VitalView® Data Acquisition System

E-Mitter® Implantation Procedure

PDT-4000 E-Mitter®
G2 E-Mitter™
PDT-4000 HR E-Mitter® with Heart Rate
G2 HR E-Mitter™ with Heart Rate

STARR™
Life Sciences Corp.

This is Part Number 910-0014-06 Rev A

STARR LIFE SCIENCES

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b) **Duration of Warranty** – The goods sold hereunder are warranted for a period of twelve months, except PDT-4000 and PDT-4000HR, which are warranted for two years.

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Safety

Some products within the E-Mitter VitalView system contain electronically active components. Examples of safety conventions follow. Please take precautions seriously, and keep your project safe.

WARNING! *– A warning indicates danger of harm to yourself or your subject, and recommends steps to avoid the problem.*

CAUTION! – A caution indicates the danger of damage to the hardware, or loss of data, and recommends steps to avoid the problem.

NOTE: Handy information important enough to highlight that may save you time and consternation.

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Thank You!

If you need assistance with your implantation, remember Starr Life Sciences support continues after the purchase. If you have any problems or questions, call our Product Support staff of technicians, engineers, and scientists. We are available by telephone, fax, e-mail, or website.

A video is available of the implantation procedure. Call Starr Life Sciences for details.

Contacting Starr Life Sciences Product Support

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Preparation for Implantation

Introduction

This manual describes the implantation of E-Mitters (PDT-4000), HR E-Mitters (PDT-4000 HR), and G2 E-Mitters.

The procedure for implantation of E-Mitters/G2 E-Mitters and HR E-Mitters is generally the same. The only difference is the surgical placement of HR E-Mitter heart rate leads, and a slightly different test procedure prior to closure.

This manual assumes you have read the appropriate sections of the VitalView manual. This will give you a better understanding of the operation of the products.

This section also assumes you are qua lified in proper techniques including sterilization, anesthesia, surgery, recovery, and have the proper instruments. If you have questions concerning any of these procedures, call us at Starr Life Sciences Our technical staff will assist you.

Make sure you are prepared for surgery well in advance. In addition to animal requirements, there are hardware and software preparations that must be made to the VitalView System.

- You must have VitalView Version 2.20 or later.
- E-Mitters must be sterilized prior to implantation. Do not leave them immersed longer than required for sterilization, but make sure they are sterile. Sterilization techniques are covered on page 3.
- Heart Rate E-Mitter leads may need advanced preparation. See “Preparing the Heart Rate Leads” on page 14.
- Depending on the species, it is often important not to feed the animal for 5 to 8 hours prior to surgery. For species specific information consult a veterinarian.
- A heating pad or other suitable heat source ***must*** be provided for the animal.
- Prepare a clean, disinfected work area with good lighting. Cold sterilants can be utilized as well as sterile surgical draping to insure a sterile work area.

Instruments and Materials Required

Non-Sterile Materials

- Anesthetic agent recommended for your study species.
- Hair clippers
- Betadine® or other surgical scrub
- Zephiran®, Alcide®, or other liquid sterilant
- Furacin®
- Adhesive tape
- Heating pad - for smaller species

Sterile Materials

- Scalpel handle (#3) and blade (#10)
- Surgical scissors (Metzenbaum)
- Toothed forceps (Adson)
- Suture materials such as stainless steel, silk, Vicryl®
- Suture needles
- Needle holder or straight six-inch heavy duty hemostat
- Mosquito hemostat
- Wound clips and applicator
- Gauze sponges and cotton-tipped applicators
- Stainless steel ferrules (if using heart rate E-Mitters)

An Implantation Kit is available from Starr Life Sciences. Call the factory for details.

Surgical Information & References

Starr Life Sciences E-Mitters can be implanted intraperitoneally or subcutaneously with a minimum of risk to the study animal, if common surgical guidelines are followed. Anesthesia and surgical procedures for each species will vary. In this section we have provided general information on preparation for surgery and a list of the surgical materials required. We recommend that VitalVie w system users consult with their local animal care professional and reference materials for specific guidelines. Explantation of E-Mitters will require the same advance preparation, anesthesia and surgical materials as implantation.

Many references are available that may be of assistance in establishing animal care and use protocols:

Guide to the Care and Use of Experimental Animals (ISBN 0-919087)

Selection and Handling of Animals in Biomedical Research by Svendsen (ISBN 084934378X)

The Laboratory Rat by Sharp and La Regina (ISBN 0-8493-2565-1)

Sterilants

E-Mitters should be sterilized prior to surgery. Ethylene oxide gas and chemical sterilants such as activated glutaraldehyde (Cidex®) and benzalconium chloride (Zephiran®) can be used effectively. Avoid leaving the transmitters in chemical solution any longer than necessary. Be certain to properly aerate implants after gas sterilization. Rinse chemically sterilized implants in sterile saline just prior to implantation.

CAUTION! Do not autoclave or exceed 60° C in gas sterilizers. Destruction of the E-Mitter may result.

Sterilize the usual instruments including the lead placement trochar provided with your Heart Rate E-Mitters. This tool consists of a 1/8" diameter stainless steel rod and a close fitting sleeve. It is used to create a tunnel under the skin and to pass the sensing lead to the proper location on the chest.

Anesthesia

If you are unfamiliar with lab animal anesthesia, you should consult an animal care professional or text references for information on recommended agents and dosages.

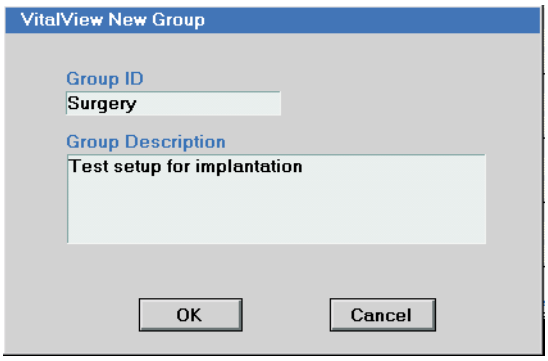
Configuring the ER-4000 Prior to Surgery

The VitalView system should be fully operational prior to implantation surgery. If possible, locate the system with an ER-4000 Energizer/Receiver near the surgery area so that subjects can be checked for a proper signal prior to closing. The configuration procedure is nearly identical for the E-Mitter, G2 E-Mitter, HR E-Mitter, and the G2 HR E-Mitter. All devices should be checked for proper communication with the ER-4000. The HR E-Mitter needs to be verified for heart rate signal.

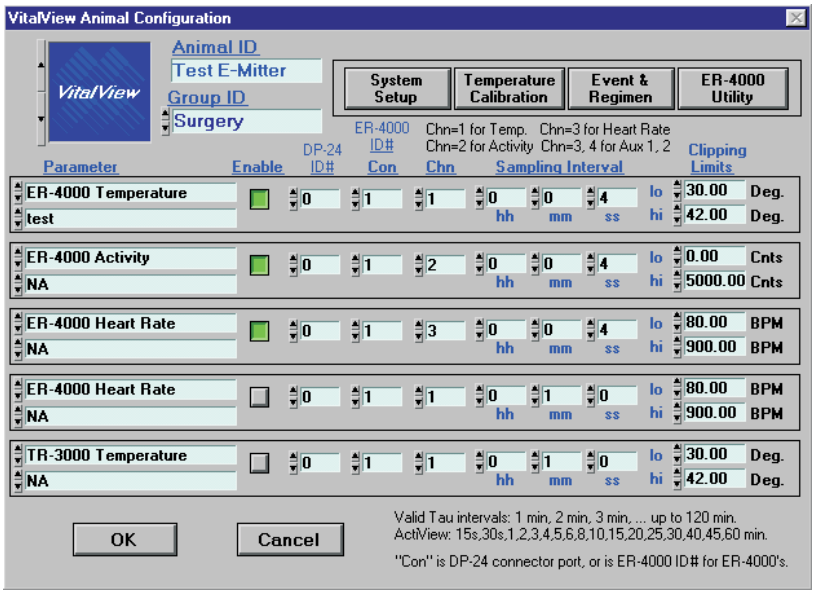
It will be necessary to use a valid configuration file for testing E-Mitter communication and data transfer. A configuration file called “Surgery” is included with the VitalView software package. If you do not have a configuration file, it will be necessary to make one. If you use an existing file, make sure the settings are changed to match the following configuration.

1. From the Main window, click on Animal & Group Setup.
2. In the Animal & Group Setup display, under Group menu, click on New.
3. At the prompt, label this group appropriately, e.g. Surgery, etc. Click OK.

Access: Main window > Animal & Group Setup > Group Menu > New



4 Click within any of the parameter panels. This will open the VitalView Animal Configuration display. Enter in the following values:



NOTE: If you are using the standard E-Mitter or G2 E-Mitter, you do not need to enable Heart Rate.

Note that the parameters are enabled, values entered, channels assigned, etc. Also note that the transmitter calibration values must be entered. This information can be obtained from the calibration sheet supplied with your E-Mitter.

5 After all the values have been entered in the above display, click on OK.

6 Under the File menu, choose Save Configuration, and save this file as "Test E-Mitter", "Surgery", or some other appropriate name. Exit to the Main VitalView window.

7 Make sure the ER-4000 is connected and operating (red LED is illuminated). Under File from the Main Window, click on Start Data Collection, and follow the prompts.

NOTE: It is advantageous to have the ER-4000 operational or near-operational prior to surgery so a minimum number of steps is necessary to monitor the E-Mitter signal.

General Implantation Preparation

Introduction

The implant procedure for E-Mitters is not difficult for those with basic surgical experience on laboratory animals. It is recommended that individuals review these procedures carefully prior to surgery.

The E-Mitter is a very reliable product. However, it is recommended that the unit be checked prior to surgery. This will assure you that the E-Mitter and ER-4000 are operational.

NOTE: The G2 E-Mitter is a miniaturized version of the standard temperature and activity E-Mitter. The implantation procedure as well as functionality is identical.

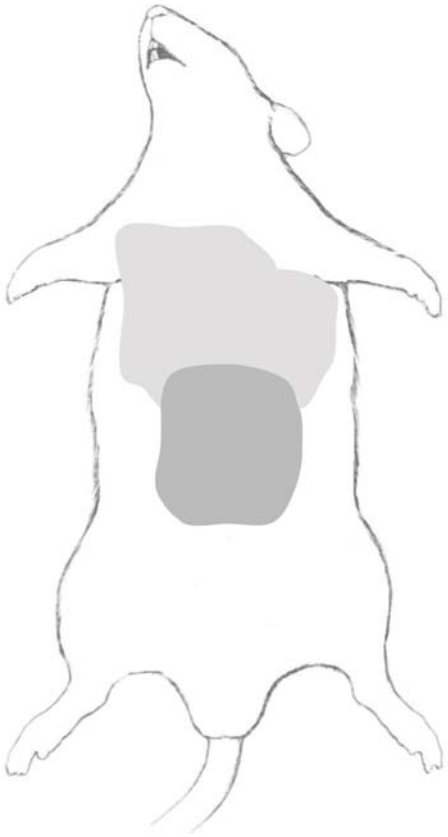
Preparation of the Implant

E-Mitters should be sterilized and kept warm prior to surgery. See page 3 for sterilization information.

The use of sterile technique, including sterile instruments, a drape, and gloves must be employed. E-Mitters offer an implant life surpassing that of the animal, so it is important not to compromise this advantage by the risk of infection.

Animal Preparation

1. Anesthetize the animal prior to preparation. Depth of anesthesia may be ascertained by using the pedal reflex technique. Pinch the toe of the animal. The lack of a withdrawal reaction means the depth of anesthesia is adequate.
2. Shave the ventral suface of the abdomen for both E-Mitter and HR E-Mitter devices (dark gray area). If implanting HR E-Mitters, shave the thorax to the area of the axilla, slightly cranial on the right side (light gray areas illustrated below).

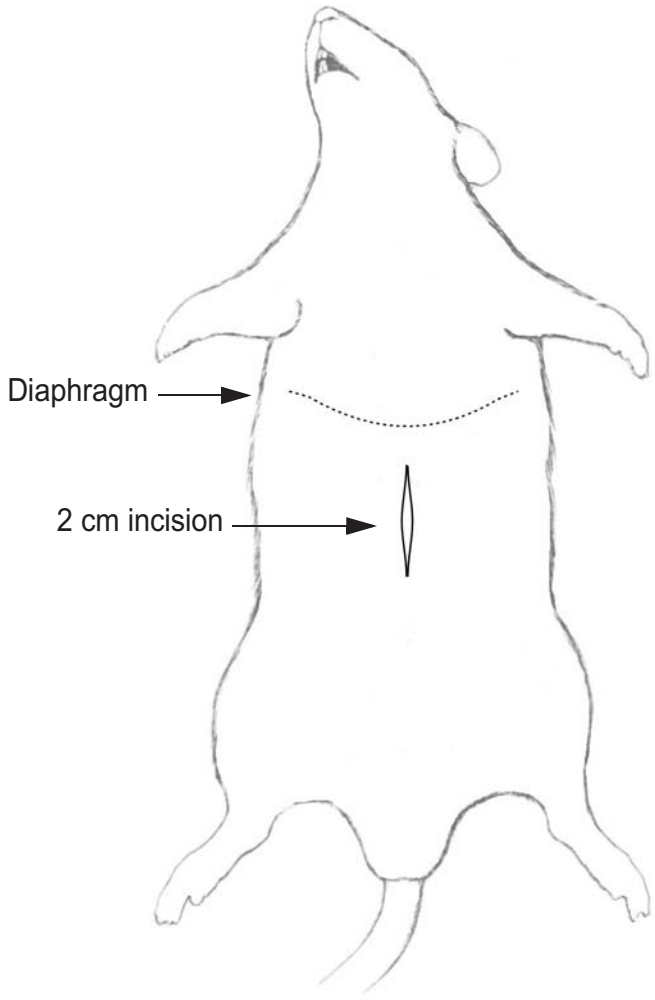


3. Scrub the shaved area with Betadine or other surgical scrub.
4. Secure the animal to a sterile surgical surface with adhesive tape. Make sure the surgical surface is heated.

CAUTION! For smaller species, a heating pad or other device is mandatory. Keeping the animal warm is essential for prompt and thorough recovery.

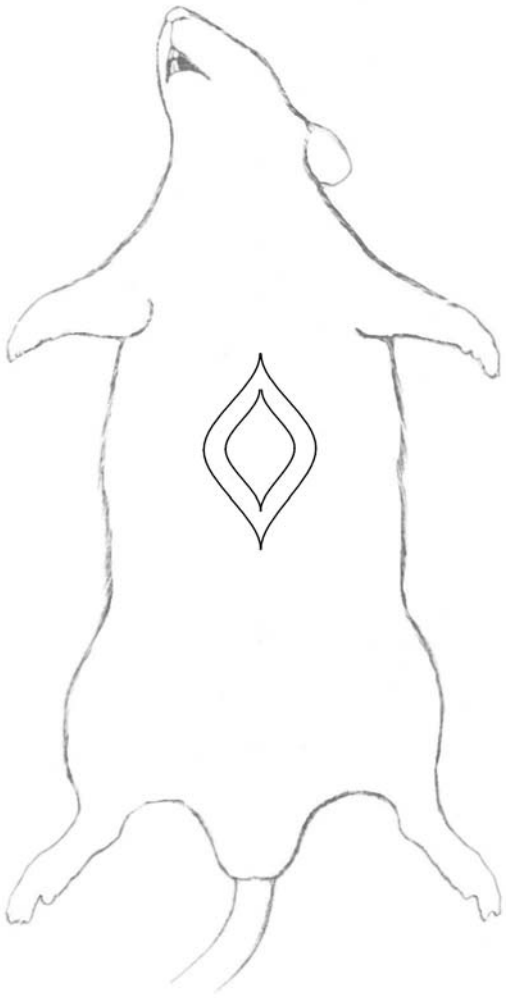
E-Mitter Implantation Technique

1 Make a midline abdominal skin incision 1 cm below the diaphragm, and no more than 2 cm in length.



2 Open the abdomen by making a 2 cm incision along the *linea abla* (the "white line" of fascia where the abdominal muscles join on the midline).

CAUTION! Take care not to cut the bowel. As the skin incision is made, the abdominal muscles tend to relax, resulting in the bowel being immediately under the surface.



3 Positioning of the E-Mitter in the abdominal cavity is important to acquire accurate temperature data. If it is too close to the surface of the skin, it may be affected by room temperature.

4 Gently reflect the intestines and colon. Slip the body of the E-Mitter into the abdominal cavity along the sagittal plane, placing it in front of the caudal arteries and veins, but dorsal to the digestive organs.

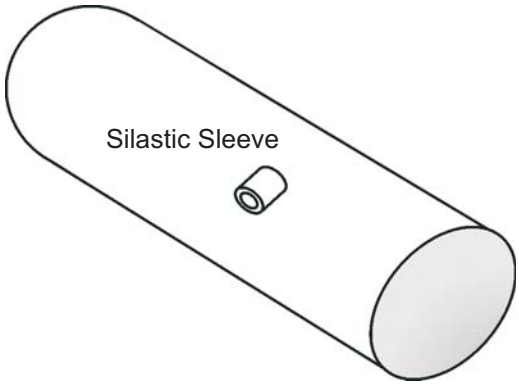
Silastic Suture Sleeve Procedure

Experience has shown that in some cases, the PDT4000 E-Mitter may migrate within an animal. The migration may allow excursions of temperature data. For example, if the E-Mitter migrates near the outside of the peritoneal cavity and the animal lies down on a cold cage surface, the temperature may register lower than the actual core temperature.

In order to reduce migration of the E-Mitter a silastic sleeve has been attached to the surface (illustration is exaggerated). This sleeve is designed to be used as an anchor point through which suture material may be passed. Its use is recommended for all temperature monitoring applications.

These instructions only apply to the PDT4000 and G2 transponder. The PDT4000HR and G2 HR do not require this additional implantation step.

Standard E-Mitter shown



Implantation using the silastic sleeve

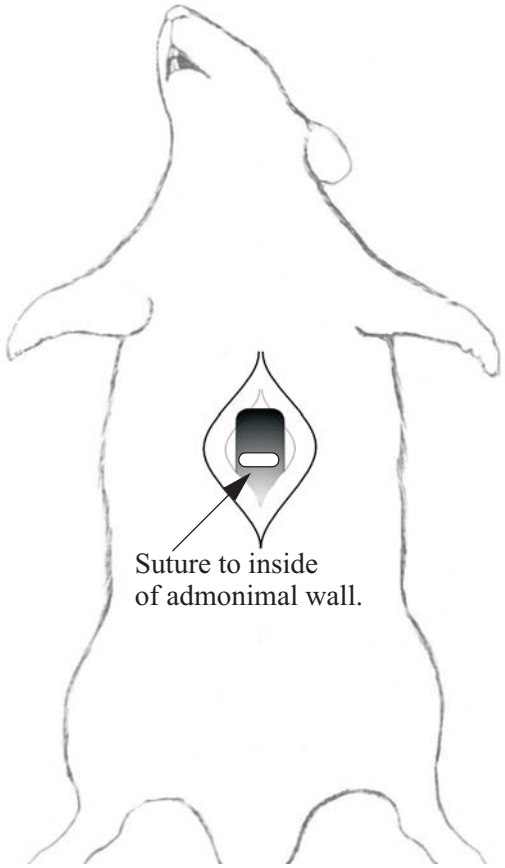
5 Pass suture material through the silastic tubing that is attached to the outer wall of the E-Mitter capsule.

6 Suture the capsule to the body wall.

Making use of the sleeve to anchor the E-Mitter to the body wall will reduce the likelihood of the E-Mitter moving freely within the peritoneal cavity. This may also decrease the need for the ER-4000 Energizer/Receiver to re-acquire a signal lock from the implanted transponder.

7 Replace the organs, effectively "burying" the E-Mitter.

8 Massage and lightly jostle the abdominal cavity to allow the internal organs to settle. Examine the small intestine and colon for kinks.



9 If you wish to check for data prior to closure, place the animal on the ER-4000. Check for a green LED, confirming signal lock. If there is no green LED, move the animal to a different spot on the ER-4000, or raise the animal slightly above the receiver surface. A green LED assures that a signal is being received.

10 From the Main window, click on Data Collection. You should see data coming from the activity and temperature channels. Remove the animal.

11 Place simple interrupted absorbable sutures as needed to close the abdominal incision. See page 28 for typical closure procedure.

HR E-Mitter Implantation Preparation

The VitalView system should be fully operational prior to beginning surgery. See the Hardware Installation section of the VitalView manual for installation details.

You will place the animal on the ER-4000 during surgery so that proper heart rate signal can be checked prior to closing. *Remember to put a heating pad between the receiver and the animal.* A simple household heating pad should not interfere with the signal.

It will be necessary to use a valid configuration file for testing the E-Mitter. If you do not have a configuration file, it will be necessary to make one. Follow the directions in the E-Mitter section on page 4. If you use an existing file, make sure the settings are appropriate for monitoring the heart rate signal.

NOTE: The heart rate leads will need preparation prior to surgery. See "Preparing the Heart Rate Leads" on page 14.

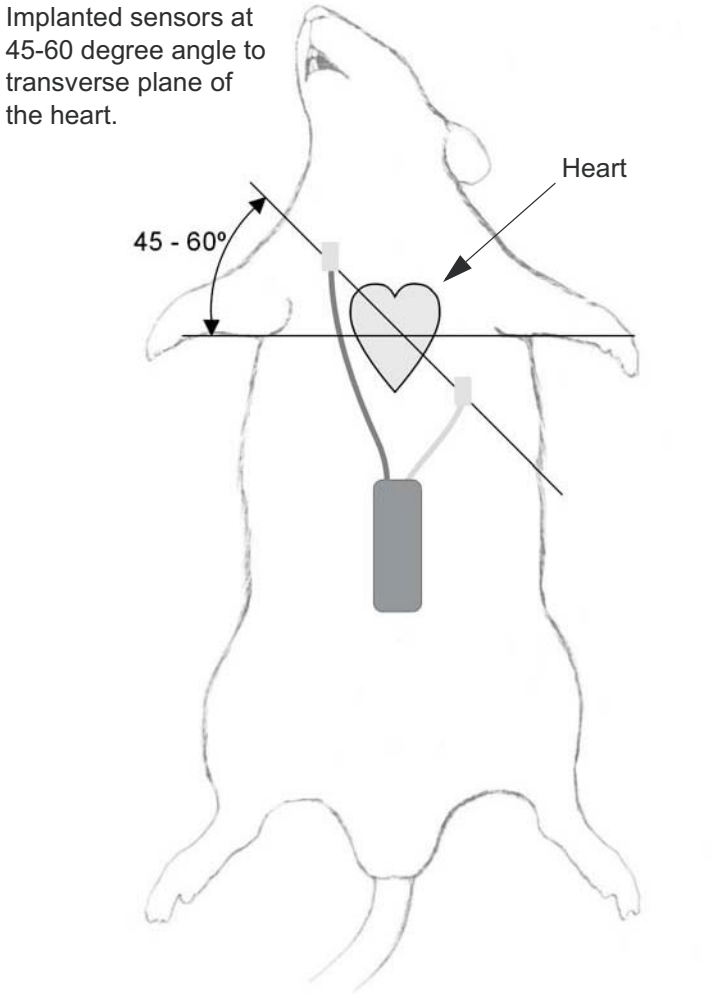
Lead preparation is important. The electrode leads must be cut to length to position them near the heart in a specific plane. To assist in fixation, a small tab is attached to the end of the heart rate lead. This tab also prevents the sharp electrode from injuring the animal. Proper lead preparation also assures good contact with the chest muscle.

CAUTION! It is very important that the two electrode lead wires be placed subcutaneously on the chest wall at a 45-60 degree angle relative to the transverse plane of the heart. Improper lead placement will result in low signal pickup and unreliable heart rate detection. Rectifying this problem will require another surgical procedure.

CAUTION! Do not pull on the leads. Although the lead attachment has been designed to withstand considerable tension, the leads can become detached from the header elements.

NOTE: If implanting an explanted HR or G2 HR E-Mitter, make sure the leads are thoroughly cleaned of all organic artifacts. Lack of cleaning may cause degradation of the heart rate signal, particularly during pre-testing.

Proper placement allows the voltage created by the R wave of the QRS complex (a phase of the cardiac electrical cycle) to trigger a pulse detected by the ER-4000 Energizer/Receiver. The heart rate is then reported by the VitalView system as a beats-per-minute value based on a computation from the R-R interval.



Preparing the Heart Rate Leads

For proper heart rate detection the sensor lead length must be taken into account. To accomodate size differences in animals, the following procedure may be used to shorten lead length.

NOTE: If the leads are too short, heart rate detection may be impaired. If the leads are too long, the spring action of the leads may push the HR E-Mitter to the bottom of the abdomen.

Be certain to allow 1 to 2 cm of excess lead wire to act as a strain relief for animal movement. Excess lead wire should be left under the skin in an 'S' curve where the leads exit the abdominal cavity. This allows for growth and flexing of the body from side to side.

NOTE: The following are approximate lengths of the HR E-Mitter leads measured from E-Mitter body to end of lead before attachment. Animals sizes vary greatly; careful measurement is highly recommended.

	Mice	Rats
Negative lead (longer, black)	35 mm	75 mm
Positive lead (shorter, clear)	20 mm	45 mm

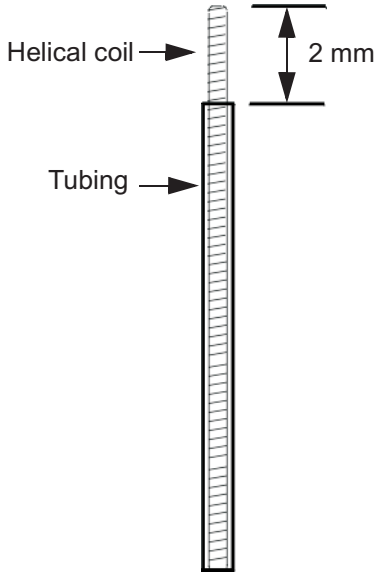
The negative lead (black) is directed to the anterior right (animal's right) side of the chest wall near the clavicle. It is the longest lead.

The positive lead (clear) is placed on the posterior chest wall to the left of the sternum and anterior to the last rib. It is the shorter of the two leads.

NOTE: The tubing acts as an insulator, and must be left in place as shown in the next illustration. Removing too much of the tubing may result in a low signal from the heart.

To prepare the leads, use the following procedure.

1 Place the HR E-Mitter on the abdomen midline of the subject as in the previous illustration on page 14. Direct the leads to the implant sites, and then mark the lead for proper length.



2 Leads should be cut cleanly across with small, sharp wire cutters or sturdy scissors. Again, be certain to leave some excess lead length to allow for growth and body movement.

3 Using a scalpel blade cut around the lead to aid in removing the insulation. Strip 2 mm of tubing from the tip of the lead to bare the helical coil inside. Pull the coating off, leaving the tip section bare. *Be certain not to nick or cut through the coil wire.* The leads are now prepared for implantation.

Monitoring the HR E-Mitter heart rate signal

1 From the Main window File menu, choose Open Configuration File. Highlight the E-Mitter test file previously saved from "Configuring the ER-4000 Prior to Surgery" on page 4, or your own configuration file. Click OK.

2 From the Main window, click on System Setup.

3 In the ER-4000 Configuration panel, click on Utility. Follow the prompts and wait for the ER-4000 to initialize.

After the ER-4000 initializes, click on Heart Signal Monitor. Your system is ready to monitor signals from the Heart Rate E-Mitter. You may leave it in this mode during surgery to test the E-Mitter prior to closing.

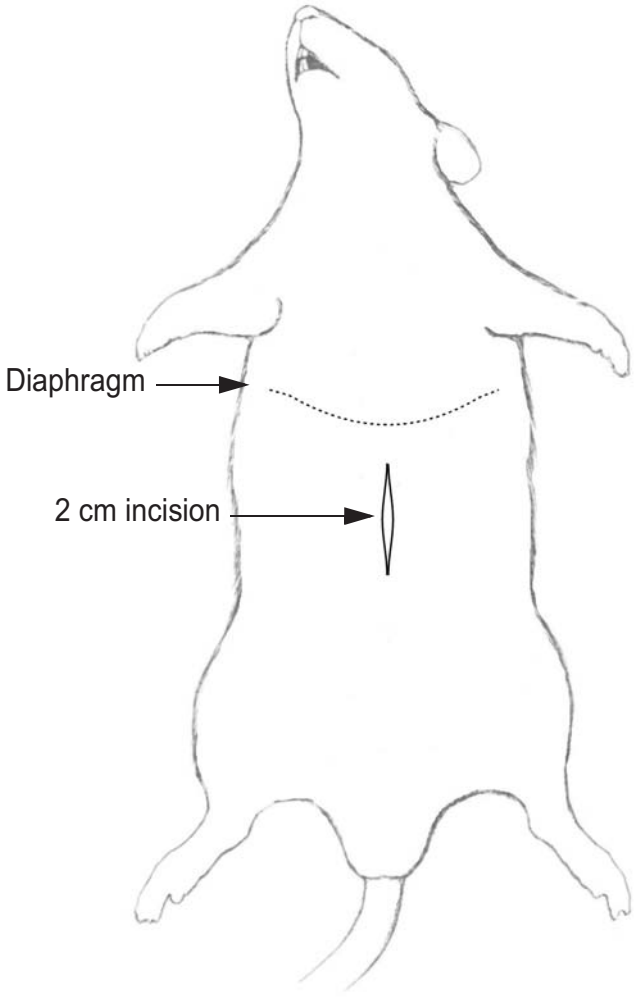
If you have any questions, refer to the System Setup section of the VitalView manual.

Animal Preparation

See “Animal Preparation” on page 7.

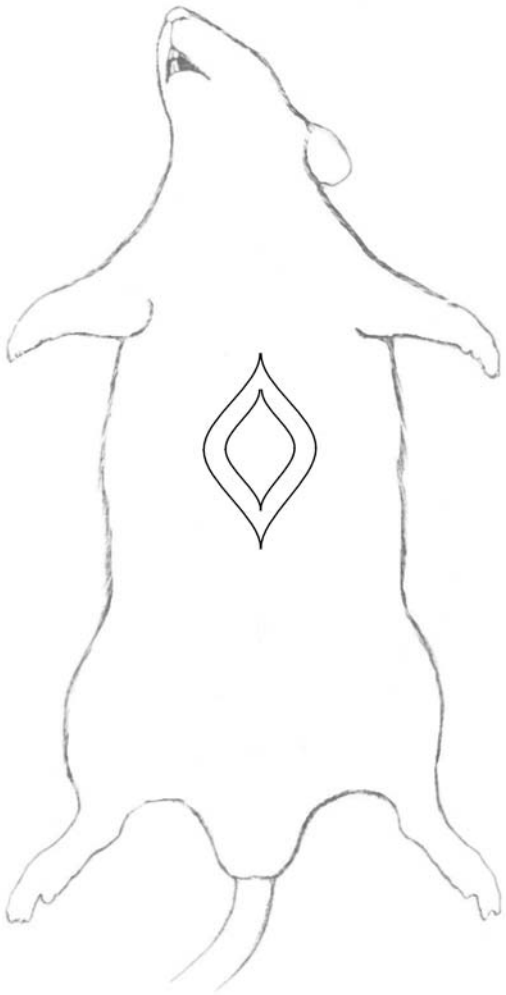
HR E-Mitter Implantation Technique

1 Make a midline abdominal skin incision 1 cm below the diaphragm, and no more than 2 cm in length.



2 Open the abdomen by making a 2 cm incision along the *linea alba* (the 'white line' of fascia where the abdominal muscles join on the midline).

CAUTION! Take care not to cut the bowel. As the skin incision is made, the abdominal muscles tend to relax, which results in the bowel being immediately under the surface.

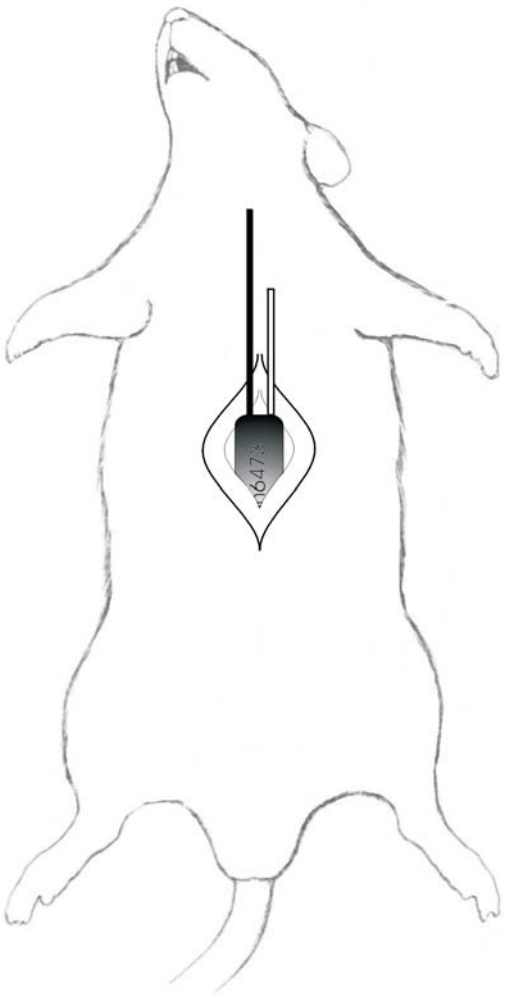


3 Positioning of the HR E-Mitter in the abdominal cavity is important to acquire accurate temperature data. If it is too close to the surface of the skin, it may be affected by room temperature.

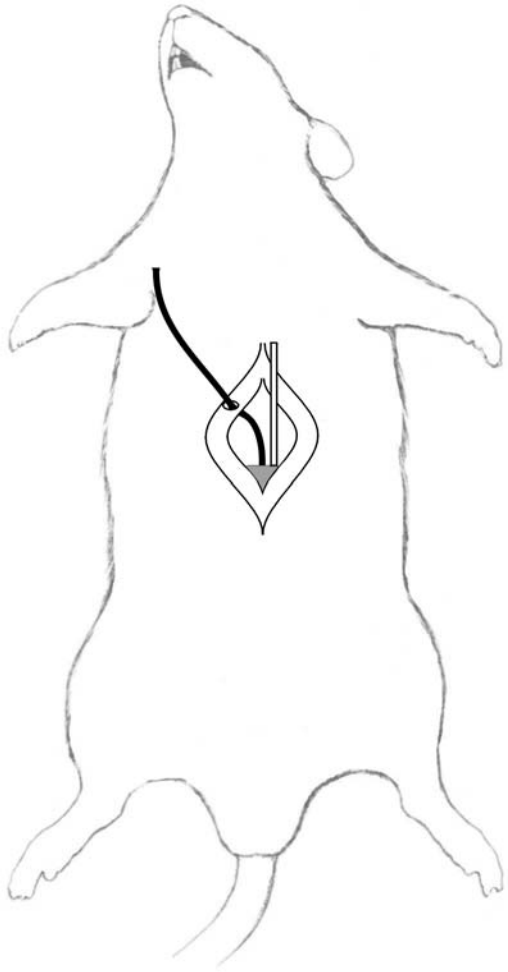
Gently reflect the intestines and colon. Slip the body of the HR E-Mitter into the abdominal cavity along the sagittal plane (with the lead wires facing toward the animal's head), placing it in front of the caudal arteries and veins, but dorsal to the digestive organs. Replace the organs, effectively "burying" the "rear" portion of the HR E-Mitter (without the leads). This is the portion of the HR E-Mitter that contains the temperature sensor.

4 Bring both leads out of the abdominal incision as shown below. The negative (black) lead should be on the animal's right; the positive (shorter - clear) lead should be on the animal's left.

5 Massage and lightly jostle the abdominal cavity to allow the internal organs to settle. Examine the small intestine and colon for kinks.



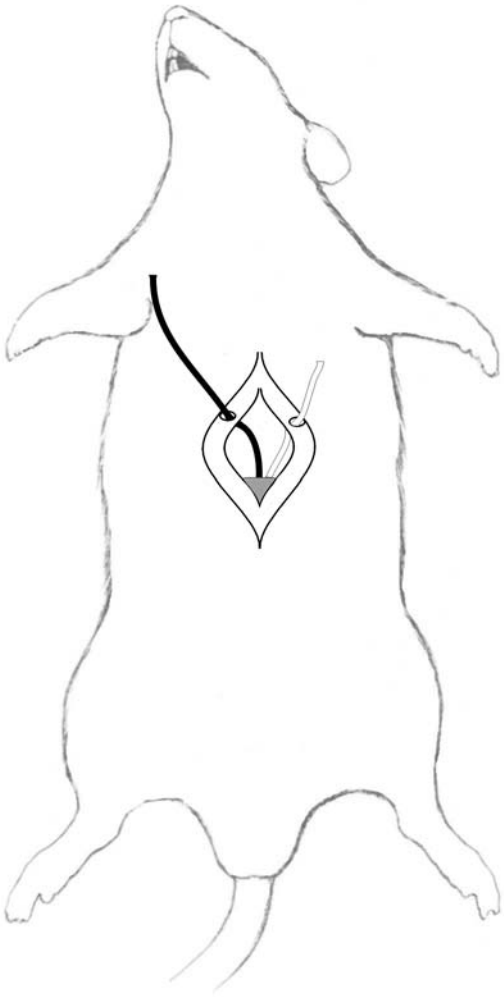
6 With a small mosquito hemostat, bluntly make a small hole through the abdominal wall (*external oblique)*. This hole should be to the right of the incision (see below). Push the positive lead from the abdominal cavity through this hole.



7 On the other side of the abdominal incision, make a similar hole through the abdominal wall (as was made in step 4). Push the positive lead from the abdominal cavity through this hole.

8 At this time, to prevent tissue necrosis, close the abdominal wall with 5-0 abdorbable suture material, using a continous interlocking mattress stitch.

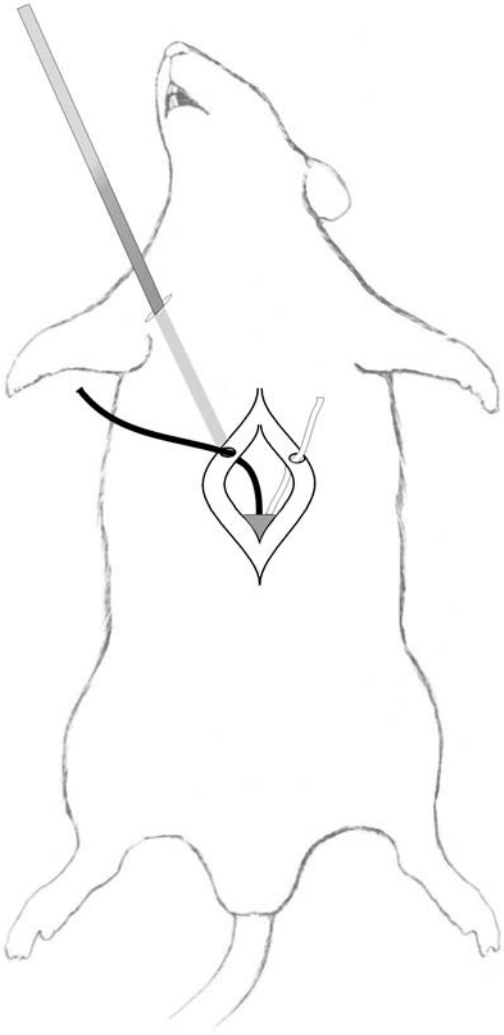
NOTE: For clarity of polarization, the following illustrations do not show the abdomen closed.



Negative Lead Attachment

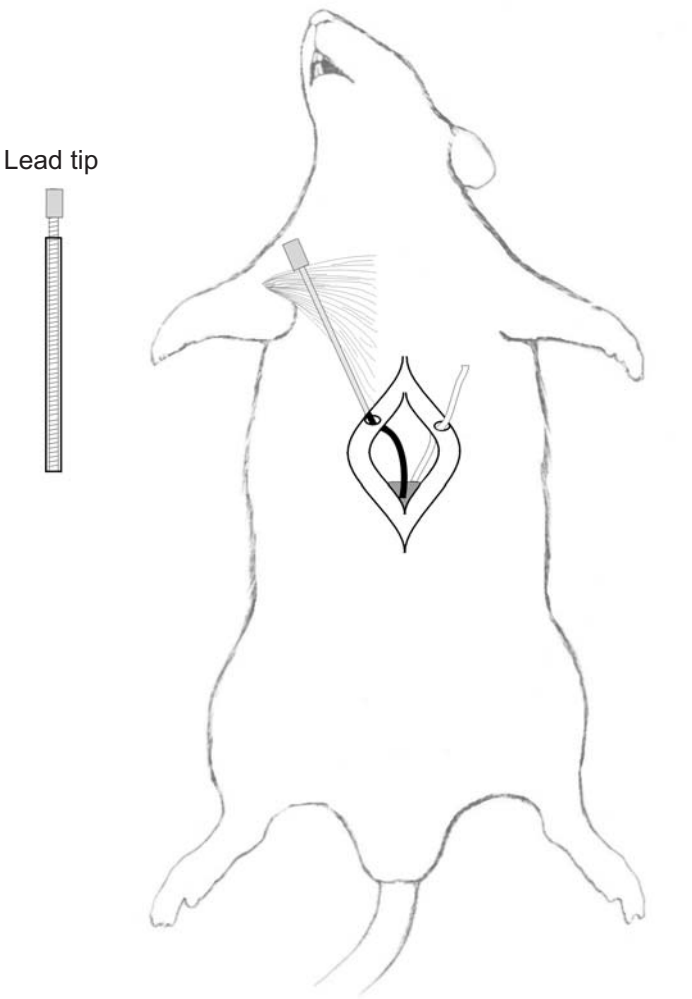
1 Make a small incision (0.5 cm) in the skin near the clavicle. Make sure the two-part lead insertion tool (trochar) consisting of sleeve and probe, is assembled. Push the trochar through the hole in the skin. Push the tool subcutaneously until it reaches the area of the lead. Pull the inside probe out of the trochar sleeve.

NOTE: When placing the leads in small animals, it may be possible to insert a hemostat in the incision and "tease" under the skin and pull the lead through subcutaneously.



2 Push the entire lead through the trochar sleeve. When the lead is completely inserted into the sleeve, remove the sleeve. The lead will remain in place between the skin and muscle wall. The end of the lead should be near the clavicle, and resting on the *pectoralis superficialis*.

3 Slip a metal ferrule over the tip of the lead, and crimp into a "tab" with a non-serrated pliers (or needle holder) (see detail below).



NOTE: In the following procedure, placing the lead in the thin layer of subcutaneous tissue will NOT provide adequate contact for a reliable heart rate signal. It must be held fast against muscle tissue with metal suture material.

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4 With metal suture material (000 or 34 gauge), place a small lock stitch at the top of the *pectoralis superficialis*, located near the clavicle. Take a rather large "bite", leaving a loop approximately 2 mm in diameter. Tighten the knot, but DO NOT TIGHTEN the loop that is through the muscle.

CAUTION! You are very near the subclavian artery and vein. Puncturing will likely cause an instant fatal hemorrhage.

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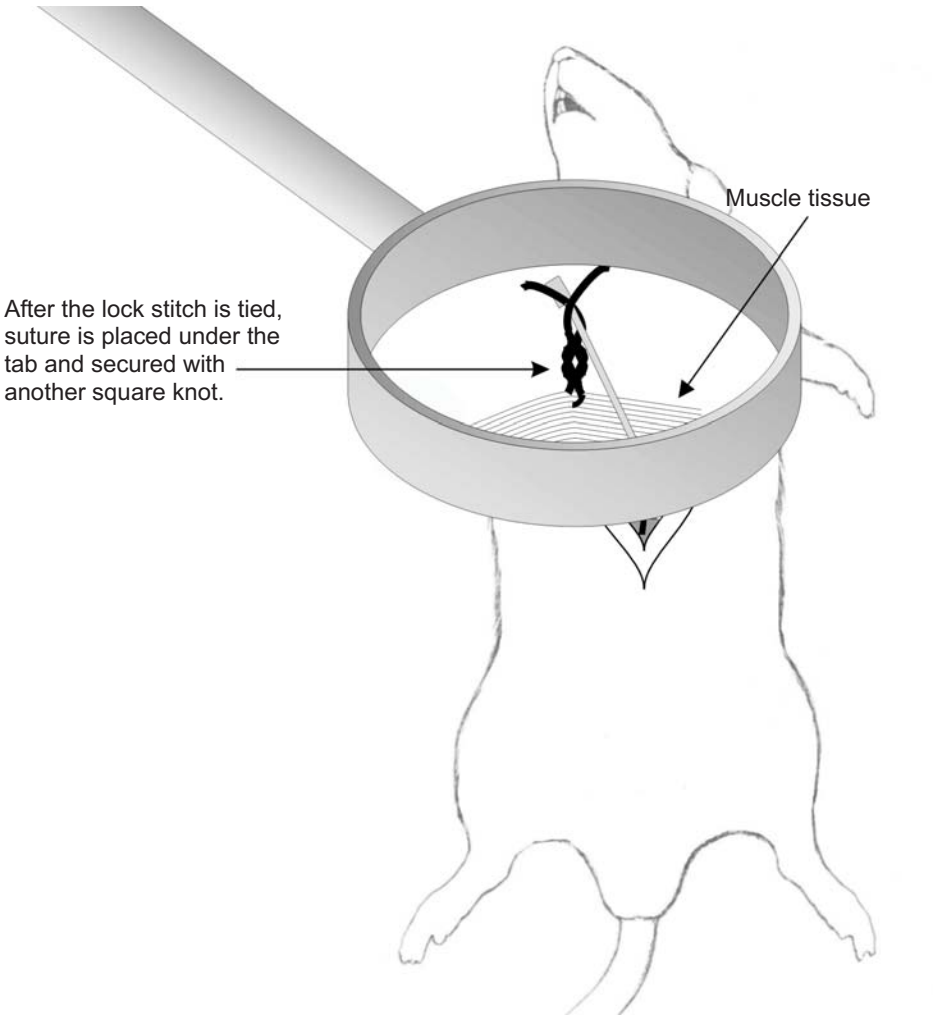
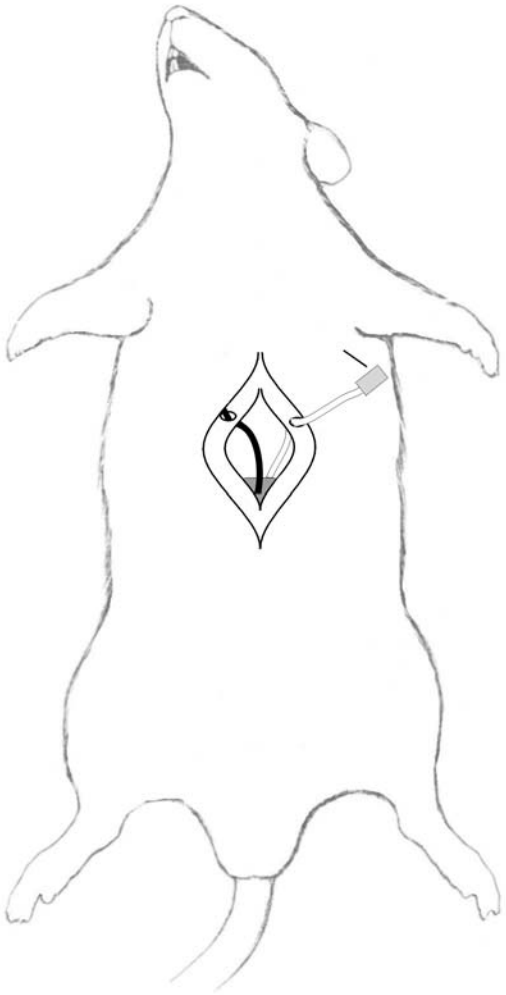
5 Place a length of suture material around the lead tip just behind the tab and complete the second throw of the suture knot to hold the lead tip firmly in place. Trim the excess.



Positive Lead Placement

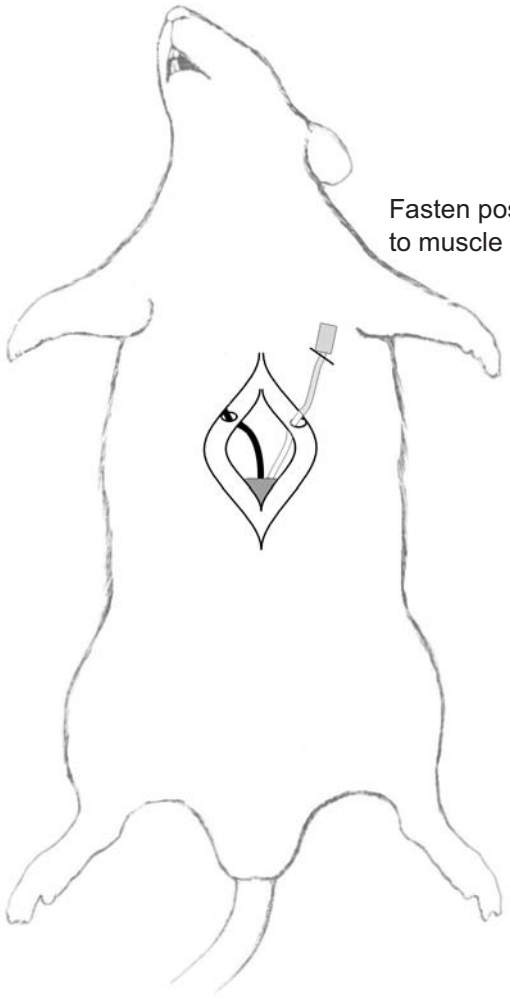
1 Make a small incision (0.5 cm) to the left of the *xiphoid process* and cranial to the last rib.



2 You may use the trochar to place the positive lead using the same technique as the negative lead, or use a mosquito hemostat to tease it into place. (If you choose *not* to use the trochar, it may be more convenient to attach the metal ferrule now as described in step 3.) Work the muscle wall away from the skin, and push the heart rate lead between the skin and muscle. Keep the lead as flat as possible.

3 Attach a metal ferrule using the same procedure as the negative lead.

4 Secure the lead against a chest muscle (*cutaneus trunci*, *pectoralis profundus*, posterior *pectoralis superficialis*, etc.) in the same manner as the negative lead, attaching the suture just behind the tab.

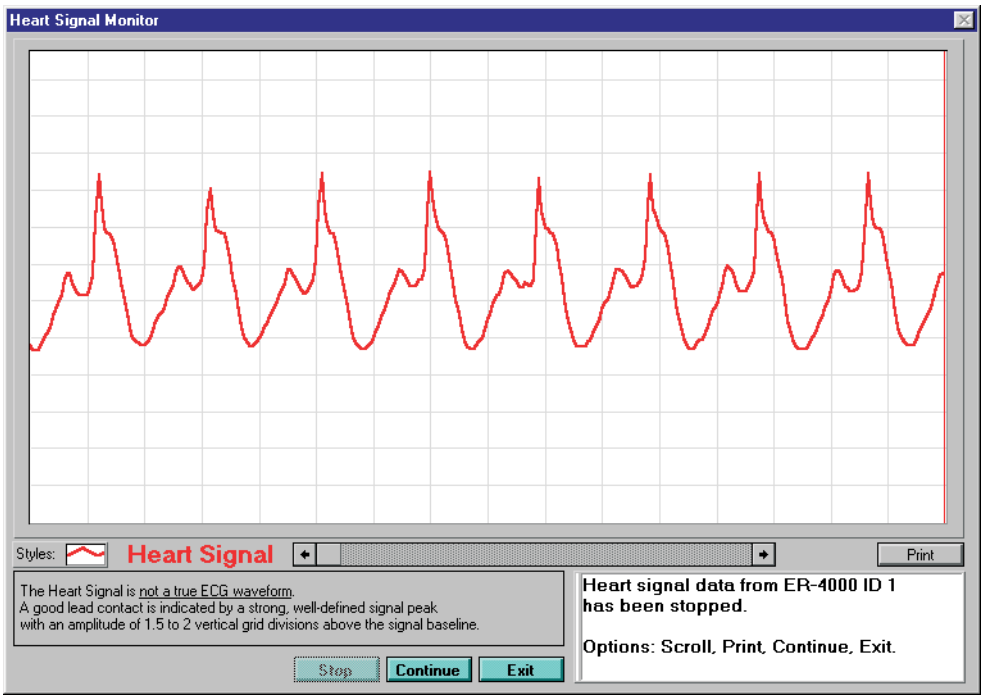


Fasten positive heart rate lead to muscle wall near diaphragm.

Confirming the Implant

1 At this time, check the heart rate signal. Place the animal on the ER-4000 with VitalView operational a nd in Heart Signal Monitor mode. Check the strength of the signal. It should be 1 ½ to 2 vertical grids in amplitude. If lower than this, reorient the subject on the ER-4000.

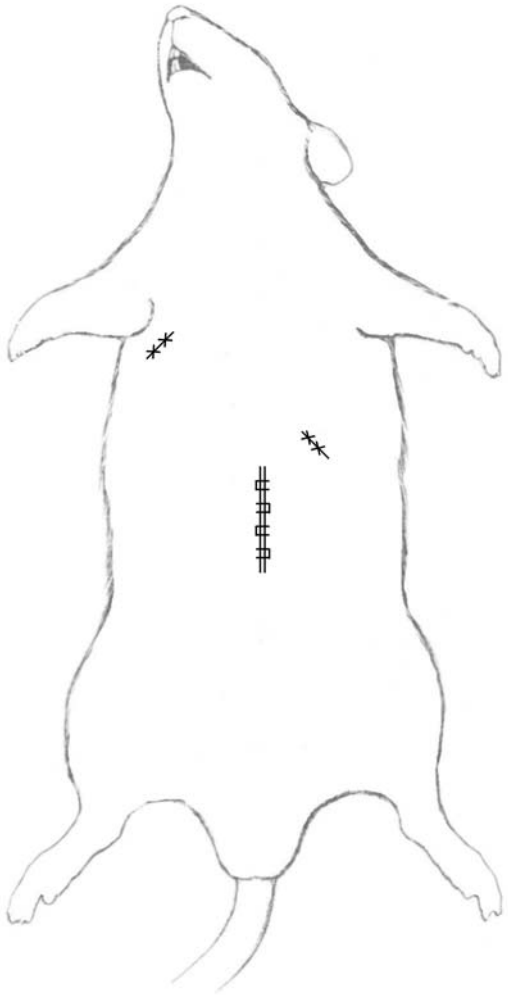
Access: Main window > System Setup > Utility > Heart Signal



2 If no improvment, the lead placement may need to be changed. Reposition the leads slightly. Check to see if the leads were placed in superficial connective tissue. If they were, dissect through the connective tissue and take a bigger “bite” into the chest muscle tissue when placing the anchoring sutures.

Closure

1. Close the smaller two-lead access points with 34-gauge stainless steel suture material.
2. Close the abdominal opening with 5-0 Vicryl® absorbable suture material using a continuous interlocking running stitch.
3. Close the skin with 34-gauge stainless steel suture material using interrupted mattress stitches.



4. Clean the skin surface with Betadine® solution, and puff on a little Furacin® powder.

CAUTION! During the animal's recovery period, pay particular attention to the temperature of the cage and surrounding environment. A lamp, cage heater, or heating pad may be used until the animal is fully ambulatory. Remember, the animal is now carrying more non-biological mass that must be heated during this recovery period.

Allow the animals to recover, and place them in their home cages positioned on top of the ER-4000 Energizer/Receivers.

The heart rate signal may be intermittent at times during the anesthesia recovery phase when the animals are hyperactive and uncoordinated in their movements.

Signal quality will generally improve within 2 to 3 days post-operatively as fibrous connective tissue forms around the lead tips.

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