## $\begin{array}{c|c} A & \bigvee & Y & A \\ \hline s \ t \ e \ a \ m & i \ n \ h \ a \ l \ e \ r \end{array}$



### **USER MANUAL**

#### **INDICATIONS FOR USE**

The Avya is a portable Steam Inhaler designed to deliver warm and soothing aerosol mist for sinus and respiratory relief.

Thank You for Purchasing Avya - The World's Only Patented, Vibrating Mesh Technology Steam Inhaler.

We've created a beautiful, ultra-portable, personal vaporizer that clears obstruction in the breathing path. AVYA uses clean nanoparticle steam to go deep into your nasal, sinus and throat passages to effectively clear sinuses, and relieve allergy, cold or flu-related symptoms. You can use AVYA anywhere- at home, at the office, on your run, at school, at the park, on vacation. It's time to stop the struggle and enjoy better breathing anywhere, anytime.

This device should be used according to the instructions and not for any other purpose. Please read instruction carefully before use.

#### WARNING AND CAUTION PRECAUTIONS

- Read instructions before using this device.
- Clean Avya before use. (See cleaning instructions)
- Clean Avya at the end of each day of use and store properly.

• This is a single patient device. Do not allow multiple patients to use the same device.

• THIS UNIT IS DESIGNED ONLY FOR WATER BASED SALINE FORMULATIONS. USING ESSENTIAL OILS OR OTHER LIQUIDS WILL DAMAGE THE DEVICE AND VOID THE PRODUCT WARRANTY!

• Do not attempt to clean mesh with any foreign objects, follow cleaning instructions when cleaning the mesh.

• Do not store liquids overnight in unit; this could cause clogging of the mesh.

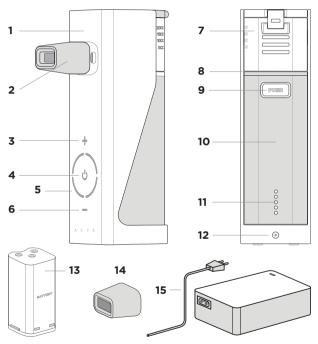
• Do not immerse control unit in water, wipe control unit with damp cloth to clean.

• Avoid dropping the unit, damage to unit could occur.

• Keep the device out of the reach of infants and children. Children should use Avya only under an adult's supervision.

• We recommend using Avya with our compatible aqueous solution.

#### DESCRIPTION OF DEVICE AND ACCESSORIES



 Main unit. 2) Mouthpiece. 3) Temperature increase button. 4) Power On/Off button. 5) Temperature indicator. 6) Temperature decrease button. 7) Water Tank.
Contact Electrode. 9) Water Tank release button. 10) Rubber cover. 11) Battery indicator. 12) DC jack socket. 13) Battery. 14) Mouthpiece. 15) AC adapter and power cable.

#### **INITIAL USE**

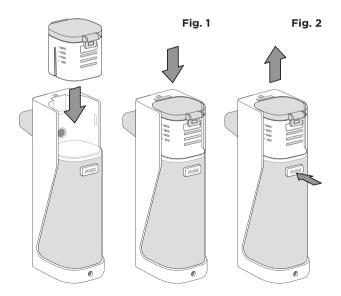
Before using Avya, the main unit and the accessories should be cleaned. Refer to Section Cleaning for instructions. Before use, ensure the device and accessories are at room temperature.

Please note: The unit comes only 50% pre-charged for safety of transport.

#### **ASSEMBLING THE WATER TANK**

Remove the device from the packaging. Connect the water tank to the Steam Inhaler main unit. Make sure to connect firmly so that you hear a "click" sound (Fig. 1)

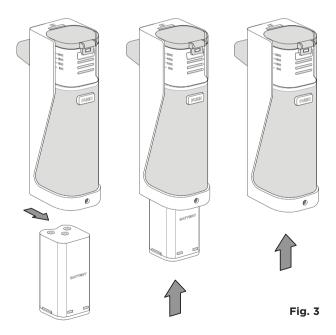
To remove the water tank from the Avya main unit, press the button and pull water tank upward simultaneously (Fig. 2)



#### **INSERTING BATTERY PACK**

Be sure to insert battery pack as indicated on the inside door of the battery compartment. With normal use, a completely charged battery pack will power Avya for about 2 hours. Complete battery recharge time is approximately 3 hours.

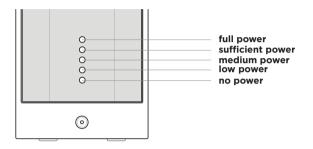
Ensure that the plastic poles protector is removed from the battery before inserting it into the device. Insert battery pack (type 18650 2200mA x 4 units). The battery pack should be aligned to their respective poles (Fig. 3).



Ensure the battery pack is tightly fixed to the main device.

#### **BATTERY RECHARGING AND STATUS**

Please recharge the battery only with the supplied AC adapter. The AC adapter will automatically recharge the battery pack when plugged into the device. Please note that the battery pack will stop charging if the unit is powered ON for use. Always unplug the AC adapter when the battery pack is fully recharged to maintain the battery service life.



**Note:** When the battery is completely exhausted the power lights will flash 5 times and then power off the device.

**Note:** When the battery pack is completely recharged, the power lights will turn off to indicate unit readiness.

**Note:** Before using the battery pack, the plastic pole protector cover on battery pack must be removed.

**Note:** ONLY use Avya's supplied battery pack for the device. Tampering with the battery pack will void the product warranty. We recommend replacing the battery pack after one year of regular use.

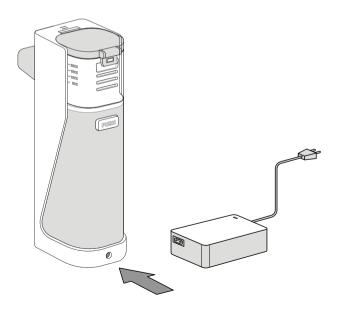
Always disconnect the AC adapter from the mains connection and the Avya unit before inserting battery pack. Check the LED power status of battery pack before use.

#### AC ADAPTER OPERATION

**Note:** Before using the AC Adapter, always check the data plate on the bottom of Avya device to ensure that the voltage and current indicated on the unit correspond to the voltage and current available.

Connect the AC adapter only to the mains voltage listed on the type plate. Insert the AC adapter connector into the connector socket provided, and the AC adapter fully into a suitable socket.

**Note:** The device can operate without the battery pack when connected with the AC adapter. Ensure that there is a socket near to where the device will be used. Ensure that the mains cable is not a tripping hazard. To disconnect the Avya Steam Inhaler from the mains after use, switch off the device first and then remove the AC adapter.



#### **DEVICE OPERATION**

**Note:** Before use, ensure the device and accessories are at room temperature.

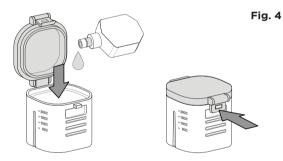
#### **Preparing Avya**

• For hygienic reasons, it is imperative that Avya and accompanying accessories are cleaned after every use. For details, see Section Cleaning.

#### **Filling the Water Tank**

- Open the water tank by lifting the latch.
- Pour Avya Aqueous Solution into the water tank.

• Close the water tank by pressing the latch firmly and securely back into place (Fig. 4)

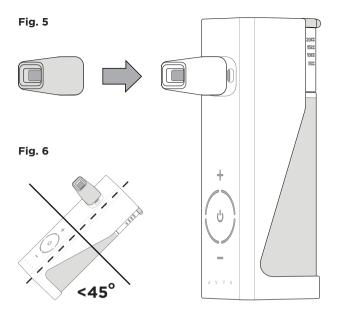


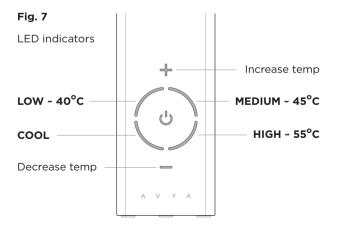
#### Inhalation with the mouthpiece

• Connect the rubberized mouthpiece to the steam outlet (Fig. 5)

• Sit upright and hold the device as upright as possible, do not tilt the device more than 45 degrees in any direction (Fig. 6)

- Place Avya at a comfortable angle under your nose
- Power the unit by simply touching the power indicator.
- Adjust the temperature control by touching the "+" or
- "-" button, the temperature LED will light up (Fig. 7).





**Note:** Please allow at least 5 minutes for the proper temperature setting to be reached.

**Note:** At any time during treatment, you can pause and turn the device off by touching the power button.

• Breathe slowly and deeply in through your nose.

• The device will automatically shut off after 25 minutes of use or if there is overheating of the heating element for safety.

**Note:** Residue may remain inside the mouthpiece or inside the device due to vapor accumulation. Remove the rubber cover after each use to release any residual fluid.

Disinfect and clean the device at the end of each day. To prolong mesh technology component, allow at least 1 hour interval between each treatment.

#### CLEANING

**Note:** The Avya Steam Inhaler device and accessories are intended for multiple use. Before you clean the device, always switch it off, unplug it and let it cool off. The Avya main device and the accessories used must be cleaned after each use.

Cleaning the water tank and vibrating mesh element with the self clean feature:

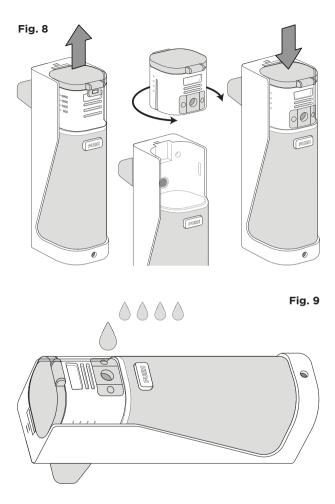
• Open the cover of the water tank and discard the remaining aqueous solution.

- Remove the water tank and rinse thoroughly.
- Insert the water tank in reverse direction (Fig. 8).

• With a liquid dropper, drop 5-6 droplets of water onto the mesh element (Fig. 9).

• Power on the device. Avya will suction the water in reverse mode into the water tank and clear out any residue.

• Power Off the device and wipe the water tank dry.



**Note:** NEVER ATTEMPT TO CLEAN THE MESH WITH ANY FOREIGN OBJECT, THIS COULD DAMAGE THE MESH AND WATER TANK. The unit will not operate with a damaged mesh.

#### **CLEANING THE ACCESSORIES**

Cleaning the accessories: Clean the accessories (mouthpiece) with diluted soap water and rinse. Allow to air dry completely

Cleaning Avya main unit: Clean the outside of Avya device with a cotton cloth dampened with water. Do not allow water to enter the device.

Cleaning the 4 stainless steel contact poles: Use a cotton swab dampened with water to clean the stainless steel contact electrodes on the Avya device (4 poles total - 2 poles on the main body and 2 poles underneath the water tank).

#### **TROUBLESHOOTING MESH PROBLEMS**

With time, the mesh holes may become blocked by unknown particles. You may notice decrease output of vapor. To test: Put 6 ml. of water inside the water tank and power on the unit. If complete atomization time takes longer than 30 minutes, then the mesh holes are clogged.

**Solution A:** To clean the mesh holes and unclog the blocked particles, put a solution of 2 drops of vinegar + 6 ml. of water into the water tank and allow the solution to vaporize completely. Afterwards, rinse and dry thoroughly before using it for a treatment.

**Solution B:** Run the reverse self cleaning procedure with a solution mix of 2 drops vinegar to 4 drops of water (refer to the reverse self cleaning instructions),

If the problem persists after checking all possible causes, please contact an authorized distributor to purchase a new water tank.

#### TROUBLESHOOTING

Please refer to the table below to troubleshoot any problems.

#### Low atomization.

- Check to ensure there is water in tank.
- Make sure water tank is firmly in place.
- Clean mesh as recommended in the instructions.
- Clean electrodes on control unit and water tank.

#### Power light goes out immediately after powering on.

- Make sure water cup is firmly in place.
- Clean electrodes on control unit and water cup.

#### Power indicator light does not come on.

• Ensure that the AC adapter is properly connected with the main device.

• Check to see if battery pack is properly inserted in control unit.

#### Power lights on but no atomization.

- Clean mesh as recommended in the instructions.
- Check mesh to see that it is not damaged.
- Clean electrodes on control unit and water tank.
- Check fluid level.
- Re-install the battery pack.
- Tilt unit forward.

#### Steam Inhaler shuts off during use.

- Make sure water cup is firmly in place.
- Clean electrodes on control unit and water cup.
- Re-install the battery pack.

• The internal temperature is overheating. Turn off the device and cool it down for 10-20 minutes until the device is completely cool.

• The treatment period has exceeded 25 minutes. To activate the device, power the ON/OFF button for another treatment.

#### Device not heating.

• The battery power is too low.

• Allow 5-10 minutes for the selected temperature to be reached.

#### Leakage from outlet of the mouthpiece.

• Open the residual port located on the bottom of the unit to allow accumulated water to release.

If your Avya Inhaler still does not function properly after troubleshooting, follow warranty service instructions.

#### **TECHNICAL SPECIFICATIONS**

Product Name Avva Portable Steam Inhaler Model<sup>.</sup> SI20 Method of Operation: Vibrating Mesh Dimensions (LxWxH): Approx. 52.5 x 52 x 126mm Device weight: \*\*\*\* excluding batteries Battery Life: Approx. 2 hrs (from 100%) Recommended Fill Approx. 20 ml maximum Atomization rate: Approx. 0.25 ml/min minimum Oscillation frequency: 100 kHz Mains connection: 100-240 V ~ . 50-60 Hz: \*\*\*\* VA Power Consumption:

#### **Operating conditions**

Temperature: 50° ~ 104°F 10°C ~ 40°C) Humidity: 30%-85% R.H. non-condensing

#### Storage and transport conditions

Temperature: -4°- 158°F (-20°C ~ +70°C) Humidity: < 85% R.H. non-condensing Atmosphere pressure 860hPa-1060hPa IPx1 Degrees of protection against ingress of water and access to hazardous parts.

#### Accessories

Rubberized Mouthpiece, Battery Pack, AC adapter, Carry bag.

#### WARRANTY AND SERVICE

The Avya Steam Inhaler unit is warranted for one year from date of purchase against defects in manufacturing. All warranties are based on normal usage. The warranty does not cover wearable accessories.

This warranty covers normal usage, failure to adhere to and/or comply with operation manual instructions will void all associated warranty obligations under the terms of this warranty, Conditions for voiding this warranty include:

- Abuse
- Failure to follow directions
- Misuse
- Improper maintenance
- Ordinary wear

For warranty and service please contact AURA MEDICAL LLC at **516.253.1063** to speak to a representative or find us online at **www.aura-medical.com/support** 



Important /Caution/Note! Read the instruction manuals.



- BF type applied part
- Not suitable for use in presence of flammable anesthetic mixture with oxygen or nitrous oxide.



- IPx22 Classification
- Continuous operation



To avoid atomizer's abnormal operation caused by electromagnetic interference between electrical and electronic equipments, do not use the device near a cell phone or microwave oven.



Discard the used product to the recycling collection point according to local regulations.

# ELECTROMAGNETIC COMPATIBILITY INFORMATION

MODEL SI20 compliance for each EMISSIONS test specified by the standard, e.g. EMISSIONS class and group. Guidance and manufacturer's declaration - electromagnetic emissions.

| Electromagnetic environment - guidance | The MODEL SI20 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. | The MODEL SI20 is suitable for use in all establishments,<br>including domestic establishments and those directly<br>connected to the public low-voltage power supply network<br>that supplies buildings used for domestic purposes. |                                     |   |
|--|---|--|-------------------------------------|---|
| COMPLIANCE                             | Group 1   | Class B  | Class A                             | Complies  |
| EMISSIONS                              | RF emissions<br>CISPR 11  | RF emissions<br>CISPR 11   | Harmonic emissions<br>IEC 61000-3-2 | Voltage fluctuations<br>/flicker emissions<br>IEC 61000-3-3 |

MODEL SI20 compliance for each **IMMUNITY** test specified by the standard, e.g. IMMUNITY test level. Guidance and manufacturer's declaration - electromagnetic immunity.

| Compliance level            | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 KV air  | 10V/m<br>80MHz-2.7GHz<br>80% AM at 1kHz   | ±2 kV<br>100 kHz repetition frequency               | ±0.5 kV, ±1 kV line-to-line;<br>±0.5 kV, ±1 kV, and ±2 kV<br>line-to-ground | 3V<br>0.ISMHz-80MHz<br>6V in ISM and amateur radio bands be-<br>tween 0.ISMHz and 80MHz, 80% AM at<br>1kHz |
|-----------------------------|---|---|---|---|--|
| IEC 60601-1-2<br>test level | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 KV air  | 10V/m<br>80MHz-2.7GHz<br>80% AM at 1KHz   | ±2 kV<br>100 kHz repetition frequency               | ±0.5 kV, ±1 kV line-to-line;<br>±0.5 kV, ±1 kV and ±2 kV<br>line-to-ground  | 3V<br>0.15MHz-80MHz<br>6V in ISM and amateur radio bands be-<br>tween 0.15MHz and 80MHz, 80% AM at<br>1kHz |
| Immunity Test               | Electrostatic<br>discharge (ESD)<br>IEC 61000-4-2 | Radiated<br>RF EM fields<br>IEC 61000-4-3 | Electrical fast<br>transient/burst<br>IEC 61000-4-4 | Surge<br>IEC 61000-4-5  | Conducted distur-<br>bances induced by<br>RF fields<br>IEC 61000-4-6                                       |

| Immunity Test  | IEC 60601-1-2<br>test level  | Compliance level   |
|--|--|--|
| Voltage dips, short<br>interruptions and<br>voltage variations | 0% UT: 0.5 cycle a)<br>At 0 <sup>0</sup> , 45 <sup>0</sup> , 90 <sup>0</sup> , 135 <sup>0</sup> , 180 <sup>0</sup> , 225 <sup>0</sup> ,<br>270 <sup>0</sup> , and 315 <sup>0</sup> . | 0% UT: 0.5 cycle a)<br>At 0 <sup>0</sup> , 45 <sup>0</sup> , 90 <sup>0</sup> , 135 <sup>0</sup> , 180 <sup>0</sup> , 225 <sup>0</sup> ,<br>270 <sup>0</sup> , and 315 <sup>0</sup> . |
| on power supply<br>input lines<br>IEC 61000-4-11               | 0% UT: 1 cycle<br>70% UT: 25/30 cycles<br>Single phase: at 0 <sup>0</sup>  | 0% UT: 1 cycle<br>70% UT: 25/30 cycles<br>Single phase: at 0 <sup>0</sup>  |
|  | 0% UT: 250/300 cycles  | 0% UT: 250/300 cycles  |
| NOTE: UT is the a.c. m   | NOTE: UT is the a.c. mains voltage prior to application of the test level  | : level  |





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B

| nity Compliance<br>evel level (r | 27                           | 28                                     | თ                             | 28  | 28  | 28  | 6                             |
|----------------------------------|------------------------------|--|-------------------------------|---|---|---|-------------------------------|
| Immunity<br>test level<br>(V/m)  | 27                           | 28                                     | თ                             | 28  | 28  | 28  | o                             |
| Distance<br>(m)                  | 0.3                          | 0.3                                    | 0.3                           | 0.3   | 0.3   | 0.3   | 0.3                           |
| Max Power<br>(W)                 | 1.8                          | 2                                      | 0.2                           | 2   | 7   | 2   | 0.2                           |
| Modulation<br>b)                 | Pulse<br>Modulation<br>18 Hz | FM c)<br>±5kHz deviation<br>1 kHz sine | Pulse<br>Modulation<br>217 Hz | Pulse<br>Modulation<br>18 Hz                            | Pulse<br>Modulation<br>217 Hz                               | Pulse<br>Modulation<br>217 Hz                         | Pulse<br>Modulation<br>217 Hz |
| Service<br>a)                    | TETRA 400                    | GMRS 460<br>FRS 460                    | LTE-Band 13, 17               | GSM 800/900;<br>TETRA 800; Iden 820;<br>CDMA 850; LTE 5 | GSM 1800-1900;<br>CDMA 1900; DECT,<br>LTE 1, 3, 4, 25; UMTS | Bluetooth, WLAN,<br>802.11 b/g/n;<br>RFID 2450; LTE 7 | WLAN 802.11 a/n               |
| Band<br>(MHz)                    | 380-390                      | 430-470                                | 704-787                       | 800-960   | 1700-1990   | 2400-2570   | 5100-5800                     |
| Test Freq.<br>(MHz)              | 385                          | 450                                    | 710<br>745<br>780             | 810<br>870<br>930                                       | 1720<br>1845<br>1970  | 2450  | 5240<br>5500<br>5785          |

NOTE: a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 %duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.



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For support or Inquires: support@aura-medical.com www.aura-medical.com