

SynCardia Systems, LLC
1992 E. Silverlake Road
Tucson, AZ 85713 USA
(520) 545-1234
(866) 771-9437
www.syncardia.com



CAUTION: The 50cc temporary Total Artificial Heart (TAH-t) is an Investigational Device - Limited by United States Law to Investigational Use.

CAUTION: In the United States, the use of the SynCardia 70cc TAH-t for destination therapy is investigational.

CAUTION: In the United States, the use of the Hand Pump with the 70cc TAH-t for the destination therapy indication or with the 50cc TAH-t is investigational.

CAUTION: Federal (USA) law restricts this device to sale by or on order of a physician.

The SynCardia Hand Pump is an accessory to the Companion 2 Driver System. The Hand Pump is designed to provide manual short-term emergency support of the SynCardia 50cc TAH-t or 70cc TAH-t in the event of a Driver failure.

The Hand Pump has two connectors that accommodate the left and right drivelines from the Companion 2 Driver. Once connected to the drivelines, the lever can be driven up and down by hand to generate pneumatic power.

*For information and description of the Companion 2 Driver System or the SynCardia TAH-t, please see the device **Operator Manual**.*

Setup of the Hand Pump

Remove SynCardia Hand Pump from shipping packaging and immediately execute the SynCardia Hand Pump Operational Check Form (found at the end of this manual).

Operation of the Hand Pump

Step 1: Connecting

In the event of a Driver failure (meaning the Driver is not pumping air), set the Hand Pump near the failed Driver:

- Pump Once: Grip the lever and pull the lever all the way up (**Figure 4**) and push all the way down (**Figure 5**) a few times. **Note**: Keep hand clear of lever slot while pumping.
- Disconnect the drivelines from the Companion 2 Driver by pushing the metal button in and lifting up (**Figures 1 and 2**).
- Quickly reconnect the Drivelines to the Hand Pump aligning **red** to **red** and **blue** to **blue** (**Figure 3**). A 'click' will confirm the Drivelines are properly connected.



Figure 1 and 2 – Removal of Drivelines from Driver

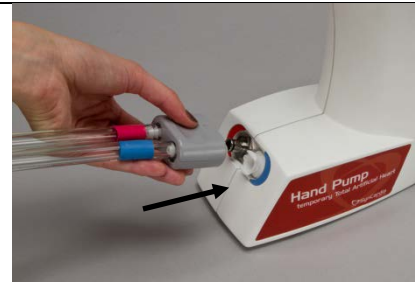


Figure 3 – Insertion into Hand Pump

Step 2: Pumping

Once the drivelines are connected to the Hand Pump, immediately begin pumping:

- Grip the lever and pull the lever all the way up (**Figure 4**) and push all the way down (**Figure 5**). **Note:** Keep hand clear of lever slot while pumping.
- Use your free hand to steady the Hand Pump during the pumping process
- One full lever stroke up and back down is one beat. Pump at 110 beats per minute. This is the same beat used in CPR compressions.
- Instruct another medical professional to obtain and start a replacement Driver
- In the event the primary operator becomes fatigued, it is recommended that a second operator be available to relieve the primary operator.



Figure 4 – Up Stroke



Figure 5 – Down Stroke

Step 3: Disconnecting

- Once the replacement Driver is ready, the drivelines must be moved from the Hand Pump to the running Driver.
- Disconnect the drivelines from the Hand Pump by pushing the metal button in and pulling the drivelines away from the Hand Pump (**Figure 6**).
- Quickly reconnect the Drivelines to the Driver aligning **red to red** and **blue to blue** (**Figure 7**).

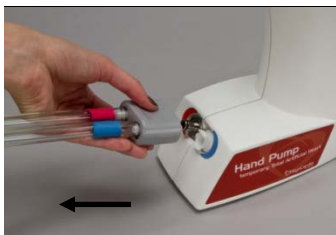


Figure 6 – Detaching Drivelines from Hand Pump



Figure 7 – Drivelines reattached to Driver

Indications for Use

- 70cc TAH-t Indication for Use

The SynCardia 70cc temporary Total Artificial Heart (TAH-t) is indicated for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from non-reversible biventricular failure.

The use of the SynCardia 70cc TAH-t for destination therapy (for patients who are ineligible for cardiac transplantation and for whom clinical indices indicate a remote likelihood of becoming eligible for a transplant) is investigational.

- 50cc TAH-t Indication for Use

The SynCardia 50cc temporary Total Artificial Heart (TAH-t) is indicated for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.

- Companion 2 Driver System Intended Use

The Companion 2 Driver System, used with the 50cc TAH-t or the 70cc TAH-t, is intended for use inside the hospital and on the hospital grounds.

- Hand Pump Indications for Use

The Hand Pump is indicated for use as an emergency accessory to the Companion 2 Driver System. It is intended to be used as an alternative source of pneumatic power for the 50cc TAH-t or 70cc TAH-t. The Hand Pump is not intended for out of hospital use.

Warnings












- Please see the Companion 2 Driver System Operator Manual for a complete description of the Companion 2 Driver System.
- No modification of this equipment is allowed. Do not disassemble the Hand Pump. If the Hand Pump needs service, the center should coordinate a return with SynCardia Systems, LLC.
- Do not expose the Hand Pump to water. Protect it from rain, showers, baths and liquid spills.
- If the Hand Pump is dropped or damaged, the center should coordinate a return to SynCardia Systems, LLC.
- Always keep the Hand Pump away from open flame. Do not operate in the presence of flammable anesthetics or other flammable gases.
- Only the Companion 2 Drivelines should be connected to the Hand Pump. No other objects should be connected to the Hand Pump.
- Use only SynCardia-approved components. The Hand Pump has been tested and approved as a system with the components listed in this manual.

Care/ Cleaning:

- Use extreme care when cleaning the equipment. Dust the equipment periodically with a soft, clean cloth.

- If you need to remove heavy dirt from the outside of the Hand Pump, dampen a soft, clean cloth and wipe the exterior of the housing gently.
- The Hand Pump has an expected mission life of at least 1 year; however, the unit may remain in the field as long as it is operational.
- No other maintenance needs to be performed on the Hand Pump.

Symbols Used in the Hand Pump Label

Symbol	Description	Symbol	Description
	Catalog Number	 or 	Refer to instruction manual/booklet
	Batch Code		Humidity Limitation
	Serial Number		Manufacturer
	Do Not Incinerate		Temperature Limitation
	Keep Dry		Atmospheric pressure limitation

Hand Pump Specifications

- Length: 40.9 cm (16.1 inches)
- Width: 15.8 cm (6.2 inches)
- Height: 23.4 cm (9.2 inches)
- Weight: 2.11 kg (4.65 lb)

Environmental Conditions

- Operating Temperature: 4.5° to 40°C (40° to 104°F)
- Transportation/Storage Temperature: -20° to 60° C (-4° to 140°F)
- Operating Humidity: 10-95% RH
- Transportation/Storage Humidity: 30– 85% RH (non-condensing)

Classification Hand Pump

- Class III Equipment, 21 CFR 860.93
- Ingress Protection: IP20
- Manually-Powered Equipment

EC

REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

CE

0086
16 MAY 2005

SynCardia Hand Pump Operational Check Form

SynCardia Systems, LLC
1992 E. Silverlake Rd.
Tucson, AZ 85713 USA
(520) 545-1234; FAX (520) 903-1782
Clinical Support: (866) 771-9437

Unit Serial Number: _____

Hospital: _____

Keep a copy of this form for your records.

Note: This procedure must be performed by trained persons only. Perform this test upon receipt and annually. Completed forms must be sent to SynCardia.

SET UP

Unpack the Hand Pump

Remove Hand Pump from Poly Bag	YES <input type="checkbox"/>	NO <input type="checkbox"/>
Remove Orange Shipping Caps from the Hand Pump's colder connectors	YES <input type="checkbox"/>	NO <input type="checkbox"/>
Record the Hand Pump serial number and hospital name at the top of this form	YES <input type="checkbox"/>	NO <input type="checkbox"/>

CHECK OUT

Perform an inspection to confirm SynCardia Hand Pump integrity:

Do the housings align?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
Are colder connectors firmly in place?	YES <input type="checkbox"/>	NO <input type="checkbox"/>

With one hand on the handle and the other on the foot of the Hand Pump, move the Hand Pump Handle up and down, through the entire stroke length

Does the Handle travel the entire stroke length easily and without obstruction?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
---	------------------------------	-----------------------------

Using Companion 2 Drivelines, connect the Hand Pump to the 70cc TAH-t and the Donovan Mock Tank with Normotensive settings. Using the Mock Tank Monitor, verify the following:

While pumping at 110 BPM does the Hand Pump achieve a minimum Cardiac Output of at least 3.5 L/min?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
---	------------------------------	-----------------------------

If the response to any of the above questions was 'NO', please contact the SynCardia Systems, LLC Help Line at (866) 771-9437.

Send a copy of this form to SynCardia Systems, LLC by FAX to (520) 903-1782	YES <input type="checkbox"/>	NO <input type="checkbox"/>
---	------------------------------	-----------------------------

COMMENTS:

Performed By: _____ Date: _____