



SAFE ENCLOSURE™

MODEL SSE-450:

COLLAPSIBLE FRAME AND ONE PIECE INSIDE HANGING CANOPY USER MANUAL

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CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. This device should only be used for the person for whom it was prescribed and only for the use for which it was intended.

If you do not have a prescription, do not use this device.

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FEATURES AND APPLICATIONS

The Soma Safe Enclosure™ provides the safe, humane, least restrictive alternative for the patient who would otherwise need to be restrained. Zippers sewn into the netting provide access to the patient. By creating a more secure, manageable environment, the patient becomes much less disturbed. Freeing the patients' extremities from restraints, patients can vent their restlessness with little or no danger of inflicting injury on themselves or others. This is a product that can be used in the acute, sub-acute, long term and home care settings.

Features and Construction

- The soft nylon mesh siding prevents patient injury while providing a safe alternative to conventional restraints.
- The durable, lightweight aluminum frame is fully padded leaving no hard or rough edges that might injure fragile skin.
- The enclosure fits most standard hospital type bed, manual or electric.
- The side panels are made from antibacterial medical grade nylon.
- The strong interlocking zippers ensure added safety.
- The canopy provides access ports for IV lines, catheters, and medical tubing.

Uses and Benefits of the Soma Safe Enclosure™

May be used for many forms of dementia or neurological disorders that require special safety measures including:

FALL RISK	Closed Head Injury
Alzheimer's Related Disorders	Cerebral Vascular Accident
Huntington's Chorea	Parkinson's patients
Limited Cognitive Ability	Rhett's Syndrome
Substance Abuse Withdrawal	Delirium

- Provides safety, comfort, and a sense of security.
- · Permits freedom of movement with open visual contact.
- Provides ease of access for the caregiver without the back strain of low beds.
- Allows peace of mind for the caregiver and dignity for the patient.

Patients who may require additional Observation

- Violent, aggressive or combative patients.
- Suicidal & Homicidal patients.
- Multiple line patients who try to pull out or disconnect their lines. Chest Tube Pullers –

Warnings against the use of the Soma Safe Enclosure™

- Burrowing behavior Patients who persistently try to push themselves into corners of the bed, other small spaces or try to climb under the mattress.
- Excessive PICA eating disorder.
- Patients who weigh less than 46 pounds or more than 300 pounds. Patients who are less than 45 inches in height or more than 6 feet 4 inches in height.

Evaluation before use of the Soma Safe Enclosure™

- Due to the nature of some patients' diagnoses, activity levels or uncontrolled movements, the Soma Safe Enclosure™ will not be suitable for every patient.
- Any adjustable bed has the potential for patient entrapment. The entrapment potential may be
 the result of the bed design and dimensions, bed configuration and articulation and the patient's
 medical condition. These issues must be assessed before and during use.
- EACH PATIENT MUST BE ASSESSED BY A TEAM OF MEDICAL PROFESSIONALS, IN-CLUDING A PHYSICIAN, TO DETERMINE IF THE SOMA SAFE ENCLOSURE™ AND AS-SOCIATED MEDICAL BED CAN BE USED SAFELY WITH THE PATIENT.

SUGGESTED PATIENT CHECKLIST

Suggested checklist for Soma Safe Enclosure™ (based on JCAHO Restraint and Seclusion Standards for Behavioral Health effective January 1st, 2001)

During the evaluation, the following should be addressed:

- 1. Check for any sign of injury.
- 2. Offer adequate hydration and check need for elimination.
- 3. Check circulation of all extremities and offer range of motion exercises.
- 4. Vital signs as ordered by the physician.
- 5. Physical and psychological status and comfort.
- 6. Readiness for discontinuation or partial use of system (e.g. at night only).

The use of video and audio equipment may be less disruptive to the individual than physical monitoring, but the equipment must be monitored frequently.

JCAHO calls for a minimum of a physical assessment at least every 2 hours. When a state regulation is stricter, that regulation overrides the organizational policy or individual order.

Monitoring determines: Physical and emotional wellbeing, patient rights, dignity, safety, and whether the device is the least restrictive possible.

For 15 minute checks:

Is the patient free from injury?
Is the patient calm and comfortable?

For 2 hour checks:

Date:

Time	Vital Signs/ Skin/ Circula- tion	Orientation to time and place	Anxiety level: Restless, Calm, Sleeping	PO Intake	Output (toileting offered)	ROM, Exercise, or Ambulation	Initials
12:00 AM							
2:00 AM							
4:00 AM							
6:00 AM							
8:00 AM							
10:00 AM							
12:00 PM							
2:00 PM							
4:00 PM							
6:00 PM							
8:00 PM							



Failure to follow these Warnings and Instructions contained in the User's Manual could result in patient entrapment, serious injury or death.

The Soma Safe Enclosure™ can only be used when authorized or prescribed by a physician's order.

The Soma Safe Enclosure™ must not be used with patients who weigh less than 46 pounds or more than 300 pounds or with Patients whose height is shorter than 45 inches or taller than 6 feet 4 inches.

Patients, who exhibit burrowing behavior, are violent, aggressive, combative, suicidal, subject to seizures, have multiple lines, or have an excessive PICA eating disorder may need to be more closely monitored as determined by a licensed caregiver and or hospital policy.

When not in direct observation of the patient, keep all side and end flaps zipped closed with zipper tabs at the extreme ends to prevent patient access to back side of zippers tabs.

Keep bed head and knee functions in the lowest possible position except when pursuant to a physician's order.

Always keep the bed hi-low function in the lowest possible position without suspending the canopy except when attending to the patient.

Put the head and foot sections in the down or flat position before raising the bed with the Hi-Low function. Raising the head or foot sections while the bed is in the Hi position could damage and breach the canopy allowing the patient to get out.

Any mattress used with this product must be at least eighty-inches long by thirty five-inches wide and no more than six inches thick and be hospital grade or is a mattress provided by Vivax Medical. Air therapy or water mattresses should only be used for medical purposes and with a physician's order.

When leaving the patient unattended, the bed side rails must be raised and secured in the up-most position.

When using a separate bed with the Soma Safe Enclosure[™], it must specifically be a medical/hospital bed with head and foot boards installed and equipped with side rails in the up position when the patient is unattended.

Keep the bed and frame casters locked at all times other than when the Soma Safe Enclosure™ needs to be moved.

The Soma Safe Enclosure™ does not substitute for regular supervision by caregivers. TO ENSURE

PATIENT SAFETY, assess patient at regular intervals as prescribed by a physician, hospital policies, JCAHO, state or federal guidelines or regulations.

Before each usage, inspect the Soma Safe Enclosure™ for damaged or missing parts, check fabric and netting for tears or separated seams ensure all zippers work freely and check for potential entrapment zones. DO NOT use the enclosure if any parts are damaged, missing or working incorrectly. ONLY use authorized replacement parts supplied by the dealer or manufacturer.

Mechanical suffocation and suffocation by ingested objects such as IV lines, small objects, plastic films and even sheets and blankets, may pose a patient risk. A physician should assess if patients can be safely left unattended with any objects or articles inside the enclosure that could cause patient suffocation.

Locations where Soma Safe Enclosures™ are used should have fire protection such as fire detectors, smoke detectors or sprinkler systems.

Soma Safe Enclosure™ low bed models may be used as a low bed or as a safety bed enclosure. When using the low bed functionality for patient safety and leaving the patient unrestrained and unattended the bed must be in the lowest possible position with the side rails removed or in the fully up position. Side or end flaps must be left either fully and completely open or fully and completely closed. There must be policies and procedures in place and being followed for use of low beds that ensure patient safety.

Never leave patient unattended in bed without following the above steps.

Due to the nature of some patients' diagnoses, activity levels, or uncontrolled movements, Vivax Medical Corporation cannot guarantee the suitability of Soma Safe Enclosures™ for every patient.

Any adjustable bed has the potential for patient entrapment. This entrapment potential is a result of both bed system configuration and patient medical condition and needs.

Each patient should be assessed by a team of medical professionals, including a physician, to determine if the bed can be used safely with that patient. If you experience patient care problems, contact the patient's physician and Vivax Medical Corporation at 866-847-7890 for assistance.

SOMA SAFE ENCLOSURE™ INSPECTION CHECKLIST

Before Each Patient Use and Periodically as Necessary

- 1. Inspect all seams of the canopy for integrity of stitching. Make sure there are no open seams or that stitching is frayed or broken.
- 2. Inspect all zippers to insure they are working properly and are not broken.
- 3. Inspect the canopy fabric for tears, holes or punctures.
- 4. Inspect the bottom of the canopy for tears or broken mesh. There are designed holes that are intended to be in the bottom. These are intended to be there. They should have sewn collars around the edges to prevent tearing. Ensure the integrity of these holes.
- 5. Make sure that all collars that hold the canopy to the frame are fully zipped closed.
- **6.** Inspect all frame parts for breaks, bending or other damage.
- 7. Ensure that the locking bolts are applied when in use.

The above items represent patient safety risks if they are not in proper condition and working order.

DO NOT USE THE SOMA SAFE ENCLOSURE™ WITH A PATIENT UNTIL ALL OF THESE ITEMS ARE CORRECTED AND THE CANOPY IS IN PROPER CONDITION.

SOMA SAFE ENCLOSURE™ PATIENT PLACEMENT CHECKLIST



Important Safety Considerations



- *** Be sure to zip zippers to <u>the absolute end of zipper track</u> with zipper tabs down and zippers tight together. Zippers on sides should be zipped to head end of bed
- Bed should be in lowest position with bed frame supporting the mattress.
 Head and knees flat unless alternate position is medically necessary. Netting should be taut.
- Side rails should be raised.
- Be sure that all unused I.V. and catheter ports are zipped closed. Any that
 are in use should be zipped as closed as possible without interfering with the
 tubing.
- Be sure that there are no objects left in enclosure with patient that could be used to hurt patient or enclosure.
- Be sure to make sure the net or vinyl has no tears or holes.
- Be sure physician order has been obtained, and proper documentation according to hospital policy has been completed.
- Be sure to monitor patient frequently according to hospital policy.

PATIENT EMERGENCY EVACUATION PROCEDURE FOR THE SOMA SAFE ENCLOSURE

- 1. Go to the Left or Right of the Soma Safe Enclosure™.
- 2. Locate the zipper pull-tabs on the Side Access Panel.
- 3. Unzip the zipper by pulling each zipper pull-tab to the left or right uppermost corner of the Side Access Panel.
- 4. Place the Side Access Panel on the top of the Soma Safe Enclosure™.
- 5. Remove the Patient through the side just opened.

SPECIFICATIONS

Dimensions	Width	Length	Height
Frame only	39.0"	93.0"	72.0"
Frame w/Net installed	40.5"	94.5"	72.0"
Frame Extended w/Net installed	40.5"	100.5"	72.0"

Weight:

- Frame Only......97 lbs.
- Net Only 24 lbs.
- Fully Assembled 119 lbs.
- Shipping Weight 124 lbs.

Materials:

- Frame: Extruded Aluminum Tubing, which is powder coated
- Enclosure: 3/8" Hexagonal Polyester Netting; 13 oz. Vinyl Laminate (flame resistant, fluid proof, color stable, mildew/fungal resistant, antibacterial, durable, and dirt/stain resistant.)
- Other:
 - o Foam Pads are 3/8" thick, closed cell polyethylene.
 - Pad Covers are stretchable reinforced vinyl.

Engineering Specifications

Frame:

The frame is constructed with 1.5" x 1.5" square .125 thick extruded aluminum tubing that has a tensile strength of 42,000 psi and yield strength of 35,000 psi. Deflection, under a 350 lb. load centered on a 7' span of this material in accordance with ASTM A513, is 2.0". The frame is powder coated to prevent corrosion.

The frame is assembled using zinc plated $3/8-16 \times 2.5$ ", nylon locknut/zinc $3/18 \times 16$, and double wire lynch pin $3/8 \times 2.25$ " grip strength.

Canopy:

The Canopy netting consists of 100% polyester, .375 hexagonal, fire retardant black netting that meets NFPA 701 large scale fire retardant test and a strength test of a minimum of 100 P.S.I.

The material used for the structure is a 5.7 oz./sq. yd., 400-denier nylon, which is FRT coated and passes fire retardant test method NFPA 701. The nylon is tested for grab tensile (lbs.), Mullens burst (PSI), crocking, cold crack, lightfastness, abrasion resistance – 1000 cycles, spray rating, fire retardancy, and ravel.

The zippers used are: YKK #10 nylon separating, extremely strong and lightweight with teeth made from Delrin with polyester tape. The zipper is corrosion resistant, self-locking and operates smoothly. The zippers have excellent resistance to heat (up to 360° F) and to cold (to 60° below zero F) and melts at 480° F, higher than normal laundry temperature.

The thread used is #92 bonded polyester teal thread.

SET UP INSTRUCTIONS FOR USE OF THE SSE-450, COLLAPSIBLE FRAME

OPENING THE FRAME



The SSE collapsible frames are designed for ease of use and storage. There are no loose parts or assembly required.

To open the frame from the fully collapsed position and secure it for use with a bed and canopy, the following procedure should be followed:

Be sure to keep all body parts clear from any potential pinch points. Be sure to support frame at all times until all pins are securely installed. Be aware of your surroundings at all times to avoid potential injury to yourself, others, and surrounding equipment.

Step 1.

Start by removing pins from both sides of all four corner brackets if previously inserted as shown below. Position the frame so you are facing one of the width ends as pictured below. To identify the width ends, the short bars with the pins toward the top and bottom should be facing you.





Step 2.Pull the pins out of the four hinge brackets (lower and upper) on both width ends of the frame.



Step 3. Spread the frame open width wise by exerting pressure outward on the vertical posts as shown below. (*Note: Continuously support the upper frame on the side you are handling until all pins are properly inserted. Also note, when opening, always start with the bottom first. When collapsing, always start with top first.)



Step 4.
Line the hole in the hinge brackets (upper and lower) with the hole in the horizontal tubes and reinsert the pins in all available holes as shown above. Make sure the small locking ball on the pin protrudes through the opposite side. (*Note: When opening, always start with the bottom first. When collapsing, always start with top first.)



Step 5.Facing the length sides of the frame, remove the pins (two per side) on both sides from the hinge brackets as shown above.



Step 6.

Spread the frame open by initially pushing outward on the vertical posts. After the frame has been opened about halfway, it will want to open the rest of the way by itself. Grab the two upper horizontal bars and gradually push them upward, as shown above, until they are in the horizontal position. (*Note: Continuously support the upper frame on the side you are handling until all pins are properly inserted. Also note, when opening, always start with the bottom first. When collapsing, always start with top first.)

Step 7.

Insert the locking pins through the holes in the upper hinge bracket and the horizontal bars on both sides until the locking ball in the pin is protruding from the other side of the hinge. (*Note: Continuously support the upper frame on the side you are handling until all pins are properly inserted.)



Step 8. Insert the 8 locking pins through the holes in the 4 upper corner brackets, as shown below, until the locking ball in the pin is protruding from the opposite side. (Tip: Slight upward pressure of jog arm may be required to properly align hole.)

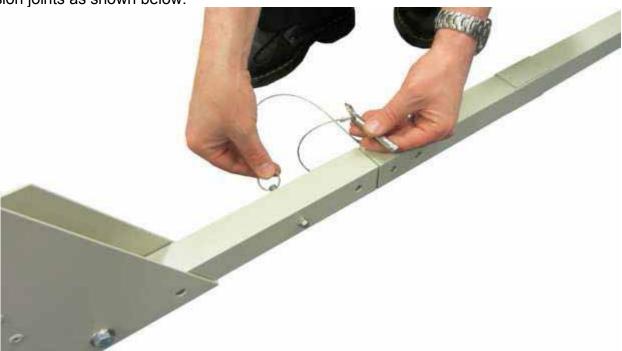


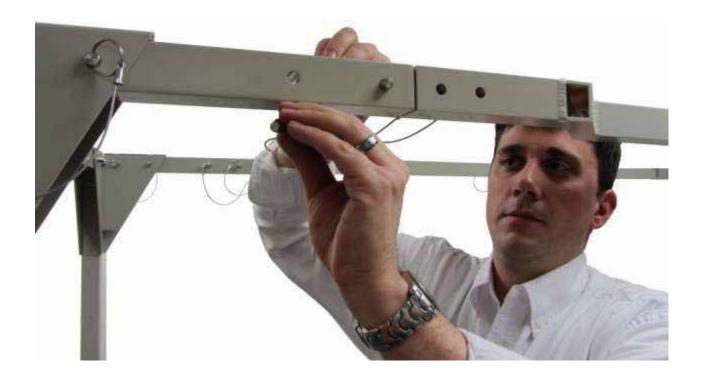
At this point, if expansion of the frame is not necessary proceed to page 18 "PLACING A BED IN THE FRAME".

EXPANDING AND CONTRACTING THE FRAME

Step 1.

There are 8 expansion points (splice bars) on each long side of the frame, 4 on the top horizontal bar (jog arm) and 4 on the bottom horizontal bar. Remove the locking pins from the top and bottom expansion joints as shown below.





Step 2.

Expand the frame by pushing outward on the horizontal bars separating the two pieces and exposing the splice bar. Try to expand the top and bottom expansion joint as evenly as possible to avoid binding. Align the holes in the splice bars and horizontal bars. (*Note: Be sure not to expand frame beyond length of splice bar.)



Step 3.Replace the locking pins by inserting each into the aligned holes until the locking ball in the pin protrudes through the opposite side and is locked in place.



Step 4. Repeat this process on the opposite side.



TO CONTRACT THE FRAME SIMPLY REVERSE THIS PROCESS. BE SURE TO CONTRACT THE TOP AND BOTTOM EXPANSION JOINTS EVENLY A LITTLE AT A TIME TO AVOID BINDING.

PLACING A BED IN THE FRAME

Step 1.Pull the pin out of the lower horizontal hinge bracket on ONE side as shown below.



Step 2.Lift both halves of the horizontal bar to the vertical position as shown below. Wrap lanyard around vertical corner post and insert pin into horizontal bar to prevent from falling. Repeat on opposite end as shown below.



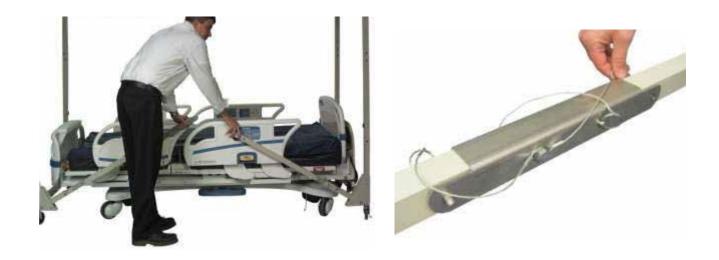
Step 3.

Push the bed in at an angle, as shown below. When one end is in as far as it will go, push the opposite end in so that the bed is totally inside the frame. (*Note: Remove headboard and footboard if necessary. Be sure to reinstall after hanging canopy.)



Step 4.

When the bed is inside the frame, lower the two halves of the horizontal bar as shown below and reinsert the pins. For added safety, the outer locking pins can be inserted from the inside of the frame to reduce lanyard slack as shown in the picture below.



CANOPY INSTALLATION

THE CANOPY MAY BE SET UP IN EITHER OF TWO POSITIONS – ONE FOR THE EXPANDED POSITION AND ONE FOR THE CONTRACTED POSITION.

There are two sets of zippers on each of the collars including the horizontal top collars and the vertical post collars. The outermost zippers on the vertical post collars are used for the expanded frame position. See Below.

The outermost zippers on the top horizontal collars are used for beds needing a lower canopy position. These beds include older hospital beds. Use outermost zipper on top head end collar, top foot end collar and 4 vertical collars when frame is in expanded position (StrykerTM beds). See below.

After the canopy is installed, insert the mattress and place the bed in its lowest position. If the canopy does not touch the pan (hammock-like position) then the outermost zippers should be used to put the canopy in the lowest position. (*Note – the canopy will settle once the mattress is installed, so be sure to examine the height after the mattress has been installed.)







Please follow the step by step installation instructions below for proper installation and use. Step 1.

Identify the head end of the canopy by the wording "HEAD END" marked on the top canopy collar. The IV zipper portals and zip to line patch are also on the head end. Lay this end on the head end of the bed.



Step 2.

Starting with an end, place the collar around the horizontal end bar and attach it securely on the bar by zipping it closed, as shown below. Go to the opposite end and place the collar around the upper horizontal end bar and secure it in place by zipping it closed.



Step 3.

Go to the side of the canopy and wrap the collar around the upper horizontal side bar and secure it on the frame by zipping it closed, as shown below. Repeat this process on the opposite side.

Step 4.

There are four vertical collars that attach the canopy to the four vertical posts. Wrap these collars around the vertical posts and secure them by zipping both sides together, as shown below.





Step 5.

Open a side access panel and place the mattress inside the canopy. If installing a Versicare™ low air loss mattress see page 28 "SOMA SAFE ENCLOSURE™ SET UP ON VERSICARE™ BED WITH AIR MATTRESS MANIFOLD"



Step 6.
BE SURE ALL PANELS ARE CLOSED WITH ZIPPERS ABOVE LINE ON "ZIP TO LINE" PATCH, AS SHOWN ABOVE!

When the Soma Safe Enclosure™ is set up, it should look like one of the pictures below. (*Note: If headboard and footboard were removed, install now.)



After bed and enclosure are in place, be sure to engage bed locks and frame caster locks.

CLOSING THE FRAME

*Note: THE FRAME <u>MUST BE CONTRACTED PRIOR TO CLOSING</u>
See page 15 "EXPANDING AND CONTRACTING THE FRAME" for instructions.

Step 1.

Facing the length of the frame, remove the pins from the upper corner posts as shown below. Remove pins from the hinge bracket in the middle of the upper and lower horizontal bars on both sides (*See magnified image below). Holding the horizontal bars, allow the top of the frame to collapse in on it self so that it forms a pyramid as shown below.

(*Note: When collapsing, always start with top first. When opening, always start with the bottom first.)



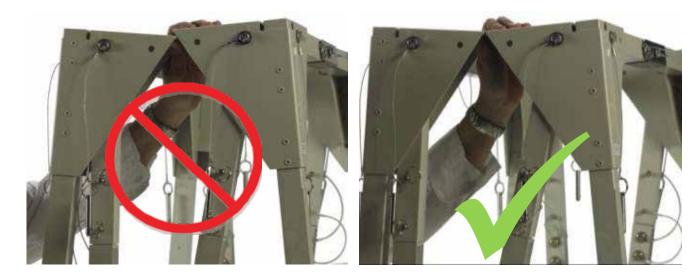
Step 2.

Step inside the frame and lift the lower horizontal bars, as shown below. This will draw the bottom of the frame to the closed position. When the frame nears the closed position, place one foot on outside of frame to prevent frame from sliding. Step out of the frame and complete the lengthwise closure from outside. (*Note: Be sure to lower your head to avoid collision with frame.)



Step 3.Make sure the lower hinge brackets fit around the vertical posts so holes on brackets and posts line up.

BE SURE UPPER CORNER POSTS DO NOT OVERLAP, AS SHOWN BELOW.



Step 4.Replace the pins through the holes in the hinge brackets ensuring the locking balls in the pins protrude from the opposite side.



Step 5.

Facing the width end of the frame, remove the pins from the upper and lower horizontal bars and push the vertical posts toward each other as shown above until the posts fit into the slots on the hinges. Align the holes in the hinges with the frame and insert the pins until the ball lock protrudes from the opposite side as shown below.

(*Note: When collapsing, always start with the top first. When opening, always start with bottom first.)





Step 6. The frame is now ready for storage and/or transport.



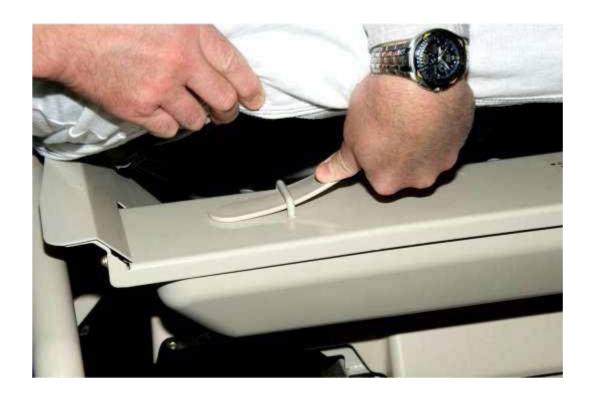
SOMA SAFE ENCLOSURE™ SET UP ON VERSICARE™ BED WITH AIR MATTRESS MANIFOLD

The HillRom Versicare™ mattress has a manifold that must be carefully disconnected prior to mattress removal, and then carefully re-connected after net installation.

To begin, the frame must be contracted by pressing the foot in button on the side rail. When the footboard is retracted to at least midway, the frame can be set up as usual.

Unplug the bed. Remove the head and foot boards; be sure the side rails are down.

Remove the mattress. The mattress is attached to the bed frame with 4 plastic tabs, 2 at the head and 2 at the foot. Lift the mattress up and carefully slide the tab out from under the retaining rod at each attachment point.



The manifold is located at the head end of the bed just below the 2 mattress tabs. The manifold is attached to the bed with 3 tabs that must be released with a small screwdriver or other small flat device.

Insert the screwdriver in-between the tab and the manifold and pry outward to the side of the bed. Gently pull the manifold out from each side.



Once all 3 tabs and the manifold are disconnected, the mattress can be removed. The net is then placed over the frame and zipped in as usual.



The mattress must then be reconnected.

To start, locate the large zippered opening at the bottom head end of the Soma Safe Enclosure™ net and unzip this opening from the outside of the net.

Placed the mattress inside the enclosure and push the manifold attachment through the opening.



The manifold must now be re-attached to the bed. Put the manifold in place and locate the 3 tabs. Center the tabs and the manifold so they can be pressed together. Press them carefully together until the tabs engage and the manifold is attached.



Place the mattress tabs (2 at the head and foot end) through the slots in the net bottom and push them under the tabs to secure the mattress.



Plug in the bed and the mattress should begin to re-inflate. Extend the foot board until it is about an inch from the SSE frame. Replace the head and foot boards.

Raise the side rails, adjust the net and frame so that the net is centered and tight.

Remind nursing that foot board must be removed prior to extending the foot board through the frame if bed is used for a tall person.

The enclosure should look like this.



ACCESSORY PORTS

There are a variety of access ports to allow I.V.'s, Foleys, air mattress support systems, vents, call buttons, remotes, etc. to be placed for patient care, comfort and safety. All access ports are zipper controlled with access only from the outside.

There are four I.V. or call button access ports – two on each side. One is located near the patient's wrist and the other is located adjacent to the vertical collar on the side panel at the head end of the enclosure. Un-zip or open the zipper and place the device through the opening. Close the zipper part way to secure the line in place. Be careful not to crimp or pinch the line.

There are two Foley ports – one on each side adjacent to the patient's lower abdomen. These openings are larger than the I.V ports to allow the bag to pass through without the need to disconnect the tubing.

There are two additional openings – one at the head end and one at the foot end. Both are located at the bottom of the zippered panel. These ports can be used for additional lines, tubing or air-mattress connections as needed.

The bottom of the net has a variety of openings which allow connection to various mattresses and support surfaces. Be sure to keep all unused ports zipped closed when not in use.



CARE AND MAINTENANCE FOR THE SOMA SAFE ENCLOSURE™ CANOPY

The Soma Safe Enclosure™ canopy should be cleaned frequently in accordance with JHACO, FDA, and Institutional Policies. Experience has shown the following procedures to work satisfactorily.

Method:

- The preferred method of cleaning the One-Piece Canopy is to use a commercial laundering machine. It is critically important that the water temperature does NOT exceed 140 degrees Fahrenheit.
- 2. When machine-washed, the rinse cycle should use cold water.
- **3.** Treatment with an antibacterial per the manufacturer's instructions is recommended.
- 4. Machine air only drying, hang drip dry or outside hang drying should be used. **NEVER dry in** a machine using warm or hot air!

VIVAX MEDICAL CORPORATION STANDARD WARRANTY

- 1. THE WARRANTIES PROVIDED HEREIN ARE THE EXCLUSIVE WARRANTIES MADE BY THE SELLER TO BUYER. SELLER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED BY LAW OR USAGE. SELLER DISCLAIMS AND BUYER WAIVES ALL EXPRESS AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. BUYER ACKNOWLEDGES THAT THE DESCRIPTION OF THE PRODUCTS OR REPAIRS STATED IN BUYER'S PURCHASE ORDER IS FOR THE SOLE PURPOSE OF IDENTIFYING THE PRODUCTS.
- 2. As more specifically provided hereafter, Buyer's remedy for Seller's liability hereunder shall be limited solely to technical support and repair or replacement, which remedy shall be at Seller's option. Seller has no responsibility for reimbursing Buyer for repair or replacement costs incurred in connection with the Products, without Seller having given prior written authorization for such costs.
- 3. EXPRESS PARTS AND SERVICE WARRANTY: Seller guarantees its Products to be free and clear of defects in workmanship and material. Provided Seller is given written notice from Buyer of any defect in, or malfunction of, the product within one (1) year commencing from the date of shipment of the Product to Buyer as stated on Seller's Order Acknowledgment, Seller, at its option, will:
- i. Without charge, and within a reasonable period of time after receipt of such written notice, inspect such Products. If Seller, in its good faith judgment, determines that such defect or malfunction was caused by ordinary wear and tear, misuse, neglect, improper maintenance, improper installation, improper repair, alteration or accident with respect to the Products, Seller will have no obligation to Buyer hereunder.
- ii. If after Seller inspects the Products, Seller determines that the Product is covered by the Warranty granted hereunder, it will at its expense, provide technical support and repair or replacement to correct such defect or malfunction.
- 4. IN NO EVENT SHALL SELLER BE LIABLE TO BUYER FOR LOSS OF PROFITS, LOSS OF USE, OR DAMAGES OF ANY KIND BASED UPON A CLAIM FOR BREACH OF WARRANTY, OR FOR FAULTY WORKMANSHIP OR MATERIALS, INCLUDING WITHOUT LIMITATION, CONSEQUENTIAL DAMAGES OR INCIDENTAL DAMAGES, EVEN IF SUCH LOSS OR DAMAGE IS CAUSED BY SELLER'S NEGLIGENCE OR OTHER FAULT. NO OBLIGATION OR LIABILITY OF SELLER SHALL ARISE OUT OF SELLER'S RENDERING OF TECHNICAL ASSISTANCE OR SERVICE IN CONNECTION WITH THE PRODUCTS.
- 5. The warranty set forth in paragraph 3 shall not apply to multiple use disposables such as top sheets, mattress covers, conveyor sheets or other items with respect to which the general practice in the industry is not to provide a warranty (together, "Softgoods"), or to provide a more limited warranty, or with respect to which the Seller advises the Buyer in advance of accepting a purchase order that there is no warranty or a different warranty (together, "Excluded Products"). Excluded Products shall specifically include products or items not of our manufacture, with respect to which Seller shall only extend to Buyer the manufacturer's warranty, if any. The warranty set forth in paragraph 3 shall not apply to Softgoods, as to which Seller makes no warranties or guarantees. The warranty set forth in paragraph 3 shall not apply to Excluded Products (other than Softgoods), as to which Seller's warranty shall be limited in accordance with general industry practice or as otherwise disclosed in writing by Seller to Buyer in advance of Seller accepting the order with respect to such product.

SERVICE AND REPAIRS

Vivax strives to provide a high level of service to its customers. If you have any problem or dissatisfaction with our products, please call our Service Department immediately. We will do everything reasonably possible to address and handle your situation.

If your product requires repair or service, whether it is covered by warranty or not, please call our Service Department and they will arrange to have the repairs made on-site or will arrange handling otherwise required to place the equipment back into serviceable condition.

You may contact the Vivax Medical Service Department at:

Address: 54 Great Hill Rd.

Naugatuck, CT 06770

Toll Free: (866) 847-7890

Local: (203) 729-0514

Facsimile: (203) 729-0489

E-mail: somasafe@vivaxmedical.com