

AbioCor[®] Implantable Replacement Heart

Instructions for Use

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1. System Description

The AbioCor System is intended to replace the patient's natural heart. It is designed for patients whose hearts are irreparably damaged or who are at imminent risk of death by heart failure.

The System can be divided into the Implanted system (Figure 1-1) and the External system. The Implanted system consists of the Thoracic Unit, the Implanted Controller, the Implanted TET, and the Implanted Battery. The External system consists of the AbioCor Console and the Patient Carried Electronics (PCE).

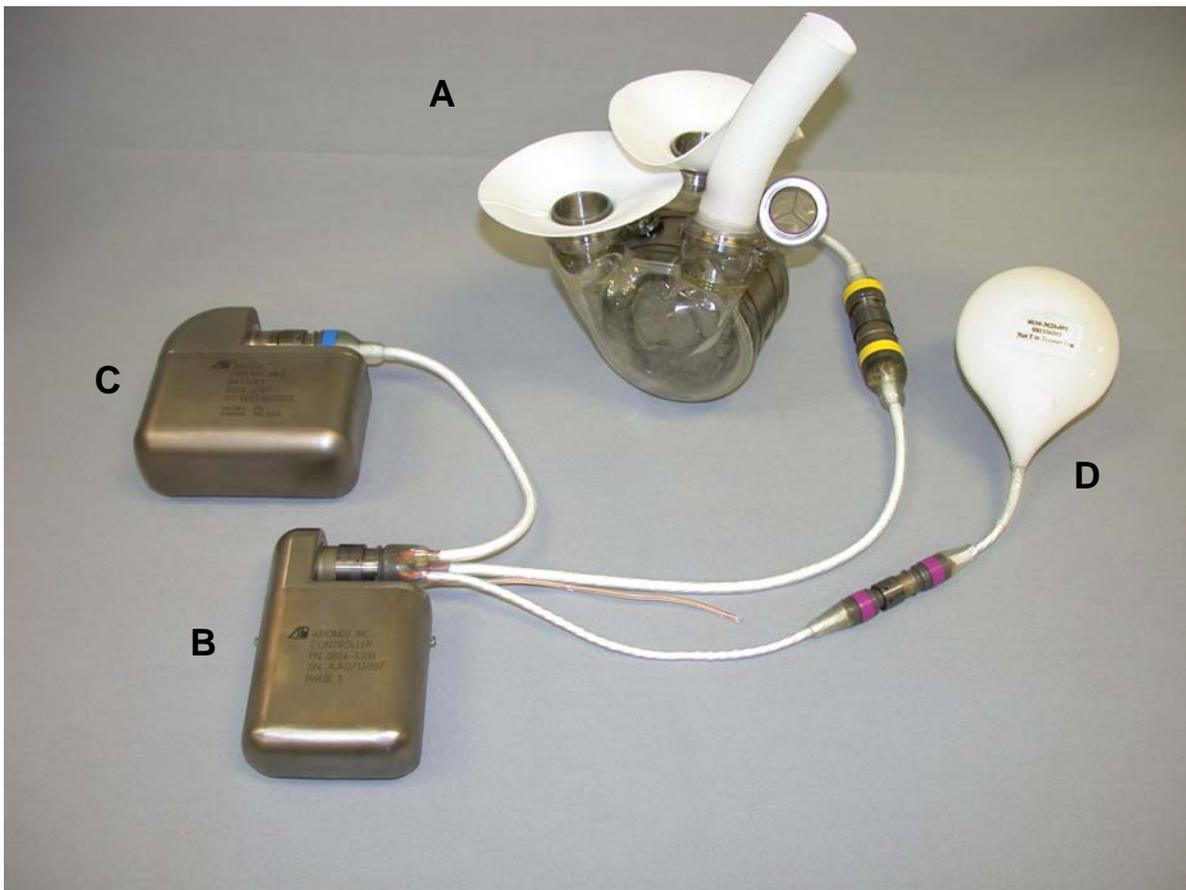


Figure 1-1 The AbioCor Implanted System; A- Thoracic Unit, B- Implanted Controller , C- Implanted Battery, D- Implanted TET.

1.1 Thoracic Unit

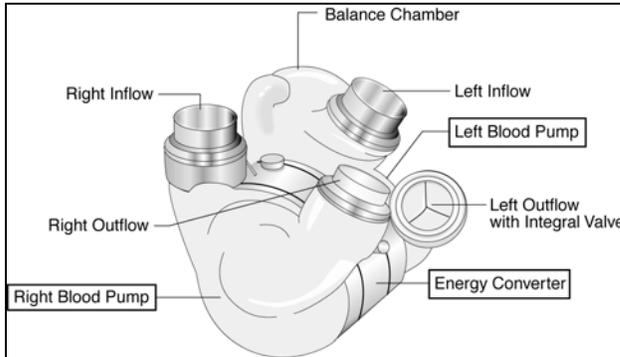


Figure 1-2 AbioCor Thoracic Unit

The Thoracic Unit (Figure 1-2) consists of two blood pumps sealed to and separated by the Energy Converter. Each blood pump can be seen as a hard-shelled chamber containing a sac filled with blood. The space between the sac and the Energy Converter is filled with hydraulic fluid.

The Energy Converter moves hydraulic fluid from one side to the other, squeezing the sac in one pump and forcing blood out of it. Simultaneously, blood is actively drawn into the other pump, filling it for the next cycle. The Energy Converter pumps hydraulic fluid in each direction alternately so that the left and the right blood pump alternately fills and ejects blood.

1.2 Implanted Controller

The Implanted Controller is the brain of the implanted System. It performs several functions:

- monitoring of the Thoracic Unit and the other implanted components
- control of the Thoracic Unit
- communication with the external components and alarms (the AbioCor Console or Patient-Carried Electronics)

The Implanted Controller contains the control electronics in a hermetically sealed titanium case. It is implanted abdominally, outside the peritoneum, on the patient's left side between the sub-costal and iliac regions.

1.3 Implanted Battery

The Implanted Battery, when new and fully charged, contains enough electrical energy to drive the AbioCor System for approximately 60 minutes with no external power supply. This allows the patient to function without a Console or PCE for short

periods. The actual time of operation on the Implanted Battery depends on the age and charge of the battery and on the blood flow rate provided by the AbioCor System.

The Implanted Battery is implanted abdominally, outside the peritoneum, on the patient's right side between the subcostal and iliac region. In this location, the battery can be replaced by a minor surgical procedure. Because the AbioCor System can get power externally, through the TET, the battery can be replaced without interrupting the operation of the AbioCor System.

The Implanted Battery recharges automatically whenever the implantable components are drawing power from the TET.

1.4 Implanted TET

The Implanted TET receives electrical energy in the form of radio waves from the External TET and converts it to the DC power used by the rest of the AbioCor System.

The Implanted TET is positioned in a subcutaneous pocket, usually in a sub-clavicular location. The details of the location depend on the patient's size and other anatomical considerations.

The Implanted TET is the primary power source for the AbioCor System's implanted components. Because the radio waves used can pass through a small thickness of human tissue, no percutaneous connections are needed. In addition, the Implanted TET can transmit an alarm signal when the TET Alarm Channel is in use.

1.5 AbioCor Console



Figure 1-3 The AbioCor Console
Communications Module.

The AbioCor Console (Figure 1-3) is the primary external component of the AbioCor System. It serves as the primary user interface in the clinical setting and provides power and data communications to the internal components, and is the interface for other patient monitoring equipment, data logging, networking, remote monitoring by ABIOMED, and other external functions. The Console transmits power via the TET, and communicates via the RF

1.6 Patient Carried Electronics (PCE)

The Patient-Carried Electronics (Figure 1-4) is a portable system that provides battery power to the implanted AbioCor System through an External TET. (The TETs used with the PCE are the same as the ones used with the Console.) The Hand held monitor. (Figure 1-5) is a PDA device that can receive information about the implanted system (Alarms, implanted battery status, flow, beat rate) over the RF link. The PCE is carried in a nylon Battery Bag that you can be worn over the shoulder. The PCE, together with a hand held alarm monitor affords freedom, away from the Console, for extended periods of time.



Figure 1-4 Patient Carried Electronics (PCE)



Figure 1-5 Hand held monitor

The relationship of the internal (implanted) components and the External components are illustrated in Figure 1-6. The Implanted components receive power and user command signals from either the AbioCor Console or the Patient-Carried Electronics (PCE).

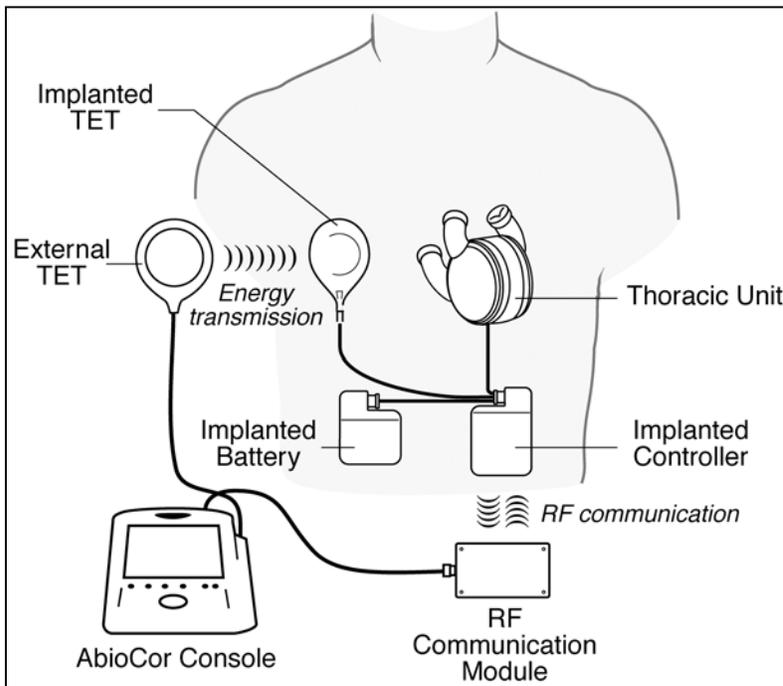


Figure 1-6 Relationship of internal components to external components of the AbioCor system.

2. Indications and Contraindications for Use

2.1 Indications for Use

The AbioCor is indicated for use in severe end stage heart disease patients who

- Are less than 75 years old,
- Are not transplant candidates at the time of assessment,
- Require multiple inotropic support,
- Are in biventricular failure not treatable by LVAD destination therapy,
- Are not weanable from biventricular support if on such support and not awaiting transplantation.

2.2 Contraindications

Contraindications include patients

- With other irreversible end organ functions that would compromise survival,
- With inadequate psychosocial support
- In whom preoperative noninvasive anatomical assessment reveals inadequate fit.

3 Warnings

NOTE: A warning indicates a situation that could result in injury or death.

- Do **NOT** subject a patient who has been implanted with an AbioCor® System to Magnetic Resonance Imaging (MRI). The strong magnetic energy produced by an MRI machine can cause the AbioCor System components to stop working. An MRI can also damage the AbioCor System's electronics.
- Do **NOT** allow any metal objects within **3 inches** of the External Transcutaneous Energy Transmission coil (External TET) while it is connected to the Console or the PCE Module. Certain types of metal objects can quickly become extremely hot and present a burn or fire hazard.
- Do **NOT** place an External TET that is connected to the Console or the PCE Module within **3 inches** of a metal surface. The TET can become overheated, causing a fire hazard.
- Keep the External TET disconnected from the Console when it is not in use. This reduces the risk of creating a fire hazard and damaging the TET because of the TET accidentally being too close to a metal surface.
- The TET cable becomes warm during normal operation. If the cable becomes hot, replace the External TET. A hot cable may present a burn hazard.
- Do **NOT** administer cardiopulmonary resuscitation (CPR) to a person who has an AbioCor System. CPR will not work and may cause life-threatening bleeding.
- Many conditions that occur during the operation of the AbioCor System can trigger AbioCor System alarms. Do **NOT** operate the AbioCor System without training in reacting to these alarms. Injury or death may result if the alarms are not handled in a timely and appropriate manner.
- Do **NOT** allow a patient who has an AbioCor® System to travel to an altitude that is more than 2,500 feet higher or lower than the location at which the AbioCor System was implanted. If emergency air

transportation is needed, tell the pilot about the 2,500-foot restriction. Changes in air pressure caused by altitude changes may cause the AbioCor System to work incorrectly, resulting in injury or death.

- Do **NOT** submerge a patient who has an AbioCor System more than 2 feet below the surface of any body of water. The change in pressure that occurs underwater may cause the AbioCor System pressure measurements to be inaccurate and result in improper operation.
- Monitor the temperatures of the Implanted Controller, Implanted TET, and Implanted Battery by checking the Parameter Window, which is available at Show Param Window on the Main Menu. Patient complaints of a localized feeling of heat may indicate that one of these components is not operating properly or is operating outside of its intended range.
- Monitor the patient closely for signs of sepsis. Infections may make blood more prone to clotting, increasing the risk of cerebrovascular accident (CVA).
- Maintain a therapeutic level of anticoagulation to decrease the risk of thrombus formation.
- A person who has an AbioCor System must **NOT** do deep forward bends. These may cause discomfort or pain because of the rigid AbioCor components and may reduce blood flow resulting in low blood pressure, and fainting.
- When using an X-ray lead shielding apron, be sure to place a pad (such as Styrofoam® or towels) at least 3 inches thick between the External TET and the shielding apron. This prevents heating of the shielding apron.
- Do **NOT** use a Swan-Ganz® catheter or other catheters to measure blood pressure within the Thoracic Unit. Cardiac catheters can damage the blood-contacting surfaces in the Thoracic Unit and promote thrombus buildup.
- During clinical use, a spare AbioCor® Console or a PCE / Handheld monitor must be available at all times.
- Do **NOT** mask (disable) any alarms without **authorization**. Alarm masking can affect patient safety.

- Waveforms and values from patient monitoring equipment are intended only for data collection. Do **NOT** use this information for patient management.
- To prevent the risk of explosion, do **NOT** operate the Console near flammable anesthetics.
- To reduce the risk of electric shock, do **NOT** attempt to remove the Console housing or replace the Console Battery.

4 Cautions

NOTE: A caution indicates a situation in which equipment may malfunction, be damaged, or cease to operate.

- To prevent overheating and improper operation, do **NOT** block the AbioCor® Console cooling vents while the Console is operating. Blocked cooling vents can cause the Console to overheat and to work incorrectly.
- When using the Console on a soft or uneven surface, use the foldout stand to help maintain adequate clearance around the vents.
- Keep an External TET that is connected to the Console at least 1 foot away from any other External TET. TET electronics can be damaged if TETs are too close to each other.
- Do **NOT** clean the External TET, Radio Frequency (RF) Communications Module, or cables with disinfectants that contain oxidizers such as iodine (Betadine® or similar disinfectants), hydrogen peroxide, hypochlorite (chlorine bleach), permanganate, or chromate. These cleaners may break down the outer coverings of these components.
- Do **NOT** use cleaners that may stain the outer coverings of components and hide the breakdown of these coverings.
- Do **NOT** resterilize the External TET or cables. Additional sterilization can permanently damage these components.
- Do **NOT** allow any liquids (including water) to come in contact with any electrical connector pins. Contact with liquid can cause corrosion or electrical malfunction.
- When possible, maintain the data connection between the Console and ABIOMED. The information collected will assist clinicians in ensuring proper operation of the AbioCor® System and in analyzing alarms.
- Minimize exposure of AbioCor® System components to sources of electromagnetic interference (EMI). Exposure to sources of EMI, such as cell phones and two-way radios, may cause operational interference. To clear interference, either increase the distance between AbioCor System components and the EMI source or turn off the EMI source.

- Operation of AbioCor System components may interfere with the operation of other devices. If interference occurs, increase the distance between the device and AbioCor System components.

5 Summary of Clinical Study

The clinical trial with the AbioCor spanned the time period between July 2001 and November 2004. Fourteen patients with end-stage heart failure and no other treatment options were implanted with the AbioCor, a fully implantable replacement heart device. Candidates enrolled in the trial had a one-month survival prognosis of not more than 30%. Candidates were not transplant eligible and were those who could not benefit from destination LVAD support.

An independent patient advocate group consisting of members devoted to end of life patient management was instituted to help patients and their family with the Informed consent process and the challenges and risks associated with living and dying on an experimental device. The trial was initially designed to assess patient survival at two months. The incremental gate for trial continuation in each group of five patients was based on one of five patients surviving to 60 days. Candidates and family members understood the trial criteria and the risks of prolonged recovery, complications of bleeding, stroke, pain, living and dying on the device.

Twelve patients of the fourteen candidates survived surgery, representing an 86% success rate for a radically new procedure. Support duration of the twelve patients ranged from 53 to 512 days. The majority of the patients (71%) survived beyond the 60 day milestone set for one of five patients (20%). The mean duration of support for the supported patients was 5.3 months. The cumulative support time was 64 patient-months substantially greater than initially anticipated.

Many of the patients had renal and hepatic dysfunctions associated with pre-existing debilitating conditions. As with all mechanical support devices, complications included post-operative bleeding requiring re-operation for resolution, and neurological events. The propensity for bleeding further challenged the need for some level of anticoagulation management desirable to minimize neurological complications. One anticipated device wearout occurred at 17 months. A device failure occurred at 5 months. Corrective actions have been implemented for these problems. In contrast to other mechanical cardiac support devices, device related infection was non-existent due primarily to its full implantability, eliminating the special attention needed for exit site care and the risks for infection.

Six patients were ambulatory. Four patients have had excursions outside of the hospital, and two of these four patients were discharged to facilities near the hospital as intermediary steps toward final discharge to home. One of these two patients was discharged to home shortly thereafter. The other discharged patient returned to the hospital while home readiness preparation and home care arrangements were being made for discharge to home. Discharge protocol was developed as needed since discharge was not anticipated for patient this initial trial. Three patients were able to go to restaurants, attend shows, sporting events, and religious services, and visit family and friends at their homes. Such activities have been conducted with wearable external components allowing for freedom and mobility. Six patients celebrated their next

birthdays on the AbioCor. One patient became a great-grandfather while on the AbioCor.

6 Patient Screening

Patients being considered for the AbioCor should, have the following screening tests administered, and these results will be reviewed by the medical team. Screening data will be used to assess whether a candidate meets the inclusion and exclusion criteria.

- Echocardiogram- for Ejection Fraction
- MRI / CT for atrial size determination for the assessment of biventricular failure
- Inotropes used and dosages
- Other support – IABP
- Doppler exam of the Carotid and Femoral Arteries, and veins
- Patient meets inclusion criteria
- Hematology workup
- Hemodynamics, including PCWP
- Medical history
- Social support system
- KCCQ evaluation

6.1 AbioFit

CT scan procedure

1. Two sets of transverse scans should be obtained:

a. Thoracic and upper abdominal scans: from the jugular notch of manubrium to the iliac crest.

b. Head scan.

2. Scan resolution (slice thickness):

a. Uniform slice thickness for the entire scan. A constant thickness between 2 and 5 mm can be selected.

3. Breathing cycle (preferred):

a. For the thoracic scan, the patient should hold breath while fully exhaled.

4. Scan quality:

a. Enhance the contrast to highlight the Pulmonary Veins and better define the great vessels and the cardiac chambers.

- b. Delay placement of catheters, if possible, until after the scan to avoid image distortion.

5. File format:

- a. DICOM. Should contain calibration scale information for each axis. Do not send encrypted or compressed files e.g. the Toshiba scanner output file.

6. Scan transfer media

- a. FTP to password protected Abiomed site: gatekeeper.abiomed.com
- b. Compact Disk
- c. Optical Disk
- d. DVD

Scanner types that have been verified to work with the Mimics program are:

- a. Philips MRI (ASCNT 1.5)
- b. GE MRI (Horizon 1.5)
- c. Picker CT (PQ-5000 & -6000)
- d. GE HiSpeed
- e. Siemens Somatom Volume Zoom (uncompressed file format only)

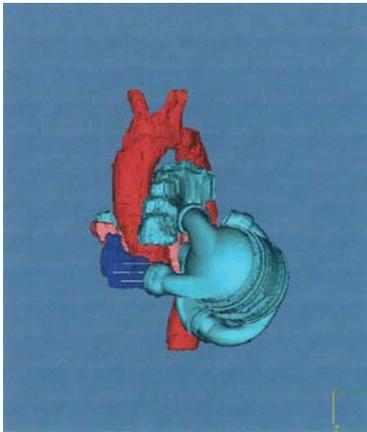
AbioFit

The primary purpose of the AbioFit program is to provide a tool to allow for a pre-assessment of the anatomic fit of the AbioCor in a recipient candidate prior to surgical implantation of the device. Such a tool reduces the possibility of fit related issues during surgery. The program uses two dimensional scans of either CT or MRI images of patients to construct a three dimensional representation of the organs within the contour of the chest cavity. Each major organ or portion of an organ can be further identified as an integral unit to permit virtual “surgical” removal of this part.

A three dimensional model of the AbioCor Thoracic Unit is stored in the program. The AbioFit operator removes the pericardium and the ventricles, and then using various editing tools places the AbioCor model into the vacated space.

The entire anatomy can be manipulated in space in order to facilitate viewing from any orientation. The final assessment of fit can be determined by stepping through two dimensional slices of the original scans with the superimposed device boundaries. This final step provides a close-up determination of interference with adjacent organs at all pertinent cranial-caudal levels. In addition to anemometrical fit, AbioFit will be used to assess candidate’s native atrial volume. The criteria for good fit includes:

1. Proper alignment of the inflows with the mitral and tricuspid valve planes without compression of the atria, of the right outflow, or the pulmonary artery.
2. Non-interference with the descending aorta and the pulmonary veins
3. The device remains completely within the rib cage.
4. Adequate atrial volume



AbioFit Operation

CT or MRI scans of a potential subject are obtained from a clinical center in the form of CD's, DVD, optical disks, Zip disks, or via the internet using FTP. Once the scans are imported into the AbioFit software tool, the cranial-caudal series of scans are treated as stacks in memory in the appropriate anatomical sequence.

With integral parts identified, Mimics can perform virtual surgery by peeling off layers to reveal the internal organs.

Figure 6-1: The AbioCor after it has been placed in the 3D reconstruction.

The AbioCor is placed
a

Graphic file Figure 6-1 shows the AbioCor after it has been aligned in the three dimensional reconstruction.

The viewing angle can be chosen by rotating the entire 3-d reconstruction to verify that proper placement of the AbioCor is achieved

Once an acceptable placement is achieved, a more detailed verification of fit can be viewed on 2-d slices with the AbioCor superimposed on the original scans.

7 Implant Procedures

7.1 Preparation

- 7.1.1 Perform Pre-implant check-out of all AbioCor equipment.
- 7.1.2 AbioCor Console setup
- 7.1.3 Implanted System check-out in a sterile field
- 7.1.4 System Operation verification
- 7.1.5 TET and Charging System operational check

7.2 Implantation

A fully detailed implant procedure is described in the manual “Pre-implant Equipment Check and Implant Procedures”. (Document # 0034-0980-00013)

- 7.2.1 Using blunt dissection, form a pocket for the Implantable TET on the right-hand side in subclavicular tissue from the sternal incision site. Place the TET in the pocket (about ½ inch deep). Tunnel the TET cable over the ribs and out through the sternotomy incision. Form pockets for the Implantable Controller and Implantable Battery below the posterior sheath of the peritoneum.
- 7.2.2 Remove the ventricles. Cut the tissue between the atria and ventricles leaving adequate left and right atrial tissue for attaching inflow cuffs.
- 7.2.3 Cut the tissue between the ventricles and the aorta and pulmonary artery (PA) distal to their respective valves. Trim or over sew excess tissue on the atrial appendages to prevent possible prolapse into the inflow valves.
- 7.2.4 Trim the left atrial cuff to the appropriate size. Then sew the cuff to the left atrial tissue and to a reinforcing layer of PTFE felt using a running polypropylene suture. Reinforce the anastomosis by sewing a second layer of felt around it. Check the right and left atrial anastomosis for leaks using the leak checkers provided.
- 7.2.5 Trim the PA outflow graft to the appropriate length and sew to the PA using a running suture and a reinforcing layer of PTFE felt.
- 7.2.6 Trim the aortic outflow graft to the appropriate length and sew to the aorta using a running suture and a reinforcing layer of PTFE felt. Check the anastomosis for leaks using the leak checker without the Foley catheter.

7.3 Placing the Thoracic Unit

- 7.3.1 Fill the blood pumps with heparinized saline, and place the Thoracic Unit in the pericardial space.
- 7.3.2 Make the connections to the cuffs and grafts.

7.4 De-Airing and Start-up

- 7.4.1 Connect the yellow connector of the Implantable Cable to the yellow connector of the Thoracic Unit and tighten with the spanner wrench.
- 7.4.2 Attach Toomey syringe bodies to the side arms of the outflow grafts and place suckers in the syringe bodies.
- 7.4.3 Release the caval tapes and allow the right atrium to fill. Partially occlude the venous return to the bypass machine.
- 7.4.4 Fill the Thoracic Unit by increasing central venous pressure (CVP) to 15 to 20 mmHg. Maintain CVP within this range during the de-airing procedure.
- 7.4.5 Begin with the low-flow Start Up states and quickly step through the first 3 states (if there are no filling problems).
- 7.4.6 When all air has been removed from the right blood pump, clamp the right side arm.
- 7.4.7 Inspect the left blood pump and valves for air. After satisfactory inspection, allow an additional 4 to 5 minutes to ensure that the left blood pump is de-aired.

7.5 Transition from CPB to AbioCor

- 7.5.1 Reduce TU beat rate to 60 bpm and CPB flow down to 1 liter of flow.
- 7.5.2 Simultaneously clamp the left side arm and open the cross clamp. Do not allow the side arm and the cross clamp to be closed at the same time.
- 7.5.3 Closely monitor inflow pressures and compensate by making changes to volume and Thoracic Unit settings.
- 7.5.4 Discontinue CPB and reverse heparin.
- 7.5.5 Increase TU beat rate to desired blood flow, making sure that filling pressure remain between 15 and 20 mmHg.

7.6 Chest Closure

Baseline fit assessment of the AbioCor is essential to ensure the device can perform according to specifications. A major cause of performance problems is limited blood flow to the right or left ventricle. Every effort should be made to ensure there are no fit complications. The following recommendations are intended to help minimize this problem:

- 7.6.1 After the AbioCor is providing full support to the patient (and hemodynamics are stable with the chest open), baseline data should be collected. This data take into account patient variables, such as atrial size, pulmonary resistance, systemic resistance, and anatomical issues:
- 7.6.2 TEE should be recorded, showing acceptable pressure gradients (not exciding twice normal) between the pulmonary veins and the left atrium.
- 7.6.3 Hemodynamic parameters should be recorded, evaluating device output, central venous pressure, left atrial pressure, and aortic pressure. If possible, these numbers should be recorded at various central venous pressure levels to allow graphing of the device output response.
- 7.6.4 After the baseline fit assessment is complete, the chest should be approximated in the closed position. TEE and hemodynamic parameters should be reassessed, and a target velocity of < 80 cm/second should be maintained.

8 Operator's Manual (Summarized)

8.1 Clinician's Manual

This Clinician Manual is designed for experienced health care professionals responsible for patients implanted with an AbioCor Implantable Replacement Heart. This manual contains clinical and technical considerations to guide care for these patients. Clinicians should have extensive experience in the care and management of postoperative cardiac surgical patients including those requiring mechanical circulatory assist devices.

Information and instructions given in this manual are not intended to supersede established medical procedures concerning patient care. Best practice, as determined by the medical community, should always be observed. In each case, the clinician must determine whether the application of information provided is appropriate for the particular clinical setting.

This manual should be used to support patients before and after implantation.

Manual overview

This Clinician Manual provides instructions for use of the AbioCor Implantable Replacement Heart System. This manual also includes important information concerning patient monitoring. The following summarizes the contents of each section of this manual:

- **Section 1 (Warnings and Precautions)** discusses the warnings and precautions pertaining to the use of the AbioCor System.
- **Section 2 (Indications and Potential Adverse Events)** discusses indications for use of the AbioCor System and potential adverse events that may be associated with its use.
- **Section 3 (The AbioCor System)** provides an overview of the AbioCor System and describes the system's major internal (implanted) and external components.
- **Section 4 (Using the AbioCor Console)** describes the procedures for setting up and operating the AbioCor Console.
- **Section 5 (Using the Console in Clinical Mode)** describes where to find information available in Clinical Mode and how to use and navigate through the Clinical Mode windows and popup dialogues.
- **Section 6 (Managing an Implanted AbioCor System)** presents the information on power management, TET management, communications management, and

hemodynamic management to aid in managing an AbioCor System that is implanted in a patient.

- **Section 7 (Caring for a Patient with an Implanted AbioCor System)** describes considerations and procedures for caring for patients with implanted AbioCor Systems.
- **Section 8 (Transitioning the AbioCor Patient to Home Living)** describes discharge planning and procedures, including home caregiver and patient training requirements.
- **Section 9 (Alarms)** describes the AbioCor alarm and warning system.

8.2 Patient Manual

The patient manual will help the patient and caregiver understand how to live comfortably with the AbioCor Replacement Heart. The manual includes information about how the AbioCor System works in the body and how it fits into the patients daily routine. The manual also instructs users in how to adjust the system and when to call the doctor or the clinic.

Manual Overview

- **Section 1** lists important warnings and precautions to avoid potential safety problems and ensure that the best results from your AbioCor System.
- **Section 2** describes the parts of the AbioCor System and how they work together to keeps blood flowing normally.
- **Section 3** is about daily living with the AbioCor Replacement Heart, on nutrition, sleep, exercise, shower, travel, and maintain other daily routines.
- **Section 4** tells how to connect and operate the external controls of the AbioCor System, using the Console.
- **Section 5** tells how to transfer control from the AbioCor Console to the Patient-Carried Electronics unit when more freedom of movement is desired.
- **Section 6** provides an overview of the AbioCor alarms.

8.3 Patient Carried Electronics

The Patient Carried Electronics (PCE) manual provides information to help the patient and caregiver understand how to use the PCE and Hand Held Alarm Monitor safely and comfortably.

Manual Overview

- **Section 1 (Warnings and Precautions)** lists important precautions to avoid potential safety problems.
- **Section 2 (PCE Overview)** describes the function of the Patient-Carried Electronics (PCE).
- **Section 3 (Basic PCE Operation)** shows how to use the PCE and how to charge, and replace batteries. It also shows how to keep the unit clean.
- **Section 4 (Transferring Support Between the Console and PCE)** tells how to transfer support from the AbioCor Console to the PCE when you want to be away from the Console **and how to transfer support from the PCE back to the Console.**
- **Section 5 (PCE Alarms)** describes the alarms you would see and hear when you are using the PCE.

8.4 Home User Training Program

The transition to home living with the AbioCor involves careful preparation and assessment of the patient, the caregivers, and the patient's home environment and support structure. Patient and caregiver training are essential for a safe and successful discharge experience. Before discharge from the hospital, the AbioCor patient and their respective caregivers will be trained by the AbioCor Center's staff. Proficiency on each training requirement listed below will be based on observational testing. The AbioCor patient and their respective caregivers should be capable of operating the AbioCor system and feel completely comfortable in their ability to address and respond to each function defined in the training requirements of the AbioCor system.

The Trainer will document each training requirement when addressed and proficiency established.

- Identify the AbioCor System Components and Functions
- Understand and Identify the AbioCor console controls and indicators.
- Use the AbioCor Controls in Home Operating Mode
- Understand and respond to AbioCor Console Alarms

- Understand and use of the External Transcutaneous Energy Transmission coil (External TET)
- Understand and establish RF communications
- Understand and use of the Patient Carried Electronics (PCE)
- Understand Emergency Procedures
- Understand and demonstrate the importance of their medications and self care.

9 Patient Management

9.1 Anticoagulation Management

- ABIOMED recommends that the immediate post-operative cardiac index should be set above 2.5 L/min/M² but should not exceed 3.0 L/min/M².
- Heparin therapy is initiated only after surgical hemostasis has been verified.
 - Starting dose should be within 2 – 5 Units/kg/hr with target PTT being around 2.5 times normal. (55 -60 sec)
 - The heparin drip will be titrated to achieve normal coagulability as indicated by TEGs using the sample without heparinase in recalcified whole blood to assess the heparin effect
- Warfarin therapy will be initiated when renal and hepatic functions improve, and prealbumin levels increase and nutritional status becomes stable.
 - Target INR should be between 2.5 to 3.5.
 - TEGs should be used to detect normocoagulability. While warfarin is taking effect, heparin should be titrated down, guided by TEGs. Heparin is discontinued when normocoagulability with heparinase has been achieved for 2 consecutive days indicating that the coumadin effect has taken hold.
- Antiplatelet therapy will be achieved with aspirin, dipyridamole, and/or Plavix.
 - Aspirin 81 – 325 mg/day
 - Dipyridamole 75mg Q6
 - Plavix 75 mg/day
 - Platelet aggregation should be used to achieve 50% inhibition
 - TEG with platelet agonist should be used for platelet function assessment.

Summary of Post-Operative Dosage and Monitoring Guidelines

9.2 Infection Management

Antibiotic therapy should be provided prophylactically from the recovery to the step down phases of AbioCor support. Longer duration and or organism specific medication administration is at the discretion of the clinician.

To minimize the chance of infection, indwelling lines should be discontinued as soon as possible. The Millar Left atrial line may be left for longer periods of time at the discretion of the physician. All discontinued line tips should be sent for routine culture.

The patient will have at the minimum the following incisions and line insertion sites:

- A median sternotomy,
- chest tube,
- central line,
- radial or femoral arterial line insertion sites.

Strict ascetic technique should be used for all dressing changes. Dressing changes should be done according to ICU policy and protocol, or per the physician's orders. It is recommended that dressings are in place during the patient's intubation phase, to prevent wound contamination. If the patient requires prolonged ventilatory support, or tracheostomy, the need for dressings should be at the physician's discretion. The incisions may be open to air after the patient is extubated, and the wounds are healed.

Nutrition is a major factor in preventing infection. Baseline nutrition values should help direct therapy. Tube feedings may be necessary to supplement some patient needs. Infection should be suspected if any of the following occurs, WBC increase, temperature increase, positive cultures, infiltrate on x-ray, skin redness, pain/tenderness and any significant decrease in blood pressure at the same device output.

9.3 Rehabilitation

Once the patient is hemodynamically stable, progressive activity as per a physical therapy plan should be initiated including:

- Turning side to side every two hours.
- Passive and active range of motion.
- Elevating the head of the bed.
- Dangling at the side of the bed.
- Out of bed to a chair.

- Ambulating with, and eventually without assistance.

The patient should be introduced to use the Patient Carried Electronics soon after as he begins to ambulate. A gradual increase in the total weight of the PCE Module and two battery packs that must be borne by the patient can be gradually increased per the physical therapists discretion, until he is able to carry all of the electronics himself.

9.4 Hospital Discharge

To ensure the safety of the patient, primary care givers and if possible the patient must:

- Complete the training and demonstrate knowledge of operating and troubleshooting the Abercorn system and responding to possible emergencies.
- Have the required emergency and back-up information, equipment, and accessories.

If the patient is stable with normal hemodynamic and the patient or family is capable of taking charge of the care plan, discharge to an “intermediate” facility near the hospital can be considered.

If in the opinion of the clinical team that the patient and family support group has demonstrated their ability to care for the patient and the Abercorn system. The patient can be discharged to home provided the following sequence of events has occurred.

Preparation for discharge is an on going activity; it should begin when the patient is transferred out of the ICU, and include the patient and the patient’s primary caregivers. The plan is developed around restoring the patients physical condition to a point in which they can participate in their own care, and to transition the care of the patient and the AbioCor system from the hospital staff to the caregivers. A general outline of events leading to discharge would include:

1. Increasing physical activity in the step down unit including:
 - Patient transferring from bed to chair without assistance
 - Patient able to care for personal hygiene
2. In hospital excursions, for example:
 - To the hospital cafeteria
 - To outside areas such as roof decks and gardens.
3. Out of hospital excursions, for example:
 - Local restaurants and parks

- 4 Day trips to Intermediate care facility such as a local hotel or apartment close to the medical center.
- 5 Over night stays at the intermediate care facility.
- 6 Discharge to home

9.5 Facility Requirements

There are no special requirements on the power needs in the home or the work environment. For travel in a car, the number of battery packs to be carried in the car should be equivalent to twice the number of hours for the roundtrip. A console should also be part of the traveling accessories to allow for data monitoring. It also serves as a backup to the PCE.

The Local EMS service should be notified of the AbioCor patient. The EMTs will be trained on what procedures can be performed such as respiratory support and those that should be avoided such as the use of a defibrillator.

9.6 Equipment Requirements

The following AbioCor equipment should be provided to the patient at time of discharge.

- (1) One console and two ten-foot TET coils (one for car one for home)
- (2) Two radio frequency transceivers
- (3) Two PCE TET drivers / battery bag
- (4) Eight external battery packs
- (5) Two external battery chargers
- (6) Two AC/DC adapters for the PCE drivers
- (7) A two month supply of Duoderm patches for the TET
- (8) Two hand held alarm monitors
- (9) Reference documents as needed

9.7 Patient requirements for discharge

System	Patient Status
Neurological	Intact
Cardiovascular	Hemodynamically stable
Respiratory	Adequate oxygenation and perfusion (home O ₂ is acceptable)

GI - GU	<ul style="list-style-type: none"> • Good appetite • Active bowel • No active GI bleeding • Adequate nutritional intake
Infection	<p>No signs/symptoms of active infection</p> <p>(or on antibiotic infusions administered by home health)</p>
Activity	<p>Independent (or with minimal assistance) with home cardiovascular exercise program</p>
Pain Management	<p>Pain controlled with minimal analgesics</p>
Wound Management	<p>Wounds free of visible sign of infection.</p>
Education	<ul style="list-style-type: none"> • Plan of care • AbioCor operation • Medication • Emergency contacts
Data Management	<p>Data connection with ABIOMED</p>

9.8 Steps for Discharge to Intermediate Care Facility

Step #	Requirement	Evaluation Criteria
1	Patient or caregiver demonstrates proficiency in operating and troubleshooting the AbioCor and shows understanding of how to respond to emergencies.	Demonstration will be evaluated based on written and oral testing
2	Supervised* day trips to intermediate care facility without overnight stay. *(with assistance of hospital staff)	Upon returning from this trip, the patient will be evaluated to assess compliance with <ul style="list-style-type: none"> • medication • care plan • ability to care for self • device operation.
3	Independent* day trips to intermediate care facility without overnight stay. *(without assistance of hospital staff)	Upon returning from this trip, the patient will be evaluated to assess compliance with <ul style="list-style-type: none"> • medication • care plan • ability to care for self device operation
4	The patient may be released to the Intermediate care facility for a period sufficient to base an evaluation on (most likely 1-3 days) with overnight stays. Patient will make return visits to the hospital as defined in the schedule.* *Schedule to be outlined by clinical team.	Consensus of the patient, the family, the clinical team.

9.9 Steps for discharge to home

Discharge steps to home will follow the same basic outline provided for in the discharge steps to intermediate care facility.

Staffing coverage Intermediate Care Facility

The patient will be accompanied at all times by appropriate qualified personnel.

Appropriate qualified personnel could include:

- Family members or friends who have been trained by the clinical team in the use of the AbioCor system.
- Trained RNs, LPNs, or Home Health Aide provided thru the clinical center, or local agency.

The Clinical Center will make available personnel, in person or by phone, in the event of an emergency.

Caregiver Availability at home

A qualified caregiver will be with the patient at all times.

Education of AbioCor implanted patients, family, and caregivers

Training for the patient and any individuals who may assist the patient will consist of information on how to care for and monitor the AbioCor, as well as how to respond to alarms and emergency situation.

Outline of topics to be covered:

- System overview
- Responding to alarms
- Adjustments of beat rate, and balance settings
- Removing external TET and care of TET area
- Maintaining proper Radio Frequency (RF) communications
- Using AbioCor Consol in home screen mode
- Use of Patient Carried Electronics (PCE)
- Use of the Hand Held Alarm Monitor
- Emergency procedures
- Medications
- Nutrition
- Exercise and activity parameters

Notification of utilities

Local Power Company will be notified of the fact that there is a customer that requires power for life support equipment.

Notification of Emergency Medical Services

The agency responsible for responding to 911 calls for emergency medical assistance should be notified.

Contact information

Each AbioCor patient will be provided with a contact list including the following numbers. See attached sample

- Hospital coordinator
- ABIOMED
- Physician
- Emergency assistance (911)

Plan of Care

Each AbioCor patient will be given a plan of care designed for that patient. The plan will be review with the patient and the family by the clinical team. With each office visit progress will be compared with the plan, and the plan will be modified as needed.

AbioCor Log sheet

The patient or their caregiver will fill out the AbioCor flow sheet at a minimum of two times a day.

Medication log

A log listing all of the AbioCor patient's medication will be reviewed with the patient and caregivers. The log will include the following:

- Medication Name
- Dosage information
- Indication

Appointment calendar

The coordinator will develop a calendar listing regularly scheduled appointments. See attached sample calendar.

Journal

AbioCor patients will be encouraged to keep a journal where they can make notes regarding any problems with the implants or external equipment. They will also be encouraged to make notes about their overall health or any other issues they may be feeling.

Equipment log

An inventory of all AbioCor external equipment will be maintained. In the event of a recall the hospital coordinator will be contacted. See attached sample.

Hospital maintained Records

- Patient demographics
- List of consults
- Equipment logs
- Medication logs
- Laboratory blood work tracking sheet.

Patient ID card

Front

 **Special Medic ALERT!** 

Patient Name: _____
 Address: _____

ATTENTION! I have a total replacement heart called the "AbioCor." Because of my replacement heart, I have special healthcare needs.

Do not perform CPR.
 Do not use an external defibrillator.
 Do not place me in an MRI machine.
 CT scans are safe.

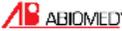
 I must not be subjected to a sudden altitude change of more than 2000 feet.

Back

If I am having a medical emergency, please immediately call the Primary Medical Center.

Contact Person: _____
 Telephone: _____
 Primary Medical Center: _____
 Implant Date: _____ Serial Number: _____
(Thoracic Unit)

Manufactured by:

 ABIOMED	978-777-5410 (voice)
22 Cherry Hill Dr.	800-422-8666 (voice US only)
Danvers, MA 01923	www.abiomed.com
USA	

10 Outline of Clinician training Program

Training on implanting, patient care of the AbioCor will involve all members of the clinical team. Depending on the individual's, involvement their training may include; classroom / demonstration training, and / or animal lab training.

Clinical centers are expected to designate critical members of the AbioCor implant teams before AbioCor training can begin. Team members should include at least the following personnel:

Surgical Team: (minimum)

- 2 surgeons
- First assistants
- Scrub nurse
- Circulating nurse
- Perfusionist
- Anesthesiologist
- Device operator

Recovery team:

4 to 5 ICU recover nurses.

The AbioCor training program will consist of a minimum of two animal implant sessions combined with classroom instruction. The organization and timing of these training sessions will be arranged on center by center bases, but re expect the program to follow the following format.

10.1 Introductory Class room session and workshop

The ABIOMED team will travel to the implant facility to conduct a one day seminar and workshop on the basics of the AbioCor operation. The morning session will be spent reviewing the system architecture, theory of operation, system software and control algorithms, and AbioCor external console user interface. The afternoon session will be hands on session that will allow participants the opportunity to get acquainted with the system components, including the opportunity to operate the system with a mock circulatory loop. It is expected that all members of the surgical team and the primary post-operative care team participate in this training.

10.2 Pre-Animal Lab training

As preparation for the first animal lab, the AbioCor training team will conduct a pre-lab training workshop. This workshop will consist of a presentation of the basic steps to implantation, followed by a mock implant using the system components, interactive video, and the mock-circulatory loop. Members of the implant team are expected to participate in this training.

10.3 Animal Lab / Peer Visit

Members of the Implant team will travel to an AbioCor Training center where they will have the opportunity to train under the direction of your experienced counterparts in an experienced AbioCor center. The objectives of these labs are as follows:

- a. Members of the implant team will complete the AbioCor pre-implant system check-out.
- b. Members of the implant team will complete the steps for implantation as described in the Implanting the AbioCor IFU.
- c. Surgical / Perfusion / and device operators will become proficient with de-airing the AbioCor and transitioning from by-pass to AbioCor support.
- d. Surgical teams will demonstrate the procedure for transitioning from Console control and power to the implanted system.

After the animal lab we will arrange for the opportunity for you to meet with members of the Training Center's AbioCor team. This will be an informal gathering of doctors from all disciplines, nurses from both the recover and step-down units, and VAD coordinators. This will give you the opportunity to exchange ideas, and hear what worked and did not work, and ask questions.

10.4 Subsequent Animal Labs

Additional training labs will be conducted at your own center's animal facility if available or at the AbioCor training center. This will give the opportunity for extended team participation. A video tape will be available for review prior to the animal lab. The same objectives, participation requirements and follow up will be a part of these labs.

Full participation in each element of the training sessions is required. In order for the clinical center to be considered ready to conduct implants, full and consistent attendance is required by the surgical team for all the training implants

10.5 Post-operative care team training

Members of the post-operative care team will participate in the initial introduction to AbioCor training session. In addition, Members of the AbioCor training team will provide class room and hands on training sessions that are specifically designed to meet the needs of the team. Topics covered will include:

- e. Review of AbioCor implanted and external components
- f. Pre-implant patient considerations
- g. Post-operative monitoring and target hemodynamic ranges
- h. Post-operative care
- i. Device management

10.6 Step-down unit training

When the time comes to transfer the AbioCor patient from the ICU to the step-down unit, we have found that the best trainers are the now experienced AbioCor recovery team members at the center. ICU nurses will cross train the nurses from the Step-down unit. The ABIOMED AbioCor Clinical Team will be available to provide basic system overview training and support as needed.

10.7 Criteria for Clinical Readiness from Training Sessions

- 1 Successful completion of two animal implantations.
 - Normal Post-implant hemodynamics must be demonstrated
 - Demonstration of understanding of system electrical connections
 - Demonstration of De-airing techniques
2. System Operator must demonstrate proficiency and knowledge by using the training loop.
- 3 Post-op team must understand device/physiologic interaction and patient management.
- 4 Clinical team must be familiar with patient selection criteria.

11 System components

11.1 Implantable Kit

Item	Part #	Qty	
Thoracic Unit	0034-6103	1	11.2 Console Kit
Implantable Battery	0034-3717	1	
Implantable Controller	0034-3345	1	
Implantable TET	0034-3213	1	
Implantable Cable Harness	0034-3400	1	
Model Kit		1	
Implantable Battery Model	0034-4130	1	
TET Implant Model	0034-4097	1	
TU Inflow Fit Model	0034-4099	1	
Thoracic Unit Implant Model	0034-4158	1	
Controller/Battery Implant Model	0034-4098	1	
Leak Checker	0034-1037	1	
Low Position Graft	0034-1116	2	
45 Degree Cuff w/ Stent	0034-1173	2	
O-Ring	0034-8149	1	
Signal Interface	0034-6046	1	
Sterile Lubricant	0034-8154	1	
Foley Catheter	5400-1008	2	
Toomey Syringes	0034-1081	2	
TET Pouch	0034-4129	1	
Case	0034-8174	1	
Case Diagram	0034-0966-00012	1	
11' External TET packaged	0034-4660	1	
Clinician Manual	0034-0980-00010	1	
Pre-Implant Check & Implant Procedures	0034-0980-00021	1	
Item	Part #	Qty	
AbioCor Console	0034-4430	1	
Power Cord	6000-0025	1	
Console case	0034-4400	1	
RF Comm Module	0034-4458-HD	2	
11' External TET packaged	0034-4660	1	
Console Alarms User's Guide	0034-0980-00020	1	

11.3 PCE and Home Kit

Item	Part #	Qty
Packaged Hand held Monitor	0034-4620	1
Handheld Monitor IFU	0034-0980-00022	1
Handspring Visor Pro	2025-0015	1
Active Armor Case	0034-4674	1
RF Module	0034-4451	1
Shipping container		1
PCE Bag & TET driver, packaged	0034-4666	1
PCE Manual	0034-0980-00016	1
Patient Manual	0034-0980-00011	1
TET Driver		1
PCE Bag		1
Packaged PCE AC Converter USA	0034-4515	1
PCE battery Packaged	0034-4664	8
5' External TET	0034-4668	2

12 Materials Matrix

The AbioCor and the AbioCor sub components are manufactured from raw materials. The following Matrix lists all materials which come in contact with tissue.

12.1 Thoracic Unit

Component	Material
Energy Converter, Exterior Metal	Titanium
Exterior Blood Pump Area	Epoxy
Interior of Blood Pump	AngioFlex (Polyetherurethane)
Cable outer insulation	Carbothane
Cuffs	Velour
Grafts	Dacron

12.2 Implantable Battery and Controller

Component	Material
Enclosure	Titanium

12.3 Implantable TET

Component	Material
Outer Covering	AngioFlex (Polyetherurethane)
Cable out insulation	Carbothane
Connector	Titanium

12.4 External TET

Component	Material
External Surface (cable and Coil Covering)	Silicone