

AbioCor[®]

Implantable Replacement Heart System

PATIENT-CARRIED ELECTRONICS MANUAL



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Humanitarian Device. Authorized by Federal law for use in the treatment of patients who have irreparably damaged hearts or who are at risk of imminent death as a result of end-stage heart failure not treatable by optimal medical treatment. The effectiveness of this device for these uses has not been demonstrated.

IMPORTANT NOTICE: Read this *entire* manual before using the Patient-Carried Electronics (PCE). The PCE is to be used only in accordance with this manual.

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The AbioCor® Implantable Replacement Heart System is covered by one or more United States Patents and patents pending.

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Glossary

AbioCor Replacement Heart	battery-powered system that takes the place of the natural heart to keep the blood flowing normally through the body
alternating current (AC)	normal household electrical power
cardiopulmonary resuscitation (CPR)	first-aid technique that uses pressure against the chest to restore the operation of a natural heart
Console	specialized computer that powers and controls the AbioCor System
External Transcutaneous Energy Transfer coil (TET)	silicone ring containing a coil of wire; transfers energy from the Console to the implanted components of the AbioCor System
heart rate	number of times per minute the Replacement Heart pumps blood
implanted	placed inside your body by a surgeon
Implanted Battery	AbioCor component that provides power to the Implanted Controller and the Replacement Heart
Implanted Controller	AbioCor component that manages the heart rate and stroke volume of the Replacement Heart to provide the needed blood flow
Implanted Transcutaneous Energy Transfer coil (TET)	AbioCor component that receives electrical energy through your skin from the External TET to keep your AbioCor System charged
magnetic resonance imaging (MRI)	diagnostic technique that produces images of the inside of the body using electromagnetic energy
Patient-Carried Electronics (PCE)	portable system that provides battery power to the implanted AbioCor System through an External TET

precaution	information that alerts you to situations that carry a risk of minor injury to you, or situations in which the AbioCor Replacement Heart may malfunction or be damaged
Replacement Heart	the AbioCor component that is implanted in your chest to pump blood to your lungs and other parts of your body
RF	radiofrequency; the type of communications signal used by the AbioCor System
RF Communications Module	external AbioCor component that sends data between the Console and the AbioCor Implanted Controller through the implanted RF Antenna
TET	transcutaneous energy transfer coil (implanted and external); transfers power from the Console to the implanted AbioCor System
warning	information that alerts you to situations that can cause death or serious injury

Introduction

The **AbioCor Replacement Heart** is a battery-powered system for patients with heart failure or another serious heart disease. It takes the place of your natural heart to keep the blood flowing normally through your body.

The **Patient-Carried Electronics (PCE)** is a portable system that provides power to the implanted AbioCor System. It allows you to keep your AbioCor Replacement Heart working smoothly while you are away from the AbioCor Console.

About this Manual

This manual will help you understand how to use the PCE safely and comfortably.

Manual Overview

After you read this introduction, take a moment to browse through this manual, so you'll know where to find the information you need.

- **Section 1 (Warnings and Precautions)** lists important precautions to avoid potential safety problems and ensure that you get the best results from your AbioCor System.
- **Section 2 (PCE Overview)** describes the parts of the Patient-Carried Electronics (PCE).
- **Section 3 (Basic PCE Operation)** tells how to use the PCE and how to charge, replace, and calibrate Batteries. It also tells how to clean the system.

- **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 might see and hear when you are using the PCE.

Definitions of Special Terms

This manual may use words that are new to you. Those terms are printed in bold type (**like this**) and listed in alphabetical order in the Glossary at the front of this manual. The Glossary also includes abbreviations used in this manual.

1 Warnings and Precautions

This section contains two kinds of information.

- **Warnings** alert you to situations that can cause death or serious injury. The word “WARNING” and the symbol  appear before warning messages.
- **Precautions** alert you to situations that carry a risk of minor injury to you, or situations in which the AbioCor Replacement Heart may malfunction or be damaged. The word “CAUTION” and the symbol  appear before precaution messages.

AbioCor System Warnings



WARNING: Call your doctor or clinic immediately if the AbioCor System Console stops working.

If the Console stops working, connect the Patient-Carried Electronics (PCE) to provide power immediately.

The AbioCor Replacement Heart will work for only about 30 minutes using its Implanted Battery power. After that, your AbioCor Replacement Heart must be connected to the Console or PCE for power. Otherwise, it will stop working, resulting in death.



WARNING: If the External TET is removed, the AbioCor System runs on its Implanted Battery power, which only lasts for about 30 minutes.

When the Implanted Battery runs down, the AbioCor System will slow down, lowering your blood pressure. This might make you feel dizzy or faint. If the Implanted Battery runs down completely, the AbioCor System will stop working, resulting in death.



WARNING: Never undergo a **magnetic resonance imaging (MRI)** procedure.

The strong magnetic energy produced by an MRI machine may cause the AbioCor System components to give you an electric shock. An MRI may also damage the AbioCor System's electronics.



WARNING: Never administer **cardiopulmonary resuscitation (CPR)** to a person who has an AbioCor Replacement Heart.

CPR will not work with an AbioCor Replacement Heart, and may cause life-threatening bleeding.



WARNING: Never travel in any airplane.



WARNING: Never travel to an altitude that is more than 2,500 feet higher or lower than the location at which the AbioCor Replacement Heart 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 Replacement Heart to work incorrectly, resulting in death or serious injury.



WARNING: Do not allow anything metal (such as jewelry, keys, metal buttons, or zippers) to remain within 3 inches of the AbioCor TET when it is attached to your chest. Metal objects will become hot.



WARNING: If you have an X-ray, the technician may put a lead shielding apron over your chest.

Put a thick pad (a Styrofoam® block or a folded towel at least 3 inches thick) between the AbioCor TET and the lead shielding apron, or remove the TET for a short time during the X-ray.

Without a thick pad, the AbioCor System components may get hot during the X-ray, causing a risk of a skin burn.

Patient-Carried Electronics (PCE) Warnings



WARNING: When using the PCE, you must always have at least one of the following backup units available within 10 minutes:

- a PCE Battery Bag and 2 pairs of fully-charged Batteries
- a fully-charged AbioCor Console

If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.



WARNING: If the PCE Temperature alarm stays on for more than 1 minute, transfer AbioCor System control immediately to a backup PCE or the Console.

This warning indicates that the PCE is overheated and may malfunction.

AbioCor System Precautions



CAUTION: Do not bend forward deeply from the waist. This posture might be uncomfortable because of the location of the Implanted Battery and Implanted Controller in your abdomen.

Bending forward may also affect the blood flow to your upper body, which may cause a momentary fainting spell.



CAUTION: Do not clean the TET, Radiofrequency (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 AbioCor components.



CAUTION: Do not clean the TET, RF Communications Module, or cables with cleaners that may stain the surfaces you are cleaning.

This staining may hide the breakdown of the outer coverings of these AbioCor components.



CAUTION: Do not allow any liquids (including water) to come in contact with any electrical connector pins.

Contact with liquid may cause corrosion or electrical malfunction.



CAUTION: Keep a TET that is connected to the Console at least 1 foot away from any other TET (for example, the PCE TET.)

This precaution prevents potential damage to the TET's electronics.



CAUTION: Never place a TET that is connected to the PCE or Console on a metal surface.

The TET may become overheated, causing a fire hazard.



CAUTION: Disconnect the TET from the Console when it is not in use (for example, when you are using the PCE.)

This precaution reduces the risk that the TET will be damaged by accidentally coming in contact with metal surfaces.



CAUTION: Keep the Console away from sources of electromagnetic radiation (EMR) such as cell phones, 2-way radios, or appliances with electric motors if you observe signs of interference (for example, static on the phone or radio or on the AbioCor Console screen).

These devices may interfere with the AbioCor's communications system.

Patient-Carried Electronics (PCE) Precautions



CAUTION: Never try to disassemble the PCE Control Module, Battery Bag, or Batteries.

You may damage the PCE and cause it to operate incorrectly.



CAUTION: Always have 2 power sources connected to the PCE to ensure that you will be able to see and hear alarms if they occur. These power sources can be:

- 2 pairs of Batteries
- 1 pair of Batteries and an AC Power Adapter.



CAUTION: Never remove Batteries while they are supplying power to the PCE.

You may damage the PCE and cause it to operate incorrectly.



CAUTION: Never cover the PCE with clothing.

Covering the PCE may cause it to overheat and operate incorrectly.



CAUTION: Never block the PCE's cooling vents.

Blocking the cooling vents may cause the PCE to overheat and operate incorrectly.



CAUTION: Never use a PCE Battery that has been dropped. It may not work correctly.

If you drop a PCE Battery, mark it DO NOT USE and return it to your doctor or clinic.



CAUTION: Never submerge any part of the PCE in liquid.

Liquids will severely damage the PCE and cause it to operate incorrectly.

2 PCE Overview

What is the Patient-Carried Electronics (PCE)?

The Patient-Carried Electronics (PCE) is a portable system that provides battery power to the implanted AbioCor System through the **External TET**. The PCE is carried in a nylon Battery Bag that you can wear over your shoulder. The PCE allows you to be mobile, away from the Console, for extended periods of time.

Like the **Console**, the PCE monitors your AbioCor System, using lights and sounds to tell you if there is a problem with the system.

Figure 2.1 shows how the PCE is used.



Figure 2.1 Using the PCE

Parts of the PCE

The PCE includes the following parts, which are shown in Figures 2.2, 2.3, and 2.4.

- Battery Bag
- Batteries (2 pairs)
- Battery cable
- External TET
- PCE Control Module
- Battery Charger
- AC Power Adapter
- Handheld Monitor (not shown; described in a separate manual)

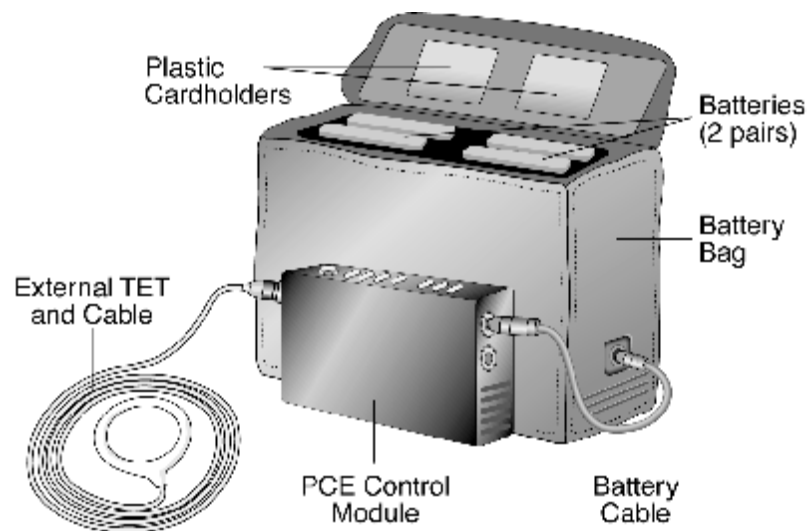


Figure 2.2 *Parts of the PCE*



Figure 2.3 PCE Battery Charger

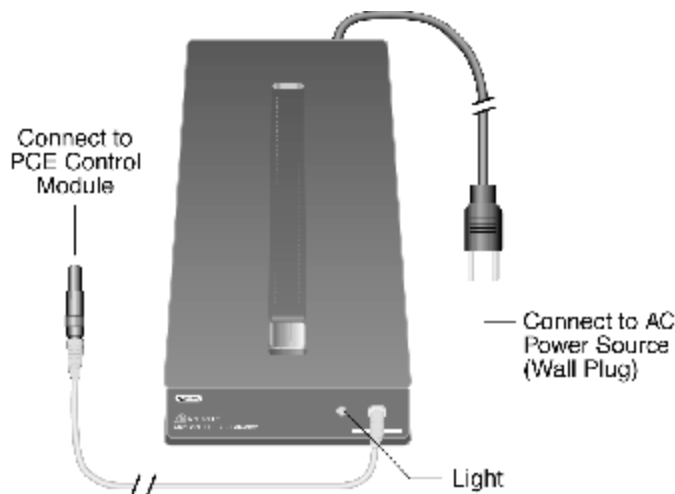


Figure 2.4 AC Power Adapter

PCE Battery Bag

The PCE Battery Bag holds 2 pairs of PCE Batteries and the Battery control electronics. The Battery Bag, which weighs about 10 pounds with the Batteries in place, has a shoulder strap so you can carry it easily. It has mesh pouches on the outside to hold the PCE Control Module, extra length of TET Cable, and other small items. Plastic cardholders inside the top cover can be used to keep emergency phone numbers close at hand.



CAUTION: Never cover the PCE with clothing.

Covering the PCE may cause the PCE to overheat and operate incorrectly.



CAUTION: Never block the PCE's cooling vents.

Blocking the cooling vents may cause the PCE to overheat and operate incorrectly.

Figure 2.5 shows the inside of the PCE Battery Bag with the zipper top opened.

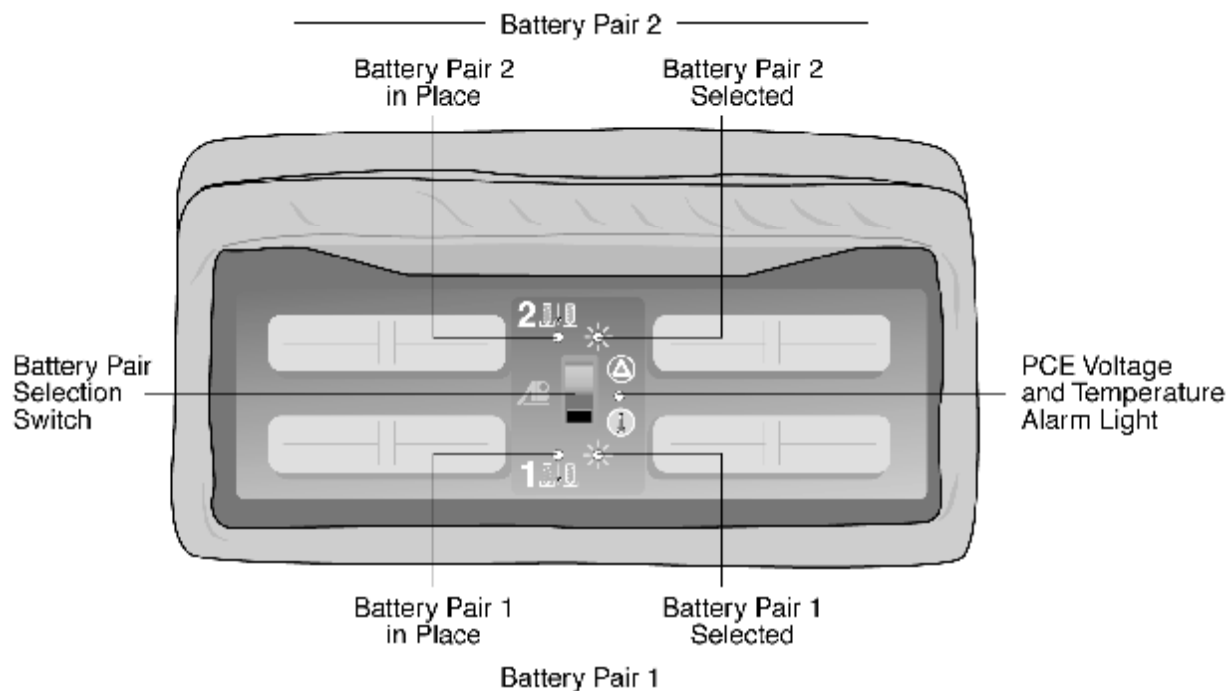


Figure 2.5 PCE Battery Bag with Batteries Installed

The functions of the Battery Bag switch and indicators are explained in Section 3 of this manual.

PCE Batteries

The PCE holds 2 pairs of Batteries—a total of 4 Batteries.

Each pair of Batteries provides power for the AbioCor's implanted components for about one hour. After that, you should switch to another set of Batteries and charge the used ones.

Information later in this manual tells you how to replace and recharge the Batteries.

Store Batteries in a dry location, out of direct sunlight, that does not exceed 100° F.

Batteries must be used in matched pairs

Batteries operate in matched pairs, and they must always be used together.

You can tell which Batteries go together in 2 ways:

- the number on the top edge of the Battery; both Batteries in a pair have the same number
- the serial number on the flat side of each Battery; both Batteries in a pair have the same serial number, except that one ends in A and the other ends in B. For example, one pair of Batteries may have the serial numbers 003000A and 003000B.

Figure 2.6 shows the serial number on the side of the Battery.

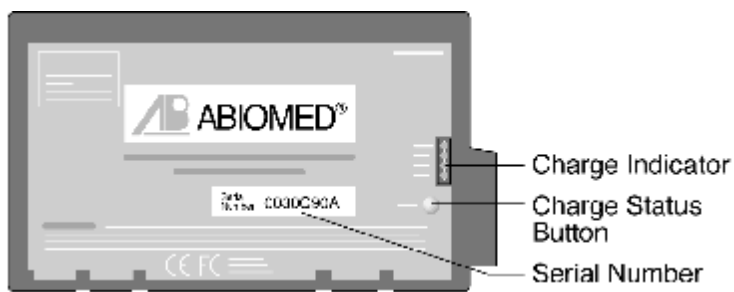


Figure 2.6 PCE Battery

Battery charge status

You can see whether a Battery is charged by checking the charge indicator on the flat side of the Battery, near the serial number (Figure 2.6). Press the Charge Status button below the Charge Indicator. If all 4 indicator lights do not turn on, the Battery needs to be charged.

If the charge on the pair of Batteries that you are using in the PCE is low, the Battery status alarm on the PCE Control Module will light. When this happens, switch to the other pair of Batteries right away.

You use the Battery charger to recharge the Batteries. Refer to “Charging Batteries” in Section 3 of this manual.



CAUTION: Never use a PCE Battery that has been dropped. It may not work correctly.

If you drop a PCE Battery, mark it DO NOT USE and return it to your doctor or clinic.

Battery Cable

The Battery Cable connects the PCE Control Module to the PCE Battery Bag. One end of the Battery Cable is permanently connected to the Battery Bag; the other end plugs into the PCE Control Module (in either the top or bottom socket).

To plug the Battery Cable into the PCE Control Module or to unplug it, hold the connector with your fingers over the arrows on the connector sleeve. Pull back the connector sleeve. Do not pull on the cord.

External TET

The External TET plugs into the PCE Control Module as shown in Figure 2.7. You can use the same 5-foot or 11-foot TETs with the PCE as you use with the Console. Cover the TET connector with the cap provided when the TET is not in use.

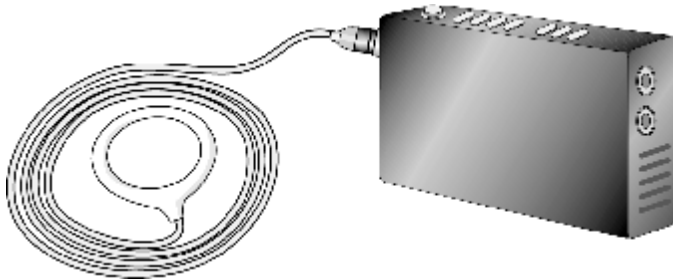


Figure 2.7 PCE Control Module with TET

PCE Control Module

The PCE Control Module (Figure 2.7) is a separate unit that is connected to the Battery Bag by the Battery Cable. It can also be connected directly to AC Power through the AC Power Adapter. The PCE Control Module does two main things:

- It converts Battery energy or AC power into energy that can be transmitted to the AbioCor System's implanted parts through the TET.
- It notifies you about alarms for the PCE or for any of the AbioCor System's implanted parts.

Refer to Section 5 of this manual for more information about the PCE Alarms.

The functions of the PCE Control Module are explained in Section 3 of this manual.

Battery Charger



CAUTION: Never remove Batteries while they are supplying power to the PCE.

You may damage the PCE and cause it to operate incorrectly.

The Battery Charger holds 5 pairs of Batteries, so you can always have enough fresh Batteries available. It plugs into a standard AC electrical power plug.

Normal charge time is 6 hours. You can charge Batteries in 3 hours, however, by using only the left-hand slot of each 2-bay unit of the Charger. This works because each pair of Batteries is charged one at a time, starting with the left side of the charging unit bay.

Always keep your Battery Charger plugged in, and keep any Batteries that are not in your PCE charged so they are ready when you need them.

Figure 2.8 shows the Battery Charger.



Figure 2.8 PCE Battery Charger

AC Power Adapter

If you are going to be away from the Console, but in a place where standard AC power is available (for example, at home or at a friend's house), you can connect your PCE to standard AC power using the AC Power Adapter. This ensures a steady source of power to the PCE while saving Batteries.

CAUTION: Always have 2 power sources connected to the PCE to ensure that you will be able to see and hear alarms if they occur. These power sources can be:



- 2 pairs of Batteries
- 1 pair of Batteries and an AC Power Adapter

The PCE's AC Power Adapter has 2 power cords:

- One connects the Adapter to an AC power source (wall plug)
- The other connects the Adapter to the PCE Control Module (in either the upper or lower socket).

The light on the front of the AC Power Adapter shows when it is plugged into AC power. Figure 2.9 shows the AC Power Adapter.

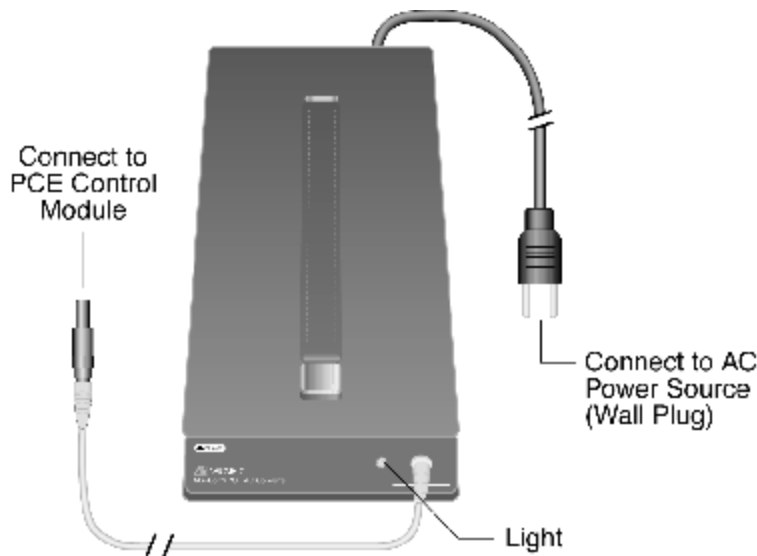
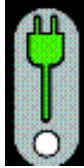


Figure 2.9 AC Power Adapter for the PCE

The AC Power Adapter has vents and a cooling fan inside. Keep the vents uncovered to ensure that the AC Power Adapter does not become overheated.

The AC Power Adapter also has a handle to make it easy for you to take it with you when you move about.



When the AC Power Adapter is being used, the AC Power selection indicator on the PCE Control Module is lighted.

3 Basic PCE Operation

WARNING: When using the PCE, you must always have at least one of the following backup units available within 10 minutes:

- a PCE and 2 pairs of fully-charged Batteries
- a fully-charged AbioCor Console

If a PCE problem alarm condition persists for more than 1 minute, exchange the PCE for one of these backup units.

If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.



This section of the manual explains how to use the PCE. Information includes:

- PCE Control Module functions
- Battery Bag switch and indicators
- charging batteries
- getting the PCE ready for use
- changing a pair of PCE batteries
- calibrating batteries
- connecting the AC Power Adapter
- cleaning the PCE

PCE Control Module Functions

Figure 3.1 shows the PCE Control Module's panel.

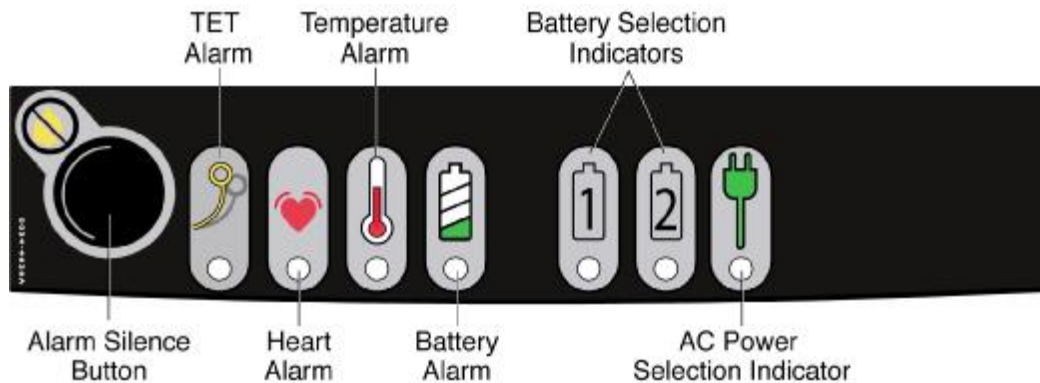


Figure 3.1 PCE Control Module Panel

Here is what the PCE Control Module panel button and lights are used for:

- Alarm silence button**
 Press this push-button switch to temporarily turn off an audible alarm while you are resolving the cause of the alarm. If you are unable to resolve the alarm after 2 minutes, it will sound again.
- TET alarm**
 The light indicates that the PCE TET is out of alignment with the Implanted TET. Reposition the PCE TET; when the light turns green, alignment is OK.
- Heart alarm**
 The light indicates that there is an alarm condition on the Implanted Replacement Heart, Implanted Controller, or Implanted Battery. Go to the Console or use the Handheld Monitor to find out what is wrong. If a setting needs to be changed, use the Console.
- Temperature alarm**
 The light indicates that the temperature inside the PCE is too hot.

Be sure that the PCE is in an open area, out of the sun, and that the cooling vents on the side of the Battery Bag are not covered by a coat or blocked by anything around them.

WARNING:

If a PCE temperature alarm condition persists for more than 1 minute, transfer control from the overheated PCE to a backup PCE or the Console.



If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.

- **Battery alarm**

The light indicates that the charge on the selected pair of Batteries is low. Switch to the other pair of Batteries or connect the PCE's AC Power Adapter.

Replace the low Batteries with freshly charged ones as soon as possible, so you always have spares ready.

- **Battery selection indicator**

The light indicates which pair of Batteries is being used.

Use the switch on the top of the PCE Battery Bag to select the other pair of Batteries.

- **AC power selection indicator**

The light indicates that the PCE is using AC Power to operate.

Battery Bag Switch and Indicators

Table 3.1 tells what the switch and indicator lights on the PCE Battery Bag panel do.

Table 3.1 PCE Battery Bag Panel

Icon or picture and name	What it does
 Battery pair selection switch	Flip the switch to 1 or 2 to select the pair of Batteries to be used.
 Battery pair selection light	The light indicates which Battery pair has been selected for use
 Indicator light: Battery pair 1 in place	The light indicates that both Batteries in pair 1 are correctly seated in the PCE Battery Bag. This light <i>DOES NOT</i> indicate whether the batteries are charged.
 Indicator light: Battery pair 2 in place	The light indicates that both Batteries in pair 2 are correctly seated in the PCE Battery Bag. This light <i>DOES NOT</i> indicate whether the batteries are charged.
 	PCE Voltage and Temperature Alarms The light between the triangle icon and thermometer indicates a problem in the PCE Battery Bag. The light may be red or yellow. A RED light indicates a serious PCE Battery Bag power problem. Connect the AC Power Adapter right away. A YELLOW light indicates that the PCE has overheated. Be sure that the PCE is in an open area, out of the sun, and that the cooling vents on the side of the Battery Bag are not covered by clothing or blocked by anything around them. WARNING: When using the PCE, you must always have at least one of the following backup units available within 10 minutes: • a PCE Battery Bag and 2 pairs of fully-charged Batteries • a fully-charged AbioCor Console If the light stays YELLOW or RED for more than 1 minute, exchange the PCE for one of these backup units. If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.

Charging Batteries

Before you can use the PCE, you need to charge its Batteries.

PCE Batteries are used and charged in matched pairs. You should charge Batteries after any period of use to ensure that you always have enough fresh Batteries.

To see if a Battery needs to be charged, push the Charge Status button below the Charge Indicator on the Battery. (See Figure 3.2.) If all 4 lights do not come on, the Battery needs to be charged.

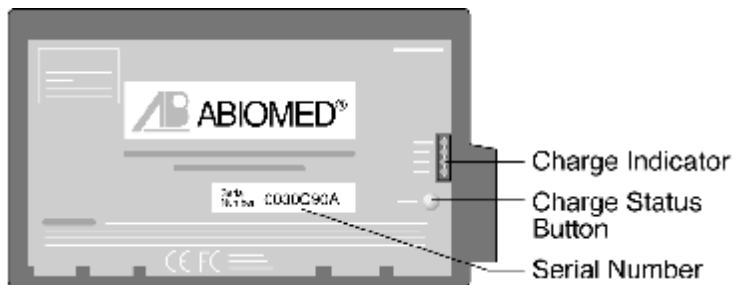


Figure 3.2 Location of the Battery Charge Indicator

To charge Batteries:

1. Plug the Charger's power cord into an AC outlet.
2. Insert the Batteries into the pairs of slots in the Battery Charger, with the connector edge down.
3. Confirm that the Charger's status lights turn on— one light for each bay. See Figure 3.3 for the location of the status lights (one light on each 2-Battery bay of the charger), and Table 3.2 for the meaning of the Status light conditions.
4. When the Batteries are fully charged, as indicated by solid green charging status lights, they are ready to use.

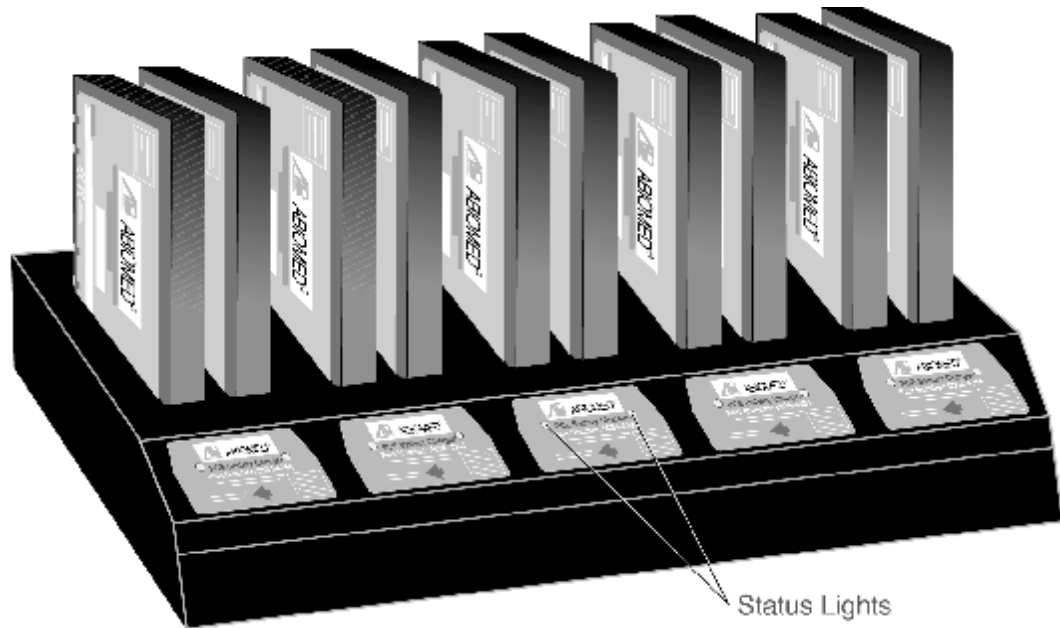


Figure 3.3 Battery Charger Status Lights

Table 3.2 explains the Charger status lights—what the different colors mean and what flashing means.

Table 3.2 Battery Charger Status Lights

Status Light Condition	What It Means
Off	No Battery, or Battery is not firmly seated in the charging bay.
Solid green	Battery is fully charged and ready to be removed.
Solid yellow	The bay of the charging unit is in Standby mode because the Battery in the other bay has not finished charging.
Flashing green	Battery is charging. Note: Each 2-bay charging unit charges 1 Battery at a time. The left bay is charged first.
Flashing yellow	The batteries are in the process of being recalibrated (discharged and recharged)
Flashing green and yellow	Battery recalibration is complete
Flashing red	A failure has occurred during charging. Do not use the Battery. Mark the Battery, "Do Not Use" and return it to your Health Care Provider.

Getting the PCE Ready for Use

The PCE comes pre-assembled in the Battery Bag. To use the PCE for the first time, follow this procedure.

1. Install 2 matched pairs of freshly charged Batteries into the PCE Battery Bag. Confirm that the Batteries are seated correctly by checking the 2 "Battery pair in place" indicator lights on the Battery Bag, between the Batteries. (Figure 3.4)

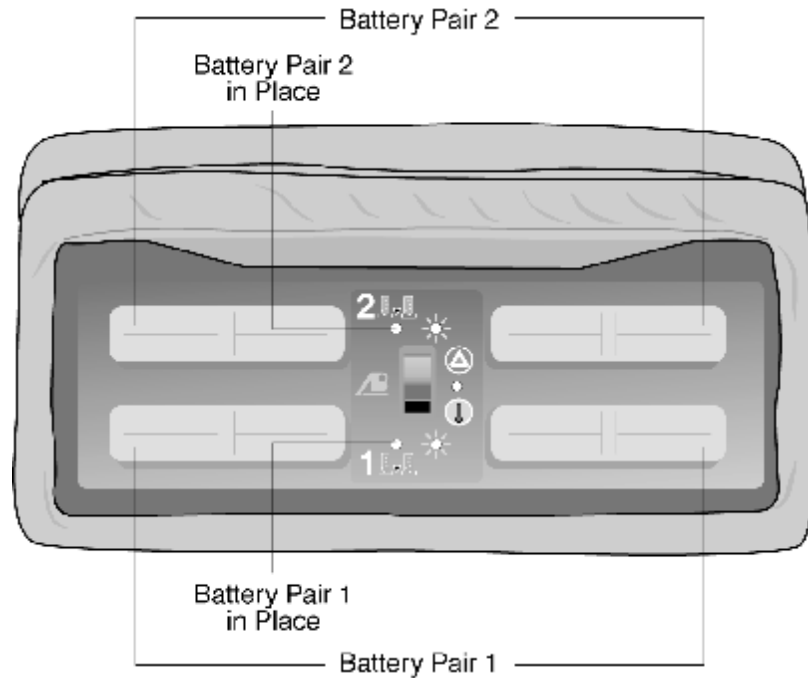


Figure 3.4 Installing the PCE Batteries

2. Plug the Battery Cable on the Battery Bag into the PCE Control Module as shown in Figure 3.5.

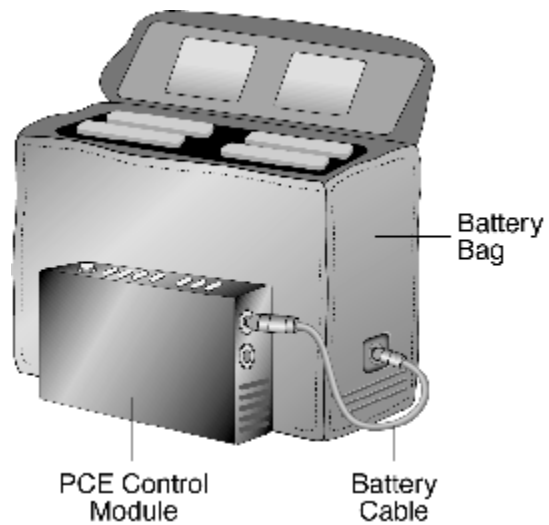


Figure 3.5 Plugging the Battery Cable into the PCE Control Module

3. Plug the TET into the PCE Control Module as shown in Figure 3.6.

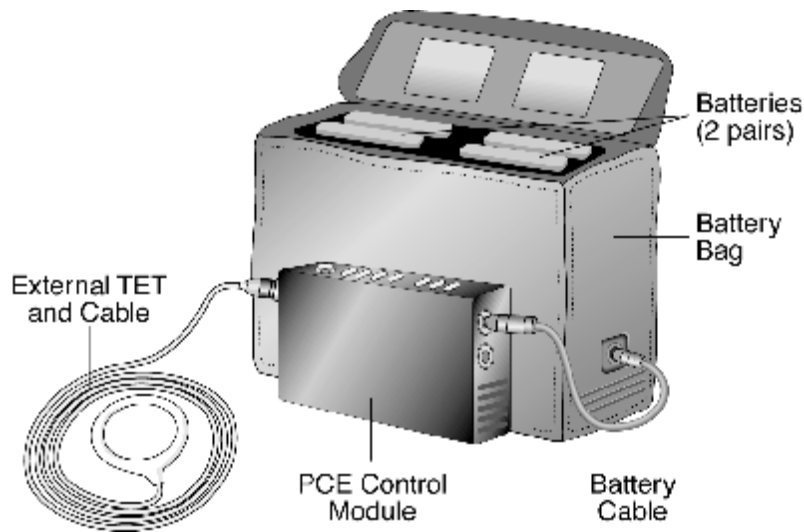


Figure 3.6 *Plugging the TET into the PCE Control Module*

4. Secure the PCE Control Module in the mesh pouch on the front of the Battery Bag (not shown) by closing the Velcro® fasteners.

CAUTION: Never place a TET that is connected to the PCE or Console on a metal surface.

The TET may become overheated, causing a fire hazard.



CAUTION: Keep a TET that is connected to the Console at least 1 foot away from any other TET (for example, the PCE TET.)

This precaution prevents potential damage to the TET's electronics.



Changing a Pair of PCE Batteries



CAUTION: Never remove Batteries while they are supplying power to the PCE.

You may damage the PCE and cause it to operate incorrectly.



Change Batteries (in matched pairs) when either one of the following occurs:

- the PCE Battery alarm light is lit on the PCE Control Module
- the Batteries have been in use for 90 minutes

To change a pair of Batteries:

1. Open the top cover of the PCE Battery Bag (Figure 3.7).

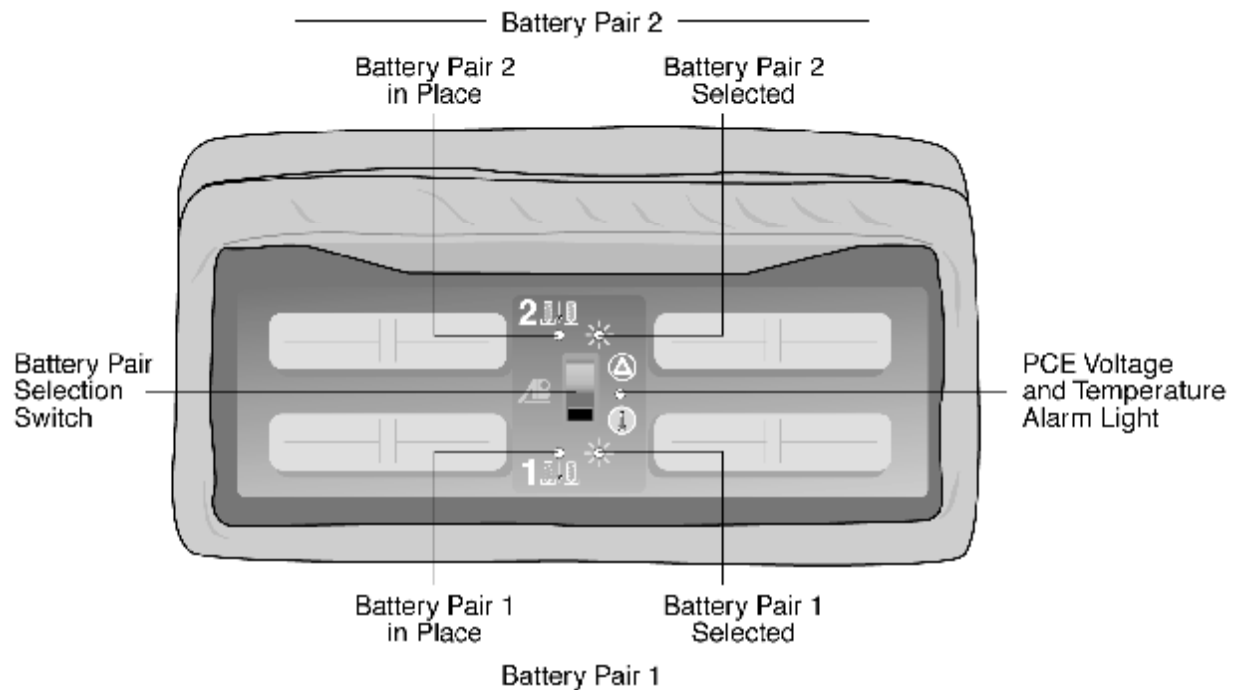


Figure 3.7 Changing Batteries

2. Flip the Battery Pair Selector switch in the PCE Battery Bag to the opposite position to select the other pair of Batteries. For example, if you were using Battery Pair 1, flip the switch to select Battery Pair 2.
3. Remove the used Batteries from the Battery Bag and place them in the Battery Charger. If the Charger is not available, set the Batteries aside for later charging.
4. Obtain a pair of freshly charged Batteries.
5. Confirm that the Batteries are a matched pair, by matching the numbers on the top ends of the Batteries and checking the serial numbers. The serial numbers should be the same, except that one should end in A and the other in B.
6. Insert the pair of Batteries into the PCE Battery Bag with the connector ends down. Confirm that the Batteries are seated correctly by checking the 2 Battery status lights on the Battery Bag panel between the Batteries (Figure 3.7).
7. Close the top cover of the Battery Bag.

Calibrating Batteries

To ensure that the Charge Indicator on each Battery is always accurate, all Batteries should be recalibrated (discharged and recharged) once a month.

To recalibrate PCE Batteries:

1. Plug the Battery Charger into an AC Power source (wall plug).
2. Insert one Battery in each of the five left-hand slots of the Battery Charger. (Leave the right-hand slots empty.)
3. Press the arrow on the front of *each* Battery Charger bay, where it says, "Press to recalibrate."
4. The Battery Charger fully discharges all the Batteries, resets their Charge Indicators to zero, and then charges the Batteries up again. The status lights on the front of the Battery Charger flash yellow during this time.
5. When the status light on the Battery Charger starts to blink yellow and green, the Battery calibration process is complete. Take the calibrated Batteries out of the Battery Charger.
6. Put five more Batteries into the left-hand slots and repeat the calibration process until all your Batteries are calibrated.

Connecting the AC Power Adapter

CAUTION: Always have 2 power sources connected to the PCE to ensure that you will be able to see and hear alarms if they occur.

If you are using the AC Power Adapter, have one pair of charged Batteries in place in the PCE.



To connect the AC Power Adapter (Figure 3.8):

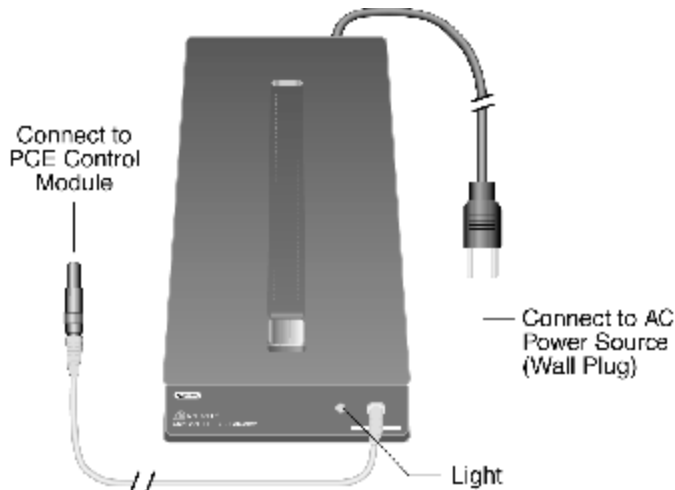
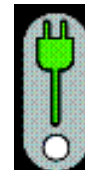


Figure 3.8 Connecting the AC Power Adapter

1. Plug the AC Power Adapter's power cord into an electrical outlet. Be sure the light on the AC Power Adapter is on to confirm that the power is on.
2. Plug the other Power Adapter cable into the unused Battery Cable socket on the outside of the PCE Control Module. (You can use either the top or bottom connector socket.)
3. Check the AC Power selection indicator on the PCE Control module to be sure that AC Power is in use. If the light is not on, check the power connections.



Note: Using the AC Power Adapter does not recharge the Batteries that are in the PCE. They must be recharged in the Battery Charger.

Cleaning the PCE



CAUTION: Never submerge any part of the PCE in liquid.

Liquids will severely damage the PCE and cause it to operate incorrectly.



CAUTION: Do not allow any liquids (including water) to come in contact with any electrical connector pins.

Contact with liquid may cause corrosion or electrical malfunction.



CAUTION: Do not clean the TET, Radiofrequency (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 AbioCor components.



CAUTION: Do not clean the TET, RF Communications Module, or cables with cleaners that may stain the surfaces you are cleaning.

This staining may hide the breakdown of the outer coverings of these AbioCor components.

Cleaning the PCE Battery Bag and Control Module

1. Unplug the AC Power Adapter from the PCE, if it is connected.
2. Wipe the PCE Battery Bag and PCE Control Module with a soft cloth moistened with a mild detergent solution.

Cleaning the PCE TET and all Cables

Wipe the TET and Cables with a soft cloth slightly moistened with isopropyl (rubbing) alcohol.

Note: ABIOMED recommends that you clean the TET every day.

4 Transferring Support Between the Console and the PCE



WARNING: When using the PCE, you must always have at least one of the following backup units available within 10 minutes:

- a PCE and 2 pairs of fully-charged Batteries
- a fully-charged AbioCor Console

If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.



CAUTION: Always have 2 power sources connected to the PCE to ensure that you will be able to see and hear alarms if they occur. These power sources can be:

- 2 pairs of Batteries
- 1 pair of Batteries and an AC Power Adapter



CAUTION: Never cover the PCE with clothing.

Covering the PCE may cause it to overheat and operate incorrectly.



CAUTION: Never block the PCE's cooling vents.

Blocking the cooling vents may cause the PCE to overheat and operate incorrectly.



CAUTION: Keep a TET that is connected to the Console at least 1 foot away from any other TET (for example, the PCE TET.)

This precaution prevents potential damage to the TET's electronics.



CAUTION: Never place a TET that is connected to the Console on a metal surface.

The TET may become overheated, causing a fire hazard.

Transferring Support from the Console to the PCE

When you want to use the PCE instead of the Console, follow the step-by-step procedure listed below. These procedures will ensure that the PCE works correctly to provide energy to your implanted AbioCor Replacement Heart.

There are two different procedures:

- one procedure for using the same TET with the PCE as you use with the Console
- another procedure for changing TETs when you transfer support to the Console

Transferring to the PCE if You Use the Same TET

If you want to use the same TET with the PCE as with the Console, follow this procedure.

- 1** Insert 2 pairs of fully-charged Batteries into slots in the Battery Bag as shown in Figure 4.1.
 - Be sure that the Battery pair indicator lights between the Battery slots in the PCE Battery Bag (Figure 4.1) turn on when the Batteries are in place.
 - If the indicator lights do not turn on, be sure the Batteries are plugged securely into place.

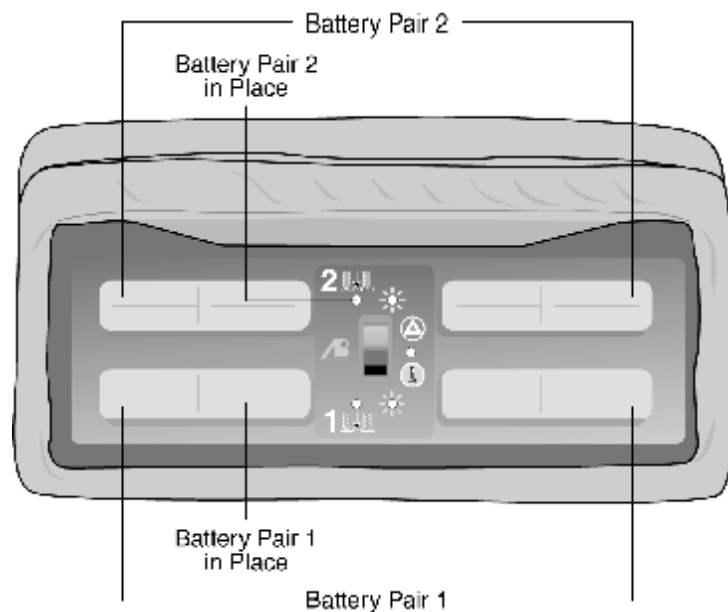


Figure 4.1 Installing Batteries in the Battery Bag

- 2** Plug the Battery Cable on the Battery Bag into the PCE Control Module as shown in Figure 4.2.

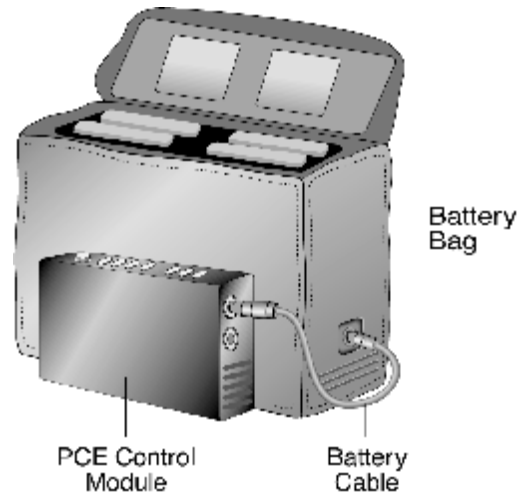


Figure 4.2 *Plugging the Battery Cable into the PCE Control Module*

- 3** When the PCE TET alarm sounds, press the Silence Alarm button on the PCE Control Module (Figure 4.3)

The TET alarm light will turn on; this is normal.

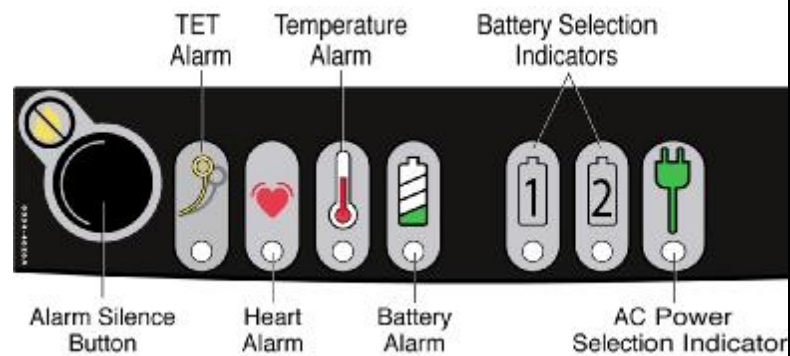


Figure 4.3 *Silencing the TET Alarm*

- 4**



Figure 4.4
Console TET Unplugged



Figure 4.5
Silencing Console Alarms

Unplug the TET from the Console.

- Do not remove the TET or the DuoDerm patch from your chest.
- The “TET Unplugged” symbol appears on the Console screen (Figure 4.4) and the TET alarm sounds. This is normal.

Press the Console alarm silence button (Figure 4.5).

- 5** Plug the TET connector into the PCE Control Module as shown in Figure 4.6.

The TET alarm light on the PCE Control Module will turn green.

Note: The TET is now powered; keep it away from metal surfaces.

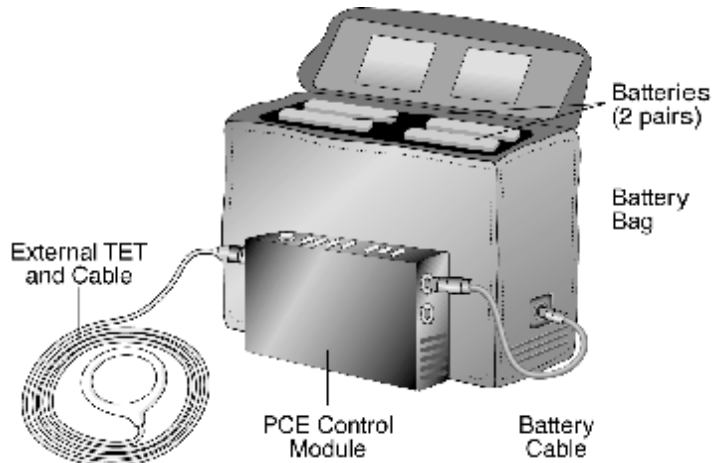


Figure 4.6 Connecting the TET to the PCE Control Module

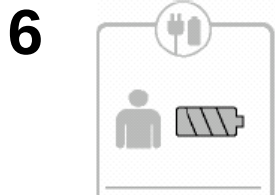


Figure 4.7 Console Power Panel After Transfer to PCE

Look at the Implanted Battery section of the Console Power Panel.

The Implanted Battery icon should be fully filled in with gray without a halo around it (Figure 4.7).

This tells you that the Implanted Battery is not the primary source of power for the Replacement Heart because the PCE is providing power.



Figure 4.8 Testing PCE Alarms

On the Console keypad, press the Test PCE alarm button (Figure 4.8). The alarm panel displays the following message:

Testing PCE alarm. You should now hear your PCE alarm buzzer. If you do not, call your Health Care Provider.



Figure 4.9 Checking the Heart Alarm Light

Be sure the Heart alarm light on the PCE Control Module turns on (Figure 4.9) and the buzzer sounds.

If you do not hear the PCE alarm, move the RF Communications Module so it is near your abdomen over the Implanted Controller.

If the alarm does not sound, use a new PCE Control Module.

If the alarm still does not sound, call your health care provider.

8

Figure 4.10
Putting the
Console on
Standby

Press the Console standby mode button (Figure 4.10) to put the Console into standby mode. This will quiet the Console alarms. The Console display shows the following message:

Enter standby mode? Only place the Console into standby mode if no one is supported by it! Press the Console standby button again to enter standby mode.

Press the standby mode button a second time to confirm that you want to put the Console on standby.

The Console display screen becomes black, with the standby icon showing in the corner, to tell you the Console is in standby mode.

Transferring to the PCE if You Use a Different TET

If you want to change TETs when you transfer support to the PCE, follow this procedure.

1

Insert 2 pairs of fully-charged Batteries into slots in the Battery Bag as shown in Figure 4.11.

- Be sure that the Battery Pair in Place indicator lights between the Battery slots in the PCE Battery Bag (Figure 4.2) turn on when the Batteries are in place.
- If the indicator lights do not come on, be sure the Batteries are plugged securely into place.

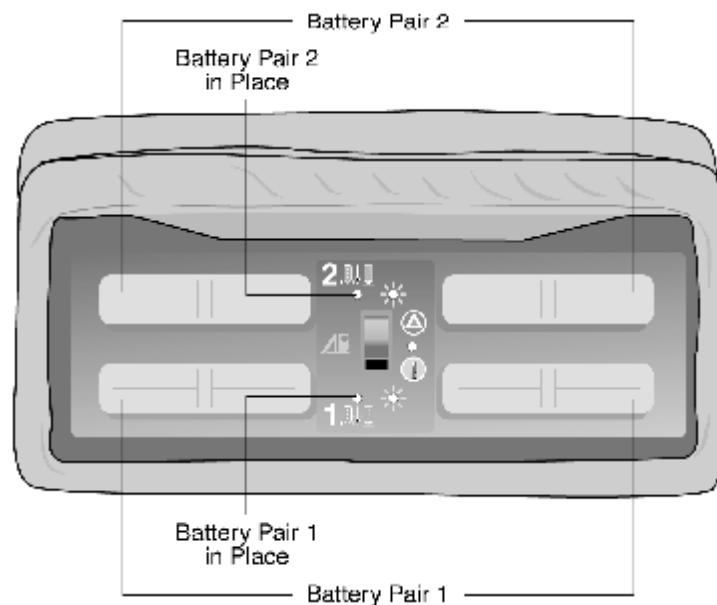


Figure 4.11 *Installing Batteries in the Battery Bag*

- 2** Plug the Battery Cable on the Battery Bag into the PCE Control Module as shown in Figure 4.12.

The PCE TET alarm will sound; this is normal. Press the PCE alarm silence button (Figure 4.17, below) to quiet the alarm.

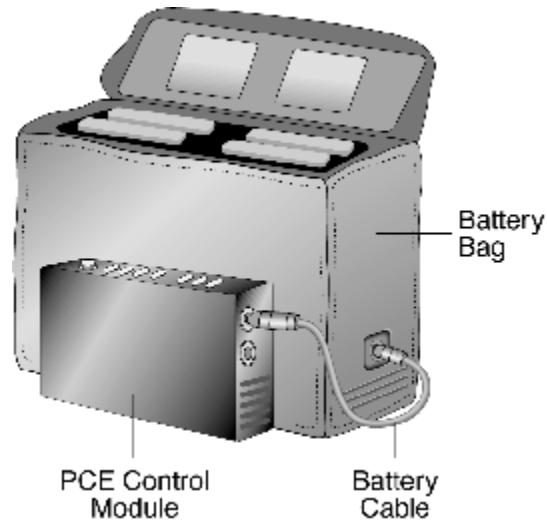


Figure 4.12 *Plugging the Battery Cable into the PCE Control Module*

3

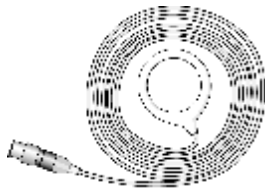


Figure 4.13 *Removing the Console TET*

Unplug the TET from the Console (Figure 4.13). Be sure to keep the Console TET at least 1 foot away from the PCE TET.

Remove the TET from the DuoDerm Patch on your chest.

4



Figure 4.14 *Console TET Unplugged*

The “TET Unplugged” symbol appears on the Console screen (Figure 4.14) and the Console TET alarm sounds. This is normal.

Press the Console alarm silence button (Figure 4.15).



Figure 4.15 *Silencing Console Alarms*

Do the next steps within 2 minutes to minimize the amount of time that the Implanted Battery is discharging.

- 5** Plug the PCE TET connector into the PCE Control Module as shown in Figure 4.16.

Note: The TET is now powered; be careful to keep it away from metal surfaces.

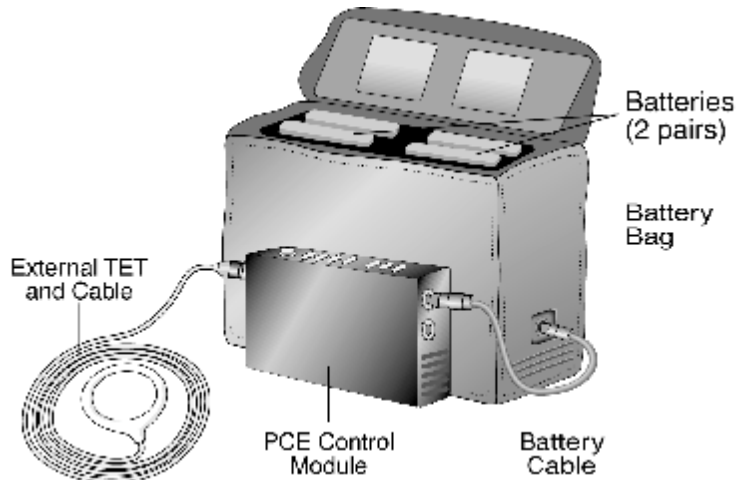


Figure 4.16 Connecting the TET to the PCE Control Module

- 6** Place the PCE TET on your chest.

Look at the TET alarm light on the PCE Control Module (Figure 4.17); when the light goes off, the TET is correctly aligned.

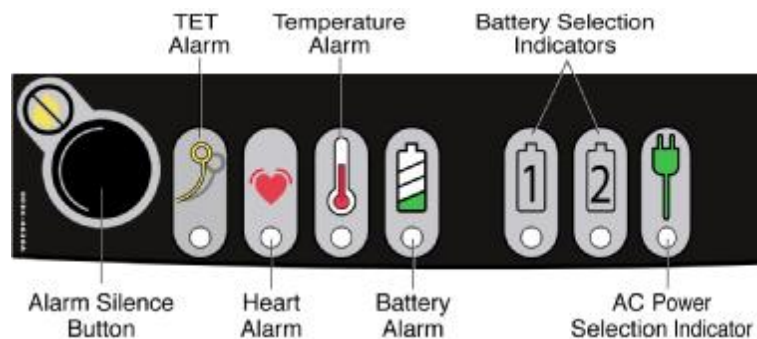


Figure 4.17 Silencing the PCE TET Alarm

Secure the TET with the Velcro strips on the DuoDerm patch.

7

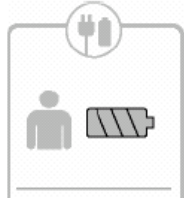


Figure 4.18
Checking the
Console Power
Panel

Look at the Implanted Battery section of the Console Power Panel.

The Implanted Battery icon should be fully filled in with gray without a halo around it (Figure 4.18).

This tells you that the Implanted Battery is not the primary source of power for the Replacement Heart because the PCE is providing power.

8



Figure 4.19
Testing PCE
Alarms

On the Console keypad, press the Test PCE alarm button (Figure 4.19). The alarm panel displays the following message:

Testing PCE alarm. You should now hear your PCE alarm buzzer. If you do not, call your Health Care Provider.

Be sure the Heart alarm light on the PCE Control Module turns on (Figure 4.20) and the buzzer sounds.

If you do not hear the PCE alarm, move the RF Communications Module so it is near your abdomen over the Implanted Controller.

If the alarm still does not sound, use a new PCE Control Module.

If the alarm still does not sound, call your health care provider.



Figure 4.20
Checking the
Heart Alarm Light

9



Figure 4.21
Putting the
Console on
Standby

Press the Console standby mode button (Figure 4.21) to put the Console into standby mode. This will quiet the Console alarms. The Console display shows the following message:

Enter standby mode? Only place the Console into standby mode if no one is supported by it! Press the Console standby button again to enter standby mode.

Press the standby mode button a second time to confirm that you want to put the Console on standby.

The Console display screen becomes black, with the standby icon showing in the corner, to tell you the Console is in standby mode.

Transferring Support from the PCE to the Console

When you want to use the Console instead of the PCE, follow the step-by-step procedures listed below.

There are two different procedures:

- one procedure for using the same TET on the Console as you used on the PCE
- another procedure for changing TETs when you transfer support to the Console.

Transferring to the Console if You Use the Same TET

If you want to use the same TET with the Console as with the PCE, follow this procedure.

1



Figure 4.22
Bringing the
Console out of
Standby

Press the standby button on the Console (Figure 4.22) to bring the Console out of standby mode.

If Console alarms sound, use the Alarm Silence button (Figure 4.23) to quiet them.



Figure 4.23
Silencing
Console
Alarms

2

Figure 4.24
Checking the RF
Communications
Signal

Plug the RF Communications Module into the Console, if it is not already connected.

Position the RF Communications Module to get a good RF communications signal.

Open the RF panel on the Console. Look for green arcs to show that the RF signal is strong in both directions (Figure 4.24). If the signal is not strong, move the RF Communications Module to improve the signal.

Do the next step within 2 minutes to minimize the amount of time that the Implanted Battery is discharging.

3

Unplug the TET from the PCE Control Module.

The PCE TET alarm will turn red and the buzzer will sound. Press the alarm silence button to quiet the alarm (Figure 4.25).

Do not remove the TET from your chest yet.

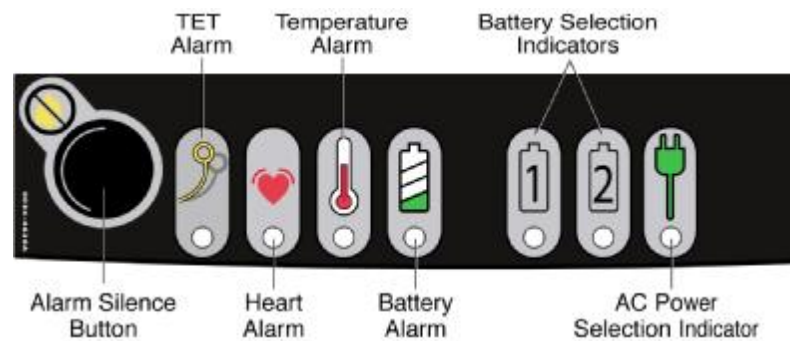


Figure 4.25 **Silencing the PCE TET Alarm**

- 4** Plug the TET into the Console TET connector (Figure 4.26)

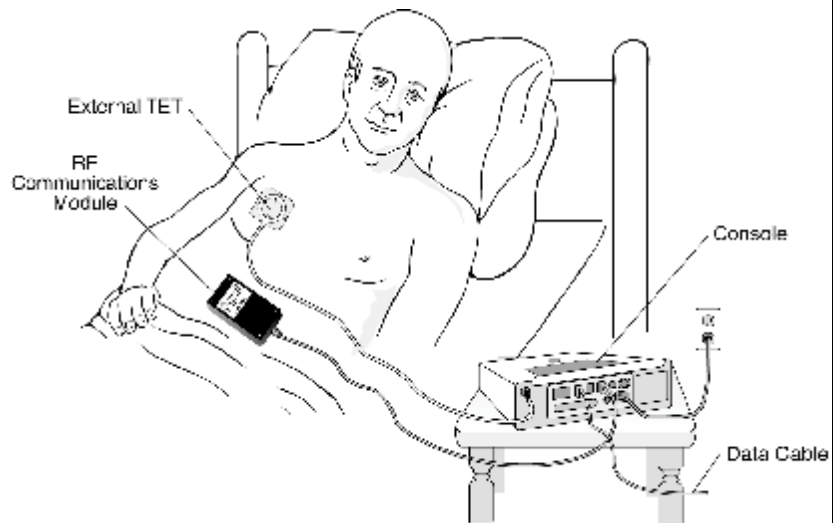


Figure 4.26 Connecting the TET to the Console

5



**Figure 4.27
Checking TET
Alignment and
Power on
Console
Power Panel**

Open the Power panel. Using Figure 4.27 as a reference,

- Be sure the TET is aligned correctly (a green TET in the center section of the panel)
- Be sure the system is receiving power from the Console (there is no halo around the Implanted Battery icon).

- 6** Open the top cover of the PCE Battery Bag (Figure 4.28).
Remove the PCE Batteries.

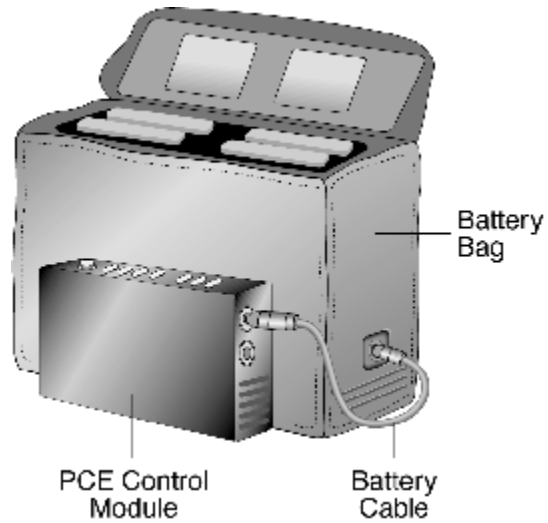


Figure 4.28 Removing the PCE Batteries from the Battery Bag

- 7** Be sure the Battery Charger is plugged in.
Place the PCE Batteries in the Battery Charger (Figure 4.29).



Figure 4.29 Charging the Used Batteries

Transferring to the Console if You Use a Different TET

To transfer support from the PCE to the Console if you want to use a different TET with the Console, follow this procedure.

CAUTION: Keep a TET that is connected to the Console at least 1 foot away from any other TET (for example, the PCE TET.)

This precaution prevents potential damage to the TET's electronics.



CAUTION: Never place a TET that is connected to the Console on a metal surface.

The TET may become overheated, resulting in a fire hazard.

**1**

Figure 4.30
Bringing the Console
out of Standby

Press the standby button on the Console (Figure 4.30) to bring the Console out of standby mode.

2

Figure 4.31
Checking the RF
Communications
Signal

Plug the RF Communications Module into the Console, if it is not already connected.

Position the RF Communications Module to get a good RF communications signal.

Open the RF panel on the Console. Look for green arcs to show that the RF signal is strong in both directions (Figure 4.31). If the signal is not strong, move the RF Communications Module to improve the signal.

Do the next step within 2 minutes to minimize the amount of time that the Implanted Battery is discharging.

3 Remove the PCE TET from your chest. Do not remove the DuoDerm patch. Unplug the TET from the PCE Control Module.

4 Place the Console TET on your chest. Secure it with the Velcro strips on the DuoDerm patch.

5 The PCE TET alarm will light and the buzzer will sound. Press the alarm silence button to quiet the alarm (Figure 4.32).

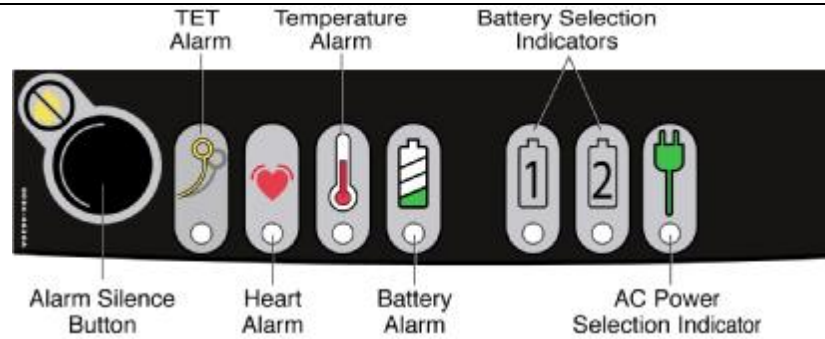


Figure 4.32 Silencing the PCE TET Alarm

6 Plug the Console TET into the Console TET connector (Figure 4.33)

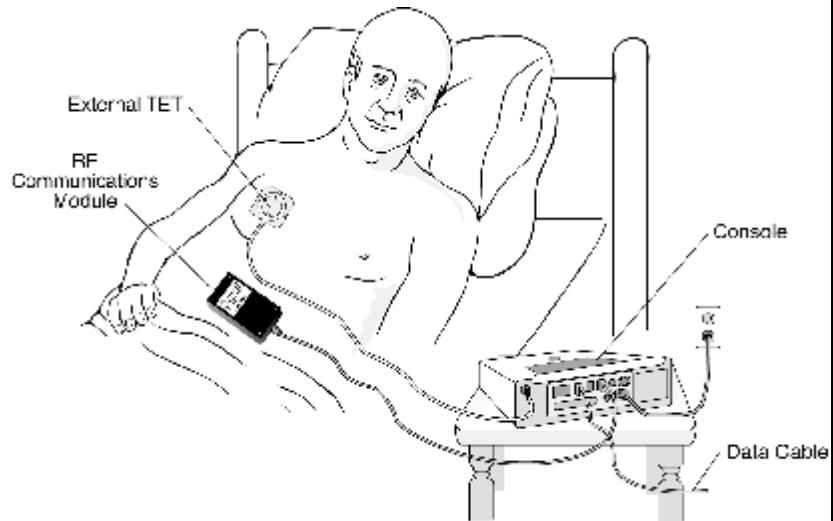


Figure 4.33 Connecting the TET to the Console

- 7** Open the Power panel. Using Figure 4.34 as a reference:
- Be sure the TET is aligned correctly (a green TET in the center section of the panel) Reposition the TET on your chest if the TET is not correctly aligned.
 - Be sure the system is receiving power from the Console (there is no halo around the Implanted Battery icon).



Figure 4.34 *Checking TET Alignment and Power on Console Power Panel*

- 8** Open the top cover of the PCE Battery Bag (Figure 4.35).
Remove the PCE Batteries.

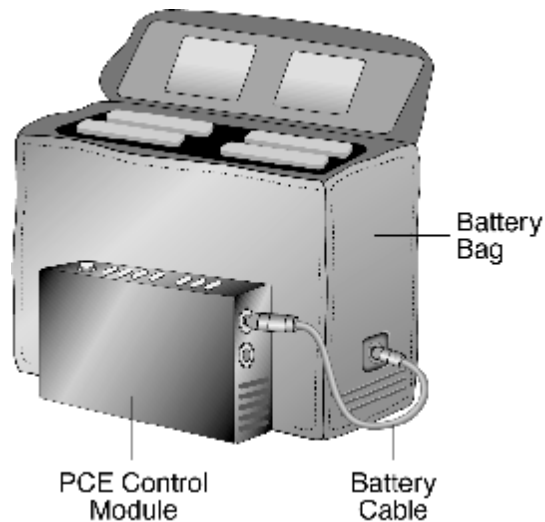


Figure 4.35 *Removing the PCE Batteries from the Battery Bag*

9

Be sure the Battery Charger is plugged in.

Place the PCE Batteries in the Battery Charger (Figure 4.36).



Figure 4.36 *Charging the Used Batteries*

5 PCE Alarms

What are the PCE Alarms?

The PCE Control Module monitors the AbioCor System's implanted components and the PCE Batteries to ensure that all the parts of the system are working correctly.

If a problem is detected, the PCE Control Module turns on an alarm indicator light and sounds an alarm.

To quiet the alarm temporarily, press the Alarm silence button on the PCE Control Module. (See Figure 5.1.) If you are unable to resolve the alarm within 2 minutes, it will sound again.

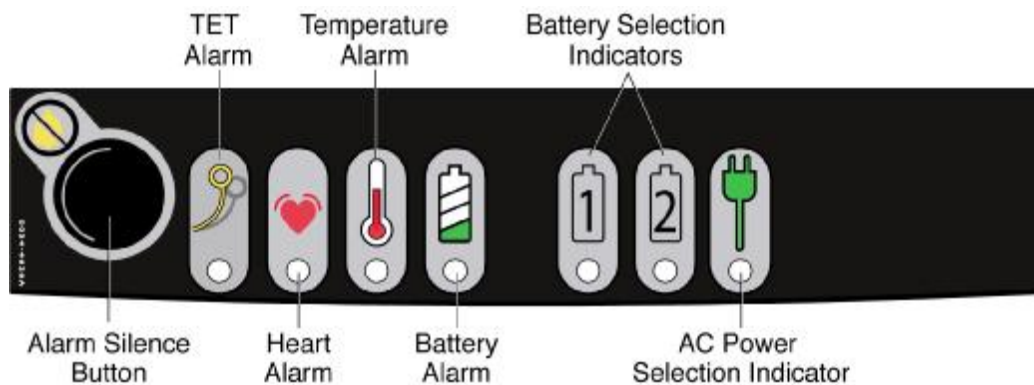


Figure 5.1 PCE Control Module Panel

PCE Battery Bag Alarms

Table 5.1 lists the PCE Battery Bag alarms that you can see on the panel inside the PCE Battery Bag and the actions you should take if they occur.



WARNING: When using the PCE, you must always have at least one of the following backup units available within 10 minutes:

- a PCE Battery Bag and 2 pairs of fully-charged Batteries
- a fully-charged AbioCor Console

If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.

Table 5.1 PCE Battery Bag Alarms

Icon	Name	Description	What to Do
	PCE Battery Bag Power and Temperature Alarms	The light between the triangle icon and thermometer indicates a problem in the PCE Battery Bag. The light may be red or yellow. A RED light indicates a serious Battery Bag power problem. A YELLOW light indicates that the PCE has overheated.	Connect the AC Power Adapter right away. If the light stays RED for more than 1 minute, exchange the PCE system for a new unit. Be sure that the PCE is in an open area, out of the sun, and that the cooling vents on the side of the Battery Bag are not covered by a coat or blocked by anything around them. If the light stays YELLOW for more than 1 minute, exchange the PCE for a backup unit.

PCE Control Module Alarms

The alarms displayed by the PCE Control Module are explained in Table 5.2.

Table 5.2 PCE Control Module Alarms

Icon	Name	Description	What to Do
	TET alarm	The red light indicates that the PCE TET is out of alignment with the Implanted TET or unplugged. An alarm sound is also heard.	Reposition the PCE TET. If the light turns green, alignment is OK.
	Heart alarm	The light indicates that there is an alarm condition on the Implanted Replacement Heart, Implanted Controller, or Implanted Battery. An alarm sound is also heard.	Use the Handheld Monitor or position the RF Communications Module over the Implanted Controller and look at the Console display to see what is wrong If a setting needs to be changed, use the Console.
	Temperature alarm	The light indicates that the temperature inside the PCE Control Module is too hot. An alarm sound is also heard. WARNING: If a PCE temperature alarm condition persists for more than 1 minute, transfer control from the overheated PCE to a backup PCE or the Console. If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.	Be sure that the PCE is in an open area, out of the sun. Be sure that the cooling vents on the side of the PCE Control Module are not covered by a coat or blocked by anything around them. If the PCE remains overheated for more than 1 minute (indicated by the temperature alarm lights and sound), transfer control from the overheated PCE to a backup PCE or the Console.
	Battery alarm	The light indicates that the charge on the selected pair of Batteries is low. An alarm sound is also heard.	Switch to the other pair of Batteries or connect the AC Power Adapter. Replace the low Batteries with freshly charged ones as soon as possible.

Appendix: Federal Communications Commission (FCC) Notice

AbioCor Components	Notice
AbioCor Console	This device complies with Part 18 of the FCC Rules.
PCE Control Module	This device complies with Part 18 of the FCC Rules.
RF Communication Module	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Handheld Monitor	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Implantable Controller	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.



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