



Autologous Fat Transfer System

BRAVA, LLC

**INSTRUCTION**  
**MANUAL**



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## Instructions for Use

### DEVICE DESCRIPTION

The Brava AFT System is intended to be used under the supervision of a doctor; it is a single person, multi-use, bra-like device consisting of four main elements:

- Domes: A pair of semi-rigid transparent shells designed to enclose the breasts; silicone filled bladders/rims which are lined with an adhesive to create a seal against the skin.
- Vacuum Generating Components (Two): A micro-processor controlled (SportBox) which creates and regulates a sustained low level vacuum pressure within the Domes, powered by two disposable AAA batteries, which can be used while awake or asleep; a rubber hand bulb pump used to generate higher pressure for short periods of time, to be used only while awake.
- Silicone Tubing and Filter: Two sets. One set is used pre-operatively and connects the SportBox and hand bulb pump to the Domes; the other attaches the Domes to the SportBox and is only used post-operatively.
- Bra: A specially designed bra that supports the Domes and helps maintain the vacuum seal.

### INDICATION FOR USE

The Brava AFT System is indicated for daily use to expand the breast before and after autologous fat grafting.

### CONTRAINDICATIONS

The product should not be used by:

- Women with a history of silicone allergy
- Women with untreated breast cancer
- Smokers
- Women that are pregnant or breastfeeding

## WARNINGS

DISCONTINUE USE IF SIGNIFICANT SKIN IRRITATION, REDNESS OR ITCHING OCCURS, OR IF DISCOMFORT DEVELOPS.

DISCONTINUE USE OR MOVE TO A DEEPER DOME SIZE WHEN NIPPLE TOUCHES THE INSIDE WALL OF THE SHELL.

DO NOT USE DEVICE WHEN TAKING ANALGESICS OR NARCOTIC MEDICATION.

KEEP AWAY FROM CHILDREN. CHOKING CAN RESULT FROM A CHILD SWALLOWING A SMALL PART, SUCH AS A FILTER, T-CONNECTOR, LUER LOCK, THAT HAS BECOME DETACHED FROM THE DEVICE.

NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

## PRECAUTIONS

1. At any sign of discomfort, the device should be removed.
2. The Dome's soft bladder and bra are made of hypoallergenic materials fully approved for prolonged skin contact.
3. The wearer should stop wearing the device if they develop symptoms of moderate to severe itching, skin redness, irritation or blistering.
4. The wearer should remove the SportBox if the unit feels very hot to the touch.
5. The device should not be used with or around flammable agents.

## ADVERSE REACTIONS

Potential adverse reactions include:

- Bruising
- Skin irritation
- Itching
- Excessive sweating
- Blistering
- Temporary increase or decrease in the sensitivity of the nipples
- Hyperpigmentation (darkening of skin)
- Costochondritis, a rare cause of chest wall pain occurring in the costal cartilages of the rib cage (where ribs connect to breast bone)
- Tietzes Syndrome (painful rib swelling)
- Lactation

## HOW TO USE BRAVA-AFT

**Step 1.** Ensure your Brava AFT kit contains:

- 1 pair of Domes. (Each Dome's hypoallergenic adhesive sole is covered by a tamper resistant safety shield. Do not use if the seal has been removed.)
- SportBox
- Two AAA - Alkaline batteries
- Rubber hand bulb pump and tubing
- T-Connector tubing
- A specially designed bra with tote bag for washing bra
- Instruction booklet
- Cleaning and maintenance kit
- Filters
- Storage container
- Optional - Brava Skin Care Kit- **STRONGLY RECOMMENDED**

**Step 2.** To ensure proper use and warranty coverage, please read and complete the following:

- Make an appointment with a Brava Coach. Call 1-800-407-5304, Option 5, M-F from 9:00am to 6:00pm EST, to arrange a time to review proper set up and use. If in Europe, contact your doctor or distributor by locating them at [www.brava.com](http://www.brava.com) or call Brava at 1-305-856-4242 or contact customer support at [customersupport@brava.com](mailto:customersupport@brava.com).

**Step 3.** Check SportBox Functioning

Insert two AAA alkaline batteries and turn ON by pressing the "POWER" button. Listen for the whirl of the pump. Once you hear the whirl, turn it OFF by pressing the "POWER" button again.

(BATTERIES LAST APPROXIMATELY 2 WEEKS AND SHOULD BE REPLACED AS NECESSARY)



#### Step 4. Prep Skin (OPTIONAL)

Each day prior to putting on the Domes, clean your breasts and underarm area with the Brava Skin Cleanser and water, rinse and dry the chest area completely. This removes the dead skin cells, deodorant, hair conditioner and moisturizes from the area where the Domes make contact with your body. Apply the No-Sting Skin Prep\*, allowing it to dry thoroughly (8 to 10 minutes) before placement of Domes (if using hair conditioner, be sure to wash with Brava Skin Cleanser at end of shower to remove residue). It is very important to clean the Domes daily after use. Use the Brava Dome Cleanser for best results, to eliminate the chance of bacteria buildup and restoring its tacky surface. Air-dry the Domes.

In addition to proper hygiene, it is recommended that you use the other Brava Skin Care products, which have been formulated to be compatible with the device and which cleanse, protect and moisturize the skin. Good hygiene and use of the Brava Skin Care products have been proven to minimize skin irritation.

#### Step 5. Connect Filter to Top of SportBox

Connect the filter (threaded side down) to the port located on the top of SportBox. DO NOT overly tighten as it may result in damage to the filter and/or SportBox. Leave the filter connected to the SportBox and set it aside for later use. (See Picture 1).



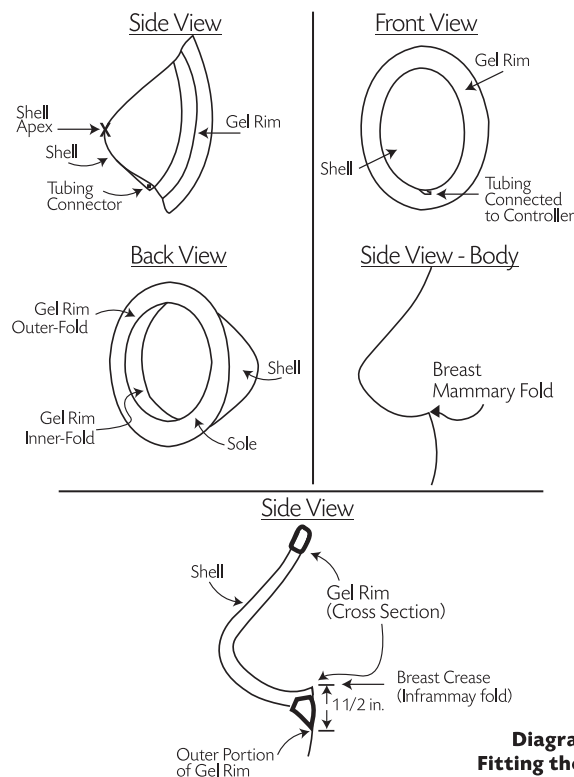
**Picture 1.**  
**SportBox with Filter**

#### Step 6. Putting On the Bra

Put the Brava bra on and zip it up completely over the bare chest, disconnecting the shoulder straps and then lower the zipped bra to your waist.

#### Step 7. Prepare To Wear the Domes

Remove the plastic temper resistant sheets from the bottom of the Domes by perforating in the middle and gently pulling from inside towards outer edges of the domes. Prior to wear, be sure that the adhesive sole is clean and free of foreign material. You can check for proper placement by ensuring that the openings of the Dome ports (tubing connector) are at the bottom and are facing each other. See Diagram 1.



**Diagram 1.**  
**Fitting the Domes**

## Step 8. Dome Placement

Put the Dome on by holding the sides of the rim between thumb and fingers. Lean forward allowing the breast to fall within the Dome's hard shell. Flair rim away from body (Picture 2).

If you are taller than 5' 7" (170 cm), place the lowest edge of the Domes at 1-3/4" inches (5 cm) from breast crease. If shorter, place them at 1-1/2" (4 cm), from crease. This allows proper airflow around the breast and an optimal fit over the rib cage. See Diagram 1.



**Picture 2.**  
**Outward Dome Rim**

Note: Nipple may not be aligned with apex of Dome.

Use forearm to support first Dome as you place second Dome.

## Step 9. Ensuring Proper Placement of Domes

Once each Dome is in place, inspect the area where they meet the skin to ensure that they sit comfortably on your body and are properly aligned under the inframammary crease (mammary fold). Use thumbs to gently flair the remaining edges of rim and hard shell outward ensuring all edges are free of air channels (i.e., skin folds).

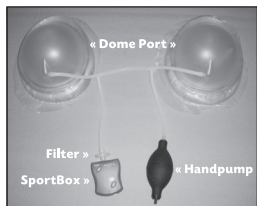


**Picture 3. Domes On**

## Step 10. Attach Tubing to Domes, SportBox and Hand Bulb Pump

**a) WHEN USING SPORTBOX AND HAND BULB PUMP (BILATERAL OR COSMETIC USE- PRE SURGERY)**

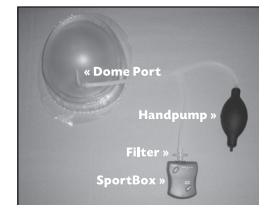
Use tubing provided that is already connected to the hand bulb pump. Loop tubing to enable proper airflow. Later, if tubing becomes frayed, trim for tight fit. (See Picture 4a)



**Picture 4a. Bilateral Use**  
**SportBox and Hand Pump**

**b) WHEN USING SPORTBOX AND HAND BULB PUMP (UNILATERAL USE- PRE SURGERY)**

Use the shorter T - Tubing to connect the handpump SportBox. (See Picture 4b).



**Picture 4b. Unilateral Use**  
**SportBox and Hand Pump**

**c) WHEN ONLY USING SPORTBOX (NOT USING HAND BULB PUMP- POST SURGERY)**

Connect T - Tubing to Dome ports (Picture 5).

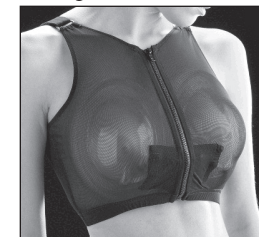


**Picture 5.**  
**T-Tubing Connection**

## Step 11. Putting On the Bra over the Domes and Tubing

*(Do not connect SportBox yet)*

Once you are satisfied that the Domes are positioned correctly, raise the "zipped" bra over the Domes and tubing. (See Picture 6). Reconnect the Velcro shoulder straps. Your bra is now in place and silicone tubing is hanging below the bottom of the bra.



**Picture 6. System On**

## Step 12. Activating and Connecting the SportBox to Achieve Vacuum.

The POWER button and the ALARM button are both toggle switches that are turned ON/OFF by the same pressing motion. Both buttons emit a short beep when they are turned ON. POWER button emits a distinctively longer beep when it is turned OFF. ALARM button does not emit a beep when it is turned OFF.

Turn the SportBox ON by pressing the POWER button and then press the ALARM button. You will hear the short beep when the SportBox is turned on and/or when the alarm is activated. Then, connect to Filter on SportBox (Picture 7).



**Picture 7. SportBox Filter T-Tubing**

Once the SportBox is activated, it will start generating a vacuum and will not stop until the appropriate vacuum level is reached. This process can take 2-10 minutes or longer for deeper Domes. Continue to hold domes against chest until seal is achieved.

You should be standing still during this process to ensure a quick and proper seal. If it takes more than 10 minutes to achieve vacuum and the ALARM goes off, press both the "POWER" and "ALARM" buttons twice to turn the pump and alarm off and on again. This resets the alarm as you continue to achieve the appropriate vacuum level.

Once the appropriate vacuum level is reached, the pump will shut off. It is normal for the pump to reactivate periodically as it regulates the pressure within the Domes.

NEVER PRESS THE DOMES FORCEFULLY AGAINST YOUR CHEST WHEN A SEAL HAS BEEN ACHIEVED AS THIS MAY DAMAGE THE SPORTBOX. BLOWN SENSORS ARE NOT COVERED UNDER WARRANTY.

## Step 13. Wearing the System

If the nipple is touching the Dome after the vacuum is achieved, check that the Dome is properly aligned under the inframammary crease. If the alignment is correct but your nipple continues to touch the inside shell, discontinue use and contact Brava Customer Care or your physician. You need deeper Domes.

While asleep, if alarm is on and the vacuum is lost for more than 10 minutes, the alarm will sound alerting you that the seal is lost. In most cases, gently pressing the Domes against your chest will recreate a seal enabling the System to restore the correct vacuum pressure.

## Step 14. Removing system

Unzip Brava bra, turn off SportBox, detach tube, gently detach dome and place in protective storage.

## Wearing System Pre-Operatively

### a) First 14 Days of Use

To allow your skin to acclimate to the Domes, it is recommended that you only use the SportBox (**do not use Hand Bulb Pump**) for 8 hours a day during the first 3 days. If there are no adverse reactions, you may begin wearing it for up to 10 hours per day for the next 11 days, and thereafter, as many hours as possible.

### b) Wearing System While Awake

Once you have acclimated to wearing the System, use the hand bulb pump during waking hours ONLY to achieve maximum expansion (leave the SportBox attached and ON). Squeeze the hand bulb pump until maximum pressure is achieved without discomfort. If tenderness or tension is felt, release pressure by detaching hand bulb pump from tubing. To reactivate, slowly begin squeezing hand bulb pump to a comfortable level of pressure. Maximum pressure is achieved once the hand bulb pump no longer re-inflates after squeezing.

### c) Wearing System While Asleep

NEVER USE THE HAND BULB PUMP WHILE ASLEEP

You may use the SportBox while asleep. Follow instructions in Step 12 to activate the SportBox and "Alarm". If while sleeping, vacuum is lost for 10 minutes or more, the SportBox will sound alarm notifying you that therapeutic pressure is lost. To correct, turn "OFF" both the SportBox and Alarm, reposition the Domes and then turn both the SportBox and Alarm ON. Press the "ALARM" button once to reactivate. Gently press the Domes against your chest to speed the process. Continue to hold until vibration stops.

### *Wearing System Post-Operatively*

**FOLLOW YOUR DOCTOR'S INSTRUCTIONS.**

**IMPORTANT: USE OF THE HAND BULB PUMP IS TO BE DISCONTINUED AFTER SURGERY.**

**AFTER SURGERY VACUUM PRESSURE SHOULD ONLY BE CREATED AND REGULATED BY THE BATTERY OPERATED SPORTBOX.**

## CARING FOR YOUR SKIN AND DOMES

After removing the System, clean the skin around your breasts with the Brava Skin Cleanser. Apply Brava Body Lotion to your chest area to soothe your skin and reduce any irritation. Wash all lotion off prior to the reapplication of the Domes.

The Domes should be washed after use with the Brava Dome Cleanser to ensure longer lasting soles. Spray on the entire Dome, wait a maximum of 10 minutes, rinse with lukewarm water and allow them to dry. You can also use IVORY®\*Bar Soap or baby shampoo.



**Picture 8. Wash Domes**

**DO NOT USE LIQUID SOAPS THAT CONTAIN ANTIBACTERIAL ADDITIVES OR ALCOHOL PRODUCTS.**

**Never scrub the Domes when cleaning as this will damage the adhesive sole, rendering the device useless. Do not allow washcloths or paper products to come in contact with the sole (Picture 8).**

## CARING FOR YOUR SPORTBOX

### *Filter Replacement and Cleaning*

#### **Attaching Filter**

Attach male end to the port on the SportBox. Over tightening can damage port (Picture 9). Attach female end of filter to T-Tubing connector until secure.

#### **Filter Replacement**

Rotate filter use daily. If you perspire or excessively wear for 10 + hours, replace filters more often.

In order to test for clogged filters, connect the filter to the SportBox and press the POWER button to turn on the pump. If the pump does not run, detach the filter from the pump while pump is turned on and if the pump turns on, the filter is clogged and should be cleaned or replaced.



**Picture 9. SportBox with filter attached**

#### **Cleaning filter**

Attach a "dry" syringe to the filter and depress plunger. This action forces air through the filter removing trapped particles. DO NOT use cleaning liquids for this procedure.

### **Dry Clean Process for SportBox (Daily Process)**

1. Detach filter from SportBox.
2. Remove rubber port cover from the SportBox (looped over vacuum port with 3 tiny holes) and hang it on port cover storage post on the Cleaning tray
3. Turn SportBox ON (audible Beep) and Alarm OFF (Silent/No Beep) and place it, upside down, on the Cleaning tray. Let it run for at least 10 minutes. (Severe cases of moisture buildup may require longer drying process.) Make sure tray is DRY.
4. When finished, replace rubber cover over vacuum port.
5. It is recommended to change batteries every 7-10 days.

\* Ivory Bar® Soap is a registered trademark of Procter & Gamble.

## Wet Cleaning Procedure for SportBox

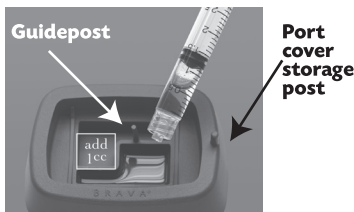
*(Only performed if SportBox is sputtering or not holding vacuum)*

NEVER TURN YOUR SPORTBOX UPRIGHT WHEN WET CLEANING TO AVOID SERIOUS DAMAGE.

**1.** Place the SportBox upside down in a DRY Cleaning tray and let it run for 2 hours. Follow Dry Cleaning Process.



**Picture 10. Cleaning Tray and Syringe. Add 1cc of alcohol.**



**Picture 11. Cleaning Kit. Add 1cc of tap water.**

**2.** After Step 1. Remove the SportBox and any residual liquid from the Cleaning tray. Fill the syringe to 1cc with isopropyl alcohol (rubbing alcohol), and empty it into the side of the Cleaning tray marked "Fill to line" (Picture 10). Repeat the procedure with 1cc of cool tap water. You now have 2cc of a 50/50 mixture of alcohol/water in the same reservoir of the Cleaning tray. (Picture 11).

**3.** Turn both the pump and alarm ON (listen for audible "beep" to indicate ON) and place it upside down into the Cleaning tray. The port will be immersed in the filled reservoir.

**4.** Allow the SportBox to run until the alarm sounds (approximately 10 minutes). The alcohol and water mix will cycle through pump, removing debris and emptying it into the dry reservoir.

**5.** Once the alarm sounds the process is complete. Turn the SportBox on again while keeping it upside down. Empty the cleaning tray of all fluid and re-place the upside down SportBox onto the now empty Cleaning tray. Turn "OFF" the alarm and allow for a Dry Clean cycle of 3-5 hours.

Upon completion remove the SportBox while maintaining it upside down. Shake-off excess fluid and dry. Re-attach rubber cover and replace batteries.

## Emergency Cleaning Procedure

PERFORMED ONLY IF SPORTBOX DOES NOT TURN ON

*To release debris from the pump check-valves, it must be manually flushed with the syringe:*

- 1.** Remove the syringe from the cleaning kit.
- 2.** Fill the syringe with 3cc of the isopropyl alcohol.
- 3.** Remove SportBox's rubber port cover.
- 4.** Turn ON the pump (listen for a single beep; you will not hear the whirl of the pump).
- 5.** Hold the SportBox upside down (over a sink to allow the alcohol to empty safely).
- 6.** Attach the syringe to vacuum port and slowly empty syringe into port. Repeat this process until pump starts running.
- 7.** Turn the Alarm OFF. Leave pump ON. Place it in Clean Tray; allow it to cycle for 3-5 hours. The pump should eventually start running, if not repeat. If not, contact Customer Service for assistance.
- 8.** Replace batteries and port cover. Leave in tray until worn again.

## HELPFUL TIPS AND FREQUENTLY ASKED QUESTIONS (FAQS)

### TIPS

- Never place the Brava components in washers or dryers (except for bra) or in dishwashers, microwave ovens, electric dryers, etc.
- Never leave the Brava System in your car. Extreme heat or cold will damage it.
- Keep Domes and other components out of the reach of children. Improper use could result in suffocation.
- Keep Domes covered in protective storage and away from pets.
- Keep all system components away from pets, pests, lint, dust, heat and humidity.
- Use only AAA alkaline batteries.
- Do not wear the Brava® System during any type of exercise activity.
- Never shower with the SportBox.
- The System CANNOT be shared due to hygiene, when shared it can cause skin breakdown.
- The system can be used in high humidity environments.

## FAQs:

### *How can I best care for my skin when using the Brava System?*

Clean torso and apply No-Sting Skin Prep where Domes come in contact with the skin, allowing the skin to dry completely before placement of Domes.

After use, always clean the Dome's tacky sole with the Brava Dome Cleanser.

After wear, use Brava Skin Lotion to soothe and nourish the skin.

### *My Domes are less tacky, what can I do?*

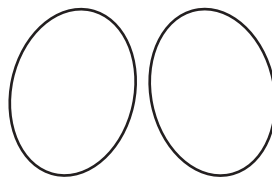
After use, always clean the Dome's tacky sole with the Brava Dome Cleanser (Baby Shampoo or Ivory® Bar Soap). Spray on, leave for a maximum of 10 minutes, rinse thoroughly and allow to air-dry. **DO NOT USE SOAPS CONTAINING CONDITIONERS OR MOISTURIZERS.**

**Do not use moisturizer, powder or deodorant when you are wearing the System. Never use paper products or towels to dry the Domes. Never dry Domes in direct sunlight. Never use harsh chemicals on the Dome's tacky surface. Never use any product that contains antibacterial or moisturizer ingredients to clean the Domes. Store Domes and keep dust and pet hair away from the surface.**

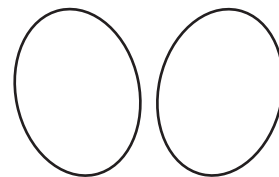
### *How do I get a proper seal?*

1. Clean the skin area in contact with the Domes.
2. Check that all connection points are secured (Domes to T - Tubing, T - Tubing to filter, Filter to SportBox and Domes to skin).

- a) For gaps between skin and Dome, apply gentle but consistent pressure with your hands, pressing the Domes to your chest preventing air from entering. Maintain pressure until seal is achieved and pump stops. Anatomical variances in rib cages and chests may require repositioning the Domes. See Figures 1a and 1b.
- b) If your chest is damp or the No-Sting Skin Wipe has not dried, you will not achieve a seal (any moisture to either surface will prevent proper contact). Remove the Domes, wash your chest, rinse, dry and re-apply No-Sting Skin Prep (one per wear session), allow it to dry for 10 minutes before re-applying Domes.



**Figure 1a: Inward Facing**



**Figure 1b: Outward Facing**

- c) Flare out the Dome's gel to prevent it from folding inside the shell when the pump is activated. If gel rim rolls underneath the shell, the seal is easily lost and over time they will become less efficient.
- d) **DO NOT** allow Domes to overlap as this can cause the loss of seal and sternum pain.
- e) Ensure that as much of your breast tissue as possible is **INSIDE** the Dome. The tacky sole should not be on the soft breast tissue thus avoiding unnecessary friction.

3. Clean the tacky sole.
4. Check for any open area between your skin and the gel rim. Excessive pilling or balling on the Dome's tacky sole can cause leaks. While pilling or balling is normal with use, excessive amounts may require Dome replacement. Always follow proper cleaning procedures with recommended products.
5. Evaluate Dome size. If your nipples touch the inside of the Dome, you need larger ones. As a rule, when the distance between the nipple and inside of the Dome is approximately 1/2" (1.27 cm) at peak swelling (i.e., at the end of your 10 hour session while your System is ON and under vacuum), you should move to a larger size dome.

### *If the alarm sounds, what does this mean and what should I do?*

If the Alarm is ON and the seal is broken for a period of 10 minutes, the alarm automatically sounds for 1-minute. Turn both the alarm and pump OFF by pressing each button and then press them again to turn both ON. Gently press both Domes toward your chest to remove excess air. Ascertain that all edges of the Domes are flat on the chest and not rolling inward and that the tacky sole is properly adhered to the chest. Maintain the gentle pressure on the Domes until the pump stops, signaling a seal has been achieved.

\* No-Sting Skin Prep® is a registered trademark of Smith & Nephew.



### ***What do I do if the pump does not turn off?***

There are a few possible solutions if the pump remains on for more than 10 minutes at a time.

- 1.** Check Dome connections. If tubing is loose, reconnect each. If the ends are frayed, trim a small amount and reconnect to ports.
- 2.** Check to ensure that both Domes are positioned securely. Press down on each to ensure a tight seal and maintain pressure until pump stops.
- 3.** If the SportBox continues to pump for more than 10 minutes and all other checks have been completed, it may need cleaning. (Refer to Caring for your SportBox) To ensure proper operation of your SportBox, connect the tubing without the filter to the SportBox port and then kink the tubing by folding, turn on the SportBox. If your SportBox turns off when the tubing is kinked, it is functioning properly. You should replace the filter and re-attach your System.

**NEVER USE THE SPORTBOX WITHOUT FILTERS. ROTATE FILTERS DAILY FOR OPTIMAL PERFORMANCE. IT MAY BE NECESSARY TO CHANGE YOUR FILTERS DURING WEAR SESSIONS WHEN POST-OPERATIVE DRAINAGE GETS IN DOMES, TUBING OR FILTERS. DISCARD SOILED FILTERS.**

- 4.** If your SportBox still does not turn off, contact Brava® Customer Care.

### ***I noticed that my breast is touching the inside of the Dome. Is that OK?***

No. If the tip of your breast or nipple touches anywhere inside the Dome, you have outgrown your Domes. Discontinue use immediately to avoid skin changes such as blistering and contact Brava Customer Care or your physician.

### ***Should I experience any pain when using the Brava® System?***

You should never feel pain when using the System; however, it will take a few days of adjustment to reach your personal comfort level. Sometimes pressure is felt at the chest mid-line area, unzipping the bra approximately 1/2 of the way down (you may secure it with a safety pin) reduces the pressure.

If pressure persists or you experience any other type of pain when using the System, please discontinue use immediately and contact your Physician or Brava Customer Care Representative.

### ***The Domes seem too large for me. How do I know that I am in the correct size?***

Domes were designed to allow for expansion. There should always be between 1/2" to 2 1/2" from your breast to the inside of the Dome at the end of a 10-hour or greater wear session and while the vacuum is on.

### ***If I see any skin irritation or experience any discomfort at the mid-line of my chest, can I keep wearing the System?***


No. Stop wearing the System if your skin is irritated or excessive tenderness is felt in chest or ribs. Call Brava Customer Support or your physician.

### ***Can I use any tapes or Band-Aids to cover tender areas while wearing Brava?***

Do not use any restrictive items such as tapes or bandages anywhere where the Domes make contact with the skin or on the skin inside the Domes. Your skin will expand during wear but the bandaged area will not. This may cause blistering, requiring you to temporarily discontinue use.

# ELECTROMAGNETIC COMPATIBILITY TABLES

Guidance and manufacturer's declaration- electromagnetic emissions			
The BRAVA AFT is intended for use in the electromagnetic environment specified below. The customer or the user of the BRAVA AFT should assure that it is used in such an environment.			
Emission test	Compliance	Electromagnetic Environment-Guidance	
RF emissions CISPR 11	Group 1	The BRAVA AFT 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.	
RF emissions CISPR 11	Class B	The Brava AFT is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes	
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies		
Guidance and manufacturer's declaration- electromagnetic immunity			
The BRAVA AFT is intended for use in the electromagnetic environment specified below. The customer or the user of the BRAVA AFT should assure that it is used in such an environment.			
IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD)  IEC 61000-4-2	± 6 kV contact  ± 8 kV air	N/A  ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines  ± 1 kV for input/output lines	N/A  N/A	Internally powered
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)  ± 2 kV line(s) to earth	N/A  N/A	Internally powered
Voltage dips, short Interruptions and voltage variations On power supply input lines  IEC 61000-4-11	< 5% <i>U</i> <sub>T</sub> (> 95% dip in <i>U</i> <sub>T</sub> ) for 0,5 cycle 40% <i>U</i> <sub>T</sub> (60% dip in <i>U</i> <sub>T</sub> ) for 5 cycles 70% <i>U</i> <sub>T</sub> (30% dip in <i>U</i> <sub>T</sub> ) for 25 cycles < 5% <i>U</i> <sub>T</sub> (>95% dip in <i>U</i> <sub>T</sub> ) for 5 s	N/A  N/A  N/A  N/A	Internally powered
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Internally powered
NOTE <i>U</i> <sub>T</sub> is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration- electromagnetic immunity			
The BRAVA AFT is intended for use in the electromagnetic environment specified below. The customer or the user of the BRAVA AFT should assure that it is used in an environment.			
IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the BRAVA AFT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div></div>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p><sup>a</sup> 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 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 BRAVA AFT is used exceeds the applicable RF compliance level above, the BRAVA AFT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BRAVA AFT.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the BRAVA AFT			
The BRAVA AFT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BRAVA AFT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BRAVA AFT as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output Power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80 MHz $d = 1.2 \sqrt{P}$	80MHz to 800 MHz $d = 1.2 \sqrt{P}$	800MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



## Technical Section:

- Internally Powered.
- Type BF Applied part.
- IP 22 protection - Ingress Protection (IP) define degree of protection. IP22 indicates that the SportBox is protected against medium size foreign bodies of diameter less than 12mm (eg. finger) and is resistant to light rain and wind.
- Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- Unit is for continuous operation.
- For any material consumed, use local guidelines when disposing of plastic and batteries.
- In the event that the device is not functioning properly due to potential electromagnetic or other interference, move to another location to avoid interference.
- Under no circumstances should this System be used with any product or product part that is not from the manufacturer.
- Batteries should be removed if the SportBox will not be used for a prolonged period of time.
- The domes are made of materials that should not be punctured or sliced. They should not be stored, transported or operated at temperatures below 5°C or above 40°C. Avoid placing the domes in a location with severe temperatures (such as a car's trunk in summer weather) as the System could become damaged.
- The electronics should not be operated, stored or transported at temperatures below 5°C or above 40°C, and should not be stored, transported or operated in an environment where the humidity is below 15% or above 93%.
- The electronics should be used under an atmospheric pressure range of 700 hPa to 1060 hPa.
- Service life of the device is in line with the product warranty and is 90 days for domes and 180 days for SportBox. All other accessories have a service life of 180 days.
- Should your system need repair, contact manufacturer.

## Symbols and Marks Explained:



· European Authorized Agent



· Operating Instructions



· Manufacturer and year built



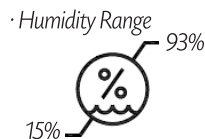
· Product number



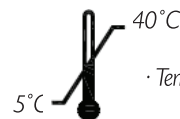
· Type BF Applied Part



· Power "ON" / "OFF" (push-push)



· Humidity Range



· Temperature Range

### FCC REQUIREMENTS

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:  
(1) This device may not cause harmful interference,  
and (2) this device must accept any interference received, including interference that may cause undesired operation.







# Help Information

For additional information on the Brava® Systems please  
visit our Web site at [www.brava.com](http://www.brava.com)

To Contact Brava® :

In U.S. call Brava® Customer Care 1-800-407-5304 or write to:



Brava® LLC  
14221 S.W. 142nd Street,  
Miami, Florida 33186, U.S.A.

In Europe, please contact the Brava® Representative:



Emergo Europe  
Molenstraat 15, 2513 BH,  
The Hague, The Netherlands

B R A V A®



Brava® is a registered trademark of Brava, LLC. SportBox, the Lotus & Stamen design and the tagline "The Only Clinically Proven Nonsurgical System for Breast Enhancement and Shaping" are also trademark of Brava, LLC.