the power on the VASER Amplifier.
2. Disconnect the VASER Handpiece from the VASER Amplifier and set aside for cleaning.
3. Wipe down the VASER Amplifier and Footswitches.
4.0 Using the VASER® Pro Amplifier

This section describes the day of surgery set-up and use of the VASER Pro Amplifier.

Before Surgery

1. Connect VASER Pro Amplifier to a source of AC power.
2. Ensure the VASER Footswitch cord is connected to the Amplifier.
3. Turn on the VASER Pro Amplifier. (the ‘C’ and ‘V’ Mode Indicators should be flashing/in Standby Mode)
4. Test VASER Pro Amplifier with the VASER Test Switch. (See Troubleshooting Section for details.)
5. In the sterile field pass the connector of the VASER Handpiece or VASERsmooth Handpiece out of the sterile field and connect the Handpiece to the VASER Handpiece Receptacle on the VASER Pro Amplifier. When you connect the VASERsmooth Handpiece to the VASER Pro Amplifier, the System will sound with 4 audible tones to indicate that the System detects the VASERsmooth Handpiece. The System will not sound any audible tones when you connect the VASER Handpiece.

During Surgery

Caution: Do not lay the VASER Handpiece or VASERsmooth Handpiece on the patient when not in use.
Notice: Do not activate ultrasonic vibration with the VASER Probe or VASERsmooth Probe in free air. Probe damage is likely to occur.

1. Select mode of operation using the Mode Selection Button (C or V).
2. Adjust the vibration amplitude using the Amplitude Control on the VASER Pro Amplifier.
3. Activate ultrasonic vibration by depressing the VASER Footswitch.
4. Reset VASER Timer using Timer Reset Button as needed.
5. In the sterile field, attach and detach different VASER Probes or VASERsmooth Probes as needed. Please reference the VASERsmooth Procedure Suggestions provided as part of your User Guide CD for additional information on using the VASERsmooth Handpiece and Probes with the VASER Pro Amplifier.

After Surgery

1. Turn off the power on the VASER Pro Amplifier.
2. Disconnect the VASER Handpiece or VASERsmooth Handpiece from the VASER Pro Amplifier and set aside for cleaning.
3. Wipe down the VASER Pro Amplifier and Footswitches.
5.0 Cleaning

This section describes cleaning procedures that must be used to assure a clean system.

Follow the cleaning procedures and guidelines recommended by your institution. The following are guidelines that may be used in conjunction with your institution’s procedures and guidelines or if no such procedures and guidelines are in place.

Shut down all power switches, and disconnect from the main power source to prevent electrical shock. Wipe down the VASER Amplifier and Footswitch using a damp cloth after each use.

Notice: Do not use chlorinated cleaning agents (bleach).
Notice: Do not use abrasive cleaning agents.
Notice: Do not apply or spray liquid or liquid cleaning agents onto any receptacles or into any cooling vents.
6.0 Troubleshooting

This section describes conditions or malfunctions that may occur before or during the normal course of surgery. Malfunctions usually can be corrected by referring to Table 2, below. If the malfunction cannot be resolved using Table 2, discontinue use of the VASER Amplifier and Accessories until the malfunction has been resolved.

For Technical Support call: 877-782-2286 (outside the U.S./Canada 1-510-786-6946)

VASER Test Switch

The VASER Test Switch is located on the right panel (between the Handpiece receptacle and the speaker switch). The purpose of the VASER Test Switch is to test the VASER or VASER Pro Amplifier without connection to the VASER Handpiece. If the system does not function, this switch will allow the user to determine if the fault is in the VASER Amplifier or in the Handpiece. The VASER or VASER Pro Amplifier should be tested before each use. To use the VASER Test Switch:

1. Connect the VASER or VASER Pro Amplifier to a source of AC power.
2. Turn on the VASER or VASER Pro Amplifier.
3. Disconnect the VASER Handpiece from the VASER or VASER Pro Amplifier.
4. Set the Amplitude Control to 10%.
5. Set the Mode Selection Button to continuous (C).
6. Depress and hold the Test Switch for at least three (3) seconds.
7. The yellow vibration and alarm signal indicators on the front panel should illuminate and the alarm tone should sound. Proceed to the second part of the test (Step 8, below). If the indicators do not illuminate or the alarm does not sound, call Technical Support.
8. Change the Amplitude Control to 30% and repeat step 6. No indicators or alarm sound should occur. If indicators illuminate or the alarm sounds, call Technical Support.
9. Reset the amplitude to appropriate level for surgery.

<table>
<thead>
<tr>
<th>Table 2. Troubleshooting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Condition</strong></td>
</tr>
</tbody>
</table>
| Amplifier does not operate (no ultrasonic vibration transmitted), front panel display is off | No power to unit | 1. Ensure VentX Console is connected to AC source (wall). If VentX Console is not included, ensure Amplifier is connected to AC source (wall).  
2. Cycle Amplifier I/O Switch.  
3. Check AC Power Cord connections (both ends).  
4. Check wall power outlet.  
5. Check fuses. |
<table>
<thead>
<tr>
<th>Condition</th>
<th>Possible Causes</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplifier does not operate (no ultrasonic vibration transmitted), front panel display is on</td>
<td>Footswitch does not function</td>
<td>1. Check VASER Footswitch connection (both ends). 2. Ensure the VASER Footswitch is being continuously depressed.</td>
</tr>
<tr>
<td>Alarm Signal Indicator is on when Footswitch is depressed</td>
<td>Improper VASER Handpiece connection</td>
<td>Check VASER Handpiece connection to Amplifier.</td>
</tr>
<tr>
<td></td>
<td>Defective VASER Probe</td>
<td>Change VASER probe.</td>
</tr>
<tr>
<td></td>
<td>Inoperative VASER Handpiece</td>
<td>Change VASER Handpiece.</td>
</tr>
<tr>
<td></td>
<td>Excessive load or torque</td>
<td>1. Disengage VASER Probe from heavy contact with tissue. Re-engage and activate Probe to check for continuing problem. 2. Select a VASER Probe that is appropriate for the type of tissue.</td>
</tr>
<tr>
<td></td>
<td>VASER Amplifier malfunction</td>
<td>Use VASER Test Switch. If VASER Test fails, call technical support.</td>
</tr>
<tr>
<td>Ultrasound vibration is inadequate</td>
<td>Inappropriate VASER Probe choice</td>
<td>Select a VASER Probe that is appropriate for the type of tissue.</td>
</tr>
<tr>
<td></td>
<td>VASER Probe is misaligned or loose</td>
<td>Check VASER Probe connection to VASER Handpiece interface for looseness or misalignment.</td>
</tr>
<tr>
<td></td>
<td>VASER Probe is worn</td>
<td>Change VASER Probe.</td>
</tr>
<tr>
<td></td>
<td>VASER Handpiece is worn</td>
<td>Change VASER Handpiece.</td>
</tr>
<tr>
<td></td>
<td>Inappropriate Amplitude setting</td>
<td>Adjust Amplitude.</td>
</tr>
</tbody>
</table>
7.0 Maintenance

Table 3. Routine Maintenance

<table>
<thead>
<tr>
<th>Item</th>
<th>When</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. VASER or VASER Pro Amplifier</td>
<td>After each use</td>
<td>Wipe down with damp cloth</td>
</tr>
<tr>
<td>2. Footswitches</td>
<td>After each use</td>
<td>Wipe down with damp cloth</td>
</tr>
</tbody>
</table>

Notice: Repairs are only to be conducted by Solta Medical authorized personnel. Unauthorized repairs or modifications by unqualified technicians may damage the unit. The User is responsible for repair or replacement costs.

Notice: Do not spray fluids directly into the vents of the Amplifier.

Caution: Dispose of all tubing and other contaminated products in accordance with your institution’s procedures and guidelines, or place in an approved biohazard container and dispose of in accordance with applicable biohazard regulations.

Figure 4. Fuse Replacement

To replace the fuses in the VASER or VASER Pro Amplifier:

1. Disconnect the AC power cord from the wall plug or other power source.
2. Disconnect the AC power cord from the Power Entry Module on the back panel.
3. Using a small-bladed screwdriver, pry open the cover of the Power Entry Module from the top.
4. Remove the fuse cartridge.
5. Remove the old fuses.
6. Install the new fuses (T 3.15 A 250 V)
7. Replace the fuse cartridge.
8. Snap the Power Entry Module cover back into place.
9. Reconnect the AC power cord to the Power Entry Module, then to the power source.

Fuses are 5mm x 20mm. Amperage and voltage ratings are indicated on the back of the VASER and VASER Pro Amplifier.
8.0 Specifications and Standards

Technical Specifications
This section contains electrical, mechanical, and operating technical specifications for the VASER and VASER Pro Amplifier. Voluntary compliance standards are listed following the technical specifications.

<table>
<thead>
<tr>
<th>Table 4. Environmental Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Temperature</td>
</tr>
<tr>
<td>Operating Humidity</td>
</tr>
<tr>
<td>Operating Altitude</td>
</tr>
<tr>
<td>Storage Temperature</td>
</tr>
<tr>
<td>Storage Humidity</td>
</tr>
<tr>
<td>Storage Altitude</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 5. VASER and VASER Pro Amplifier Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>The VASER and VASER Pro Amplifier requires a minimum of one hour exposure at its operating temperature range before use.</td>
</tr>
<tr>
<td>Dimensions (H x W x D)</td>
</tr>
<tr>
<td>Weight</td>
</tr>
<tr>
<td>Input Power</td>
</tr>
<tr>
<td>Ultrasonic Operating Frequency</td>
</tr>
<tr>
<td>Controls</td>
</tr>
</tbody>
</table>
### Table 5. VASER and VASER Pro Amplifier Specifications

The VASER and VASER Pro Amplifier requires a minimum of one hour exposure at its operating temperature range before use.

| Indicators | Amplitude Display (10% to 100%)  
ContINUOUS/VASER Mode (C, V)  
Ultrasound Vibration Active (Visual)  
Ultrasound Vibration Time (MM:SS) |
|---|---|
| Alarms | Fault Condition Visual Indicator  
Fault Condition Audible Indicator  
VASERsmooth™ Handpiece Connection Audible Indicator (VASER Pro Amplifier Only) |
| Connections | VASER Handpiece, VASER Footswitch, AC Power Cord |
| Power Cord | Hospital Grade (See AC Power Cord Specifications Table) |
| VASER Footswitch, if applicable | The VASER Footswitch must be “GEM SWITCH” with the following markings:  
3A, 25 VAC, 50/60 Hz  
IP68 minimum (watertight rating)  
UL registered and CE marking |
| Fuse | T 3.15 A 250 V (2x) (5 mm x 20 mm) |
| IEC Safety Classification | Class I, Type BF, Continuous Operation, Ordinary Equipment with Respect to Ingress of Water |

### Table 6. VASER AC Power Cord Specifications

The power supply cord used for this device must be a Hospital Grade detachable cord meeting the following specifications:

<table>
<thead>
<tr>
<th>Agency Approval</th>
<th>USA and Canada</th>
<th>Europe</th>
<th>Other Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agency Approval</td>
<td>UL - USA and CSA/CUL - Canada</td>
<td>HAR listed</td>
<td>Country Specific</td>
</tr>
<tr>
<td>Technical Data</td>
<td>125 VAC, 3 x 18 AWG min., SJT or equivalent</td>
<td>250 VAC 1.0 mm² min.</td>
<td>125 or 250 VAC (Country Specific) 1.0 mm² min.</td>
</tr>
<tr>
<td>Appliance Coupler</td>
<td>IEC 60320 Connector (right angle optional)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The VASERlipo System is intended for use in the electromagnetic environment specified below. The customer or the user of the VASERlipo System should assure that it is used in such an electromagnetic environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The VASERlipo System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td>The VASERlipo System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
# Table 8. Electromagnetic Immunity

The VASERlipo System is intended for use in the electromagnetic environment specified below. The customer or the user of the VASERlipo System should assure that it is used in such an electromagnetic environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD)</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical Fast Transient/Burst</td>
<td>±2 kV power supply lines ±1 kV I/O lines</td>
<td>±2 kV power supply lines ±1 kV I/O lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV line-line ±2 kV line-earth</td>
<td>±1 kV line-line ±2 kV line-earth</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply lines</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle &lt;5% UT (&gt;95% dip in UT) for 5 seconds</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle &lt;5% UT (&gt;95% dip in UT) for 5 seconds</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the VASERlipo System requires continued operation during power mains interruptions, it is recommended that the VASERlipo System be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>N/A</td>
<td>The VASERlipo System does not contain components, which are sensitive to magnetic fields.</td>
</tr>
</tbody>
</table>

Notice: UT is the A.C. mains voltage prior to application of the test level.
The VASERlipo System is intended for use in the electromagnetic environment specified below. The customer or user of the VASERlipo System should assure that it is used in such an electromagnetic environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment</th>
</tr>
</thead>
</table>
| Conducted RF      | 3 Vrms               | 3 Vrms           | Portable and mobile RF communications equipment should be used no closer to any part of the VASERlipo System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: \[ d = 1.16667\sqrt{P} \]
|                   | IEC 61000-4-6       | 150 kHz to 80 MHz | \[ d = 1.1666 \sqrt{P} \] 80 MHz to 800 MHz \[ d = 2.333 \sqrt{P} \] 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). |
| Radiated RF       | 3 Vrms               | 3 Vrms           | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: |
| IEC 61000-4-3     | 80 MHz to 2.5 GHz    | 80 MHz to 2.5 GHz | Notice 1: At 80 MHz and 800 MHz, the higher frequency range applies. Notice 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VASERlipo System is used exceeds the applicable RF compliance level above, the VASERlipo System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VASERlipo System. |
Voluntary Standards
The VASERlipo System complies with the following biocompatibility, safety/performance, and regulatory standards for medical equipment.

Materials, Biocompatibility
ISO 10093-1 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Safety, Electrical
Electrical Safety
Medical electrical equipment - Part 1: General requirements for safety

UL 60601-1: 2003
Medical electrical equipment - Part 1: General requirements for safety

CAN/CSA C22.2, No. 601.1:M90
Medical electrical equipment - Part 1: General requirements for safety

IEC/EN 60601-1 (3rd Edition)
Medical equipment – Part 1: General Requirements for basic safety and essential performance
(Contains requirements applicable to medical electrical systems)

Regulatory
Food and Drug Administration (FDA) - Class II Medical Device (General and Special Controls)
9.0 Installation, Returns, and Warranty

Unpacking and Assembling the VASER or VASER Pro Amplifier

Installation Requirements:
The Amplifier and Accessories should only be unpacked and installed by a Solta Medical employee or other authorized technical personnel, following the instructions below.

- To ensure the system functions properly, the equipment must be installed correctly and the following conditions must be met:
- The electrical equipment at the installation site must comply with IEC/NEMA requirements and the supply voltage must correspond to equipment specifications;
- The equipment must be placed on a flat surface with adequate ventilation and cooling of the internal parts;
- The equipment must be located on a suitable, flat surface with the front panel turned toward the operator.

THE UNIT SHOULD NOT BE INSTALLED:
- Close to sources of heat;
- In an area subject to water or humidity;
- In an area exposed to violent shocks.

The appropriate environmental conditions for correct use of the unit are the following:
10° to 28° C (50° to 82° F), 10% to 90% RH, 697 mb to 1,017 mb

The appropriate environmental conditions to correctly store the system are the following:
0° to 50° C (32° to 122° F), 10% to 90% RH, 572 mb to 1,017 mb

Unpacking and Inspection

The VASER/VASER Pro Amplifier will be shipped to you and typically includes the following:
  a. VASER or VASER Pro Amplifier (with Main Power cord)
  b. Two Sterilization Trays (full/standard instrument set)
  c. Yellow Ultrasound/VASER corded footswitch
  d. CD with User Guide and IFUs.

NOTE: The VASER Back Panel and Black Power Cord Adapter will be included with the VentX Console if Amplifier is sold in conjunction.
1) Remove VASER/VASER Pro Amplifier from Box:
   - Open box and remove accessory box. Take out yellow VASER Footswitch, instrument tray(s), power cord and back panel (if applicable).
   - Remove upper Styrofoam from box, lift Amplifier and remove plastic protective wrap.

Assembly of the Equipment

Place VASER/VASER Pro Amplifier on a solid support so that control panel is facing the front.
Connect main gray power cord to VASER Amplifier power module.
Connect the VASER Footswitch cord to the VASER Footswitch Receptacle.
Connect the VASER Handpiece to the VASER Handpiece Receptacle.

Servicing the VASER and VASER Pro Amplifier

Repairs are only to be conducted by Solta Medical authorized personnel.
THERE ARE NO USER-SERVICEABLE PARTS IN THE VASER AND VASER PRO AMPLIFIER.
(See Maintenance Section for directions on fuse replacement.)

Return Material Authorization (RMA)

Before returning any VASER System component (including VentX Console and Accessories) for repair, contact Solta Medical Technical Service for a Return Material Authorization (RMA) number or instruction for repair. Call the number shown below to obtain a RMA number:
   877-782-2286 - Solta Technical Service (outside U.S./Canada 1-510-786-6946)
Product returned to Solta Medical without an RMA number may be returned to sender.

Limited Warranty

Solta Medical will provide a limited warranty on the Products as described in the agreement under which the Products were acquired. No person is authorized to expand or vary this limited warranty in any way.

Exclusion of Other Warranties

Except for the limited warranty stated above, we make no warranty, express or implied, including without limitation any warranty of merchantability or fitness of the Product for any particular purpose. You are solely responsible for determining the suitability of the Product and the system of which it may form a part for any particular use or procedure.