Data Sciences International

Getting Started Guide

PhysioTel Hybrid Digital Platform

DSI™

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PhysioTel Hybrid Digital (HD) Platform Getting Started Guide

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WELCOME

DSI recognizes that every lab environment is different. Please contact Technical Support (Support@datasci.com) after reading this manual with any comments or concerns. DSI partners with our customers to ensure proper validation of a special product use case. DSI offers many additional tools that can be ordered to complete the solution depending on the facility needs (see Appendix D).

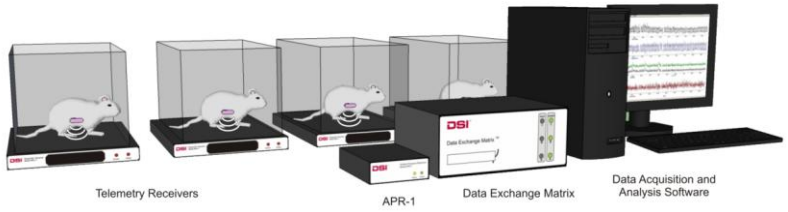
DSI has also added these Scientific Service offerings:

- Surgical Services
  - On-site surgical training
  - On-site pre-implanted animals
  - Surgical videos and manuals
  - Surgical training at DSI headquarters
  - Rodent pre-implanted animals at DSI headquarters
- GLP and Validation Services
  - On-site assistance and system setup
  - Organization of lab resources
  - GLP documentation
- Data Analysis Services
  - Detection of hemodynamic changes
  - ECG evaluation
    - Arrhythmia detection
    - Interval quantification
  - Heart rate variability (HRV)
  - EEG analysis
    - Sleep scoring
    - Seizure detection
  - Respiration analysis

This user manual will give basic instructions that are required to be successful with the use of this DSI product. The manual is written so that users who know very little about telemetry and users who have extensive experience have access to DSI's recommended telemetry system setup.

TELEMETRY SYSTEM OVERVIEW

Implantable telemetry systems have been in use since the 1980's. They enable researchers to obtain physiological data directly at the source without restraining the animal physically or chemically. The implant (also called a device, telemeter or transmitter by different researchers) senses the physiologic data through its internal sensors, transmits the physiologic signal to the receiver which is pictured under the cages. The receiver acts as an antenna and brings the wireless signal to the Data Exchange Matrix which filters and assimilates the data before storing it on the computer. DSI's software program then displays the raw or calculated physiologic values in real time on the monitor and saves the data for viewing and filtering after acquisition. A system diagram is shown below to help illustrate this.



This is a representation of the HD small animal platform used with rats. See the "Caging and Shielding Requirements" section or contact Technical Support for more system setup options. The small animal products can also be used with guinea pigs, rabbits, hamsters and other rodents. The extra small or mini products are mouse sized and are also available with these platform features. These are smaller and therefore can be used in neonatal rodents >19 grams. The HD platform mouse sized implants have the same digital features, but may offer less battery life than the small animal models.

Specialized surgical expertise is required as these devices are implanted much like a pacemaker is for clinical applications. The implant body is placed subcutaneously or intra-peritoneal (IP) and the biopotential leads and catheters are then routed to the source of the physiologic signal. Although surgery, once mastered, can be simple and quick, many surgeons have found that survival surgery requires strict attention to detail as infection or animal discomfort can impact study results. DSI provides a surgical manual also included on this CD with DSI's recommended methods (proven over 30+ years of experience) on how to implant the device depending on the physiologic parameters of interest. Further hands-on training by DSI's trained surgical staff is recommended and has been found to be the most helpful for DSI customers.

DSI's experienced surgical services team is available to answer any questions by phone or email. In person, hands-on surgical training is available onsite or at DSI headquarters. Training at headquarters often includes a tour of manufacturing, as well as some time with DSI's technical support for specialized hands on software training and the opportunity to meet with other DSI employees. DSI also offers high quality pre-implanted animals for any surgical technique we recommend.

QUICK SETUP INSTRUCTIONS

In order to ensure success the first time, DSI recommends checking that the system is functioning correctly before implanting any animals. After the system is set up appropriately, be sure to follow these instructions to prevent erroneous data. These steps should be treated as a "cheat sheet" on how to setup the system quickly and can be printed off as a standard protocol for use in the research lab.

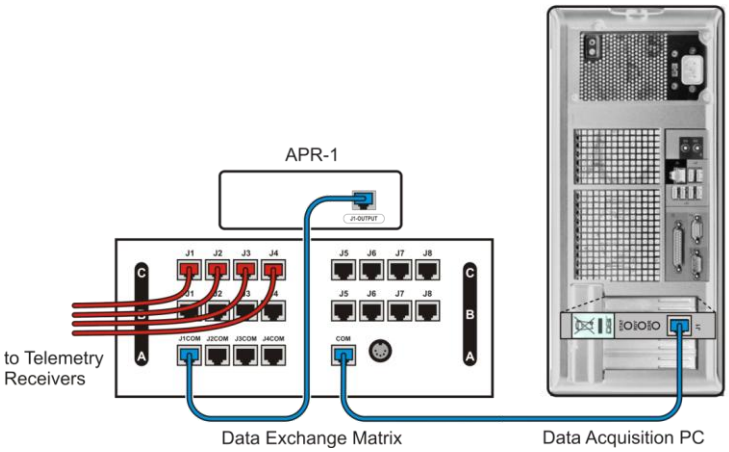
Before Beginning

- It is important the device remains in the sterile package or it will need to be re-sterilized before implantation. For detailed sterilization instructions see Appendix A.
- **Always check the battery life** when the device arrives and **pressure offset** before surgery to be sure there hasn't been any damage in shipping or long term storage (see step 6 & 7).
- If the device has been used already, inspect the device for defects. Make sure it has been properly sterilized and the explant procedure did not harm the catheter or cut the leads too short.

There are several hardware products that are required to be able to monitor from the new implant. There are four main components of the acquisition system; the data acquisition computer, the ambient pressure reference (APR), the Data Exchange Matrix (DEM) and the receivers.

Hardware Setup

1. Start by connecting the separate pieces as shown in the diagram below:



2. After connecting the hardware, make sure the receivers have adequate spacing in between them (see "Shielding Recommendations" section for more detail).

Configuring the Device

3. Using the data acquisition software DataquestART or Ponemah (with OpenART) go to Hardware Configuration and verify the hardware is connected correctly by clicking "Verify" under "Hardware" or pressing Ctrl+Y.
4. When configuring the HD implant the software will include a wizard to assist with device configuration.

a. Right click on the receiver to connect the device to this specific receiver
b. Click on "New Transmitter"
c. When the wizard launches, select the appropriate HD implant model
d. Follow the outlined steps in the wizard that instruct when to turn the device ON in order to allow for transmission of the serial number and calibrations. See the "HD Platform Features" section to learn more about the platform's digital features.

To turn the device on:

i. Take the implant and place it on top of the receiver (at least within a few inches).
ii. Power on a Short wave radio and tune it to 18MHz
iii. Bring the radio close to the packaged device.
iv. Bring a strong magnet (included in DSI's HD Starter Kit) in close proximity to the implant in the package.
v. A tone should be heard on the radio within two to five seconds of the magnet swipe indicating that the device has been turned on.

e. In the final step assign a unique animal ID (alpha or numeric) per local lab requirements and select a species.

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Check Device Functionality: Important!

5. **Check the battery life on-time to be sure the implant didn't accidentally turn on in shipping.** Refer to the "Battery Life, On Time and Voltage with PhysioTel HD Transmitters" to learn how to check this value in Dataquest ART. In Ponemah the device on time and battery voltage will automatically display in the "Source Status" pop-up when acquisition is started.
    a. DSI's shipping procedures attempt to protect the devices but stray magnetic fields exist outside of DSI's control so there is always the possibility that the device could potentially turn on in shipping before it gets to the lab space.
    b. Less than 3 days of device on time should not impact the study, however if concerns arise please notify DSI technical support and if necessary we will advise on how to return the product and receive a new one. Standard lead times may apply. We will also track this occurrence and use this information to improve our shipping processes in the future.
6. **Check the pressure offset at ambient pressure and temperature.** Always check the pressure offset of an implant upon receipt and/or before implantation into an animal. DSI's highly sophisticated test calibration equipment ensures that the product will be within specification upon receipt unless the product has somehow been damaged in shipping. Follow these instructions to learn how to estimate gross pressure offset inside sterile packaging, in air and at ambient temperature, after initial receipt:
    a. Turn on the implant for a minimum of 1-4 hours to let the electrical components stabilize. If this stabilization exceeds 4 hours contact technical support.
    b. Ensure that the APR-1 is connected to the system and has been calibrated within the last 2 years.
    c. Start Acquisition of the pressure signal. This assumes the device and study has already been set-up properly.
    d. Check the baseline pressure reading at room temperature (~23C) from the device and compare it to the APR-1 recording. This is the pressure offset for the implant.
    e. Record this value for tracking purposes.
    f. If the pressure offset is less than the specified drift at room temperature then the device is safe to implant.

g. However, if the offset is greater than the specified drift and is still within the sterile packaging contact DSI's technical support as they will help you determine how to proceed with the use of this pressure implant.
h. If the product has been sitting on the shelf for a few months or if it this is a used implant technical support may recommend entering a pressure offset into the software to account for pressure drift over time at body temperature. **Never enter a pressure offset into the software without checking the device at the appropriate temperatures.** Follow the instructions in the "Instructions for Implant Use" section for the most accurate method to determine the actual pressure offset at body temperature and to learn how to enter the pressure offset into the software platform.

Begin Surgery

7. Once the device is configured and properly checked for functionality surgery can start.
8. **Remember, for pressure products it is important to hydrate the catheter for a minimum of 15-30 minutes in sterile saline.** Remove the protective tip cover on the catheter before implantation under sterile conditions. If needed, re-gel the catheter using a re-gel syringe right before surgery. For explicit instructions on how to re-gel go to DSI's website for a tech note and video or read the surgical manual.
9. Always keep the DSI provided surgical manual nearby to ensure the surgery is being performed correctly as this is a critical step to the success of the study and to maintain the best care for the animal. Personal on-site training or surgical courses at DSI are available if a hands-on experience is desired.
10. When the catheters and leads are surgically placed, the physiological signals from the implanted device can be viewed in the software immediately during acquisition.
11. Give the animal at least 10-14 days to recover from surgery before collecting baseline data. This has been verified and proof sources are available. Information can be found by searching in the Bibliography section on our website. Please note DSI expects:
    a. Local inflammation, as expected from any surgery, will heal over time.
    b. Mean pressure will stabilize over time (approximately 4 hours) as the catheter and implant body acclimates to the *in vivo* hydrated and thermal environment. This timing may vary depending on if heating and hydrating of the catheter was performed before surgery and for how long.
    c. If conducting a pair house study, keep the animals apart for at least 10-14 days prior to placing them in the same cage.

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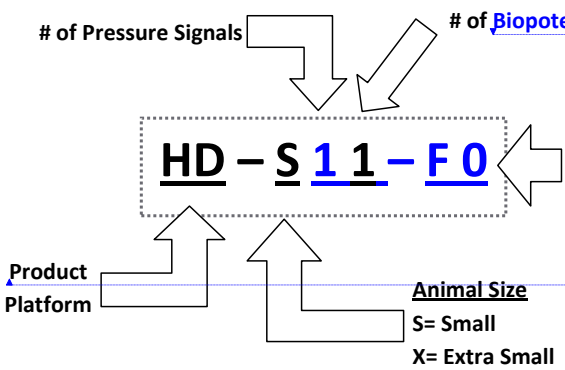
ABOUT THE IMPLANT

Nomenclature

HD stands for "Hybrid Digital" and is used to distinguish the platform from other DSI products. See the diagram below for instructions on how to de-code a model name for this platform of devices.



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Model	Animal Model	Pressure Signals	Biopotential Signals
HD-S21	Rat or similar	2	1
HD-S11-F0*	Rat or similar	1	1
HD-S11-F2*	Rat or similar	1	1
HD-S10	Rat or similar	1	0
HD-X11	Mouse or similar	1	1
HD-X10	Mouse or similar	1	0

*Note that the –F0 represents a 455kHz frequency for the device. The –F2 represents an 18MHz frequency (used for pair housing studies). The frequencies are the only difference between the HD-S11-F0 and the HD-S11-F2; therefore an additional naming system was added to distinguish between the two HD-S11 devices.

HD PLATFORM FEATURES

The HD platform digitally transmits the Animal ID, implant ON time and battery voltage with the physiologic signals. During system setup the HD implant will also transmit the stored factory calibration data to remove human error from manual entry of these values.

Animal ID

The Animal ID (or serial number) digital feature enables an implant to be specifically linked to the receiver when it is configured in the software. Ambient electromagnetic noise generated by large power sources and other equipment (even other telemetry equipment) can impact signal quality. With this device the impact is minimized because the hardware is intelligent enough to know where the implant signal is coming from. If noise is detected, the signal will disappear, the theory being researchers would rather have clean data or nothing at all. Shielding from potential noise sources is important to understand for telemetry studies. See the "Shielding Recommendations" section to learn more.

Factory Calibrations

When setting up the software the factory calibrations will be auto populated when the device is turned on (see the "Quick Setup Instructions" section to learn more). The implant sends out these calibration values every time it is turned on. This may mean there is a slight delay in obtaining physiologic data when the device is initially turned on as the system is verifying the device's identity. This feature removes human error of placing the wrong animal in the wrong cage after dosing or behavioral testing, and it means that the calibration values on the label do not need to be tracked as closely as they are stored digitally in the device itself. However, researchers should still keep the sterile tray the device comes in if they wish to participate in the DSI Exchange Program as it is used to return product back to DSI. See Appendix E and www.datasci.com to learn about the DSI Exchange Program and its subsidiary programs which help keep cost down and drive efficiency for other DSI customers.

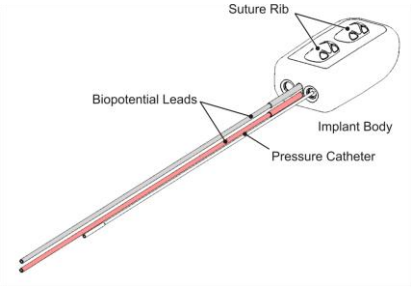
Battery Voltage

An alarm in the software will go off when the implant gets close to the end of its life because of the battery voltage feature. This is important because the measured physiologic parameters may become inaccurate when implants are used past their warranted battery life even though the device may still "operate". Implants are calibrated at a certain battery voltage and as the battery loses life the voltage becomes unstable and this may impact the physiologic signal. DSI's manufacturing calibration systems are state of the art and engineers design with this in mind. However customers should check calibration values before device implantation to ensure that the product is still accurate especially if explanted and re-used from study to study. The battery voltage feature gives researchers even more insight into the calibration accuracy of the device and can be used as a supplement to this information.

Battery on Time

At any point in time, because of the implant ON time feature, researchers can now see how much battery life has been used. On time is separate from the battery voltage as the on-time is a digital feature calculated off of an internal clock which is temperature dependent and only records on time correctly at body temperature. The on-time usage is updated every 16 hours of continuous use. Battery life specifications are stated as warrantied battery life which means duration of continuous on-time. When the implant is turned off, it is not using battery life and so the implant on time will not be tracking battery life either.

IMPLANT COMPONENTS



Drawing of HD small animal implant

IMPLANT BODY

The biocompatible housing that contains:

- Pressure sensor: receives pressure fluctuations from the fluid-filled catheter and sends the signals to the electronics module.
- Reusable electronics module: translates the pressure fluctuations and biopotential signal into digitized signals and transmits them to a receiver. Temperature data is sent digitally. The reusable electronics module also contains a magnetically activated switch that allows the device to be switched on or off.
- Battery: provides the power supply for the electronics module. Battery ON time and voltage parameters are sent digitally during sampling.
- Suture rib: allows the surgeon to suture the device securely in place at the implant site.

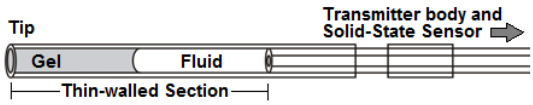
SUTURE RIB

On most implants the suture rib is optional and therefore it is important to understand when it is necessary. The suture rib is recommended for IP placement of the device and should be secured to the abdominal wall to restrict movement. Subcutaneous placement of the device does not require a suture rib as the connective tissue will hold the implant in position.

PRESSURE CATHETER

The pressure catheter is made of high performance polyurethane tubing that extends out of the device body and contains:

- Non-compressible fluid: relays pressure fluctuations to the sensor in the device body.
- Thin-walled section: tip of the catheter farthest from the device body that senses the dynamic portion of the pressure wave. It is designed to be completely inserted into the vessel or space where the desired pressure can be sensed. It contains biocompatible gel at the very tip, which prevents the non-compressible fluid from leaving the catheter and blood from clotting in the catheter tip.
- Tip cover: removable section of silicone tubing that protects the catheter tip until it is actually inserted into the desired vessel.



Detailed diagram of catheter components with the tip cover removed

Some catheter components are optional. For example, the ligation aid is offered for catheter placement in the left ventricle, right ventricle, or bladder. It is a groove between the end of the thin-walled section and the additional thin band of tubing. This feature can be best described with the image below. It is intended to provide a secure location to suture which aides in the anchoring of the catheter to the surrounding tissue. This particular feature is only available on the HD and PhysioTel Digital platforms.

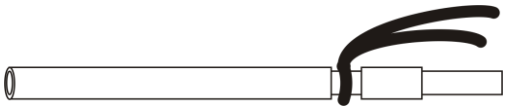


Diagram highlighting the ligation aid option

Many catheter lengths are also available. See the configuration options in Appendix C to learn more about what features are available and their common surgical placement. See the "Understanding Specifications" section below to learn more about the importance of catheter specifications.

BIOPOTENTIAL LEADS

Two leads (clear and pink) extend out of the device body and are made of:

- Silicone tubing which provides insulation from external electrical activity
- Helix of medical grade stainless steel wire which senses the desired biopotential voltage changes

The leads are designed to be cut to a length suitable for the biopotential signal to be monitored. The clear lead is used to collect the negative signal of the biopotential and the red lead is used to collect the positive signal. The biopotential signal monitored could be an ECG, EEG, EOG, EMG, etc. Examine the biopotential specifications listed in Appendix B to learn more about the product specifications including measurement sensitivity and range. This is especially important for special applications.

The small animal sized implants come with tip covers (as shown below) to prevent the end of the steel helix from irritating the surrounding tissue. Mouse sized implants do not come with these as the leads are too small. See the surgical guide to learn more about how to make tip covers from the existing lead material and for placement of the leads.

Photo of leads with tip covers placed appropriately

UNDERSTANDING SPECIFICATIONS

See the quick specification reference in Appendix B for specific specification values for the particular HD implant of interest. Listed below is more information about certain implant specifications that DSI sees as being the most valuable for customers to understand. Please contact Technical Support (Support@datasci.com) with any additional questions.

ANIMAL IMPLANTATION RECOMMENDATIONS

The **minimum animal size** is listed because that is the smallest animal DSI's surgical team feels that this product can be implanted in without complications. Smaller animals can be used, but concerns about growth of the animal and surgical complications increase as smaller animals are used. Please contact DSI's surgical service team if the study requires implantation in smaller animals than DSI recommends as there may be some things we can suggest to ensure success.

The **maximum cage size** is listed due to the standard recommended DSI configuration setup for the intended animal model. If a different animal model and/or caging configuration is required, DSI offers some additional hardware options to make the system more flexible. View the receiver portion of this user manual and the shielding requirements section to better understand caging restrictions before contacting Technical Support.

DEVICE WARRANTY

DSI's goal is to achieve high standards of product reliability and performance and our Limited Warranty Policy is unparalleled in the wireless monitoring industry – this reflects DSI's confidence and over 25 years of experience as well as our increasing investments in product design and testing.

The *in vivo* environment presents significant product reliability challenges, especially for electronic devices used for chronic applications. Included in our warranty policy is a three-part program covering our implanted devices with separate warranty durations for (i) battery life, (ii) implant life, and (iii) maximum warranty period. For complete details on device warranty information and description see Appendix B and Appendix G.

PRESSURE SPECIFICATIONS

Understanding the pressure specifications is key to understanding the accuracy of the data over a long period of implantation (>1 month).

DSI's catheters are filled with a patented non-compressible fluid which is biocompatible and designed for long term chronic use. Any catheter will have issues with **patency** over time, but some handle it better than others. Because of the material selected and after many years of experience, DSI has perfected the technology that ensures the catheter will stay patent over the warranted implantation duration and over the calibrated temperature range.

As a rule of thumb: the shorter the DSI catheter the better the **frequency response**. The required frequency response of the pressure signal depends on the physiologic signal of interest. For most applications, DSI catheters have more than enough frequency response for the basic physiologic signals being measured in the most common animal models. In the catheter configuration guide in Appendix C, surgical placement and recommended length for a particular parameter is identified.

If more information is required or questions arise about this parameter in particular, please contact technical support for assistance. Please be equipped with what physiologic signal is being monitored, what analysis is required and if possible the highest frequency component of the signal that is used in this analysis. This only applies if a signal is being analyzed in a new way or if the device is being used in an untested animal model. Again for basic pressure

measurements such as heart rate, blood pressure, and pulse pressure the frequency response will be adequate for the recommended animal models.

The sensor used in this device is a solid state sensor which is protected within the device housing. This sensor has been characterized for long term use and its **pressure drift** over time is very low. As with any sensor, the calibration can vary depending on temperature, humidity, and voltage and may not be consistent over time.

Sensors drift over time due to a variety of factors. DSI's sensors are solid-state and are protected within the device body. Because of this, the HD platform has proven to have the lowest pressure drift specifications of all DSI small animal telemetry devices. This ensures the calibration accuracy of the device is consistent over time and little to no adjustment needs to be made to the data over the duration of implantation.

BATTERY LIFE

DSI is known for its technical ability to optimize **battery life** with the smallest devices on the market today. DSI devices have guaranteed battery life specifications which means that if the product fails prematurely DSI will replace the device under full warranty. Because of this, customers can have confidence that DSI treats the listed warranted battery life as the absolute minimum requirement. No maximum battery life is listed so the added battery voltage feature and On Time counter are much more useful for researchers to use to better plan the study protocols.

Calibrations are dependent on battery voltage and therefore the calibration data may be compromised if used past the warranted battery life. Each battery is different which is why the minimum life is all that is specified. Use past warranted life is at the discretion of the researcher as eventually the battery will degrade and the impact to the study calibrations or actual end of life may vary. When considering device re-use, see Appendix A.

The HD implants have an **On Time Counter** which means the implant is tracking how much time it's spent on. On time increments in 16-20 hour periods (depending on temperature) and so it is accurate to about 24 hours. The software will also notify the researcher if battery life goes below the recommended battery voltage. Consult the software help menu or contact technical support if battery voltage as an output is of interest for monitoring end of life manually.

Battery's naturally degrade over time, regardless of if they are standard o rechargeable. The batteries in this product will not last forever. Leaving them unused on a shelf is considered in the **shelf life** specification. It is not recommended to use old implants as batteries discharge over time whether they are used or not. The battery life specification will then be invalid. It would be prudent to send them back to DSI if they have gone past the shelf-life as the battery life and product calibrations will be compromised. Because DSI's devices are magnetically activated, be sure to consider keeping the battery far away from any strong magnetic fields during storage. See Appendix A for more storage tips.

DETAILED INSTRUCTIONS FOR IMPLANT OPERATION

OPERATIONAL MODES

The HD implants are activated with a magnet, similar to other DSI products. In order to properly activate the implant, turn on a radio and tune it to the low end of the AM band. Next take a magnet and hold it near the implant for two seconds before pulling it away. The device is ON when distinct tone is heard from the radio (as opposed to static noise).

HD implants are equipped with two operational modes: ON and OFF. Implants are shipped in the OFF mode. The battery in the implant is not activated. When switched to ON, the implants begin to sense and transmit data. The switch to change between these two modes is in the interior of each device and is therefore not visible. The switch is magnetically activated and will switch between modes when exposed to a strong magnetic field.

To switch operational modes:

- Power on a short wave radio and tune it to 18 MHz.
- Bring the radio close to the device.
- Momentarily bring a strong magnet within approximately one inch of the device for two to five seconds.

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The order of modes is:

- Off (No tone on the radio)
- On (Tone on the radio)

ENTERING A PRESSURE OFFSET

Entering an offset in the software will automatically adjust for the initial pressure drift (see specifications for maximum expected pressure drift). However, entering in an offset is optional and only applies to the studies where absolute pressures are being compared. Only enter an offset in the software when all of these criteria are met:

- The device was used once in an animal and is being re-used or the product has been unused for more than a month.
- The ambient pressure reference has been calibrated within the last 2 years
- The pressure offset was taken at over the calibrated range (body temperature)
- The pressure offset is within specification (initial pressure offset + monthly pressure drift) at body temperature. See the warranted product specifications for these precise values.

Entering in an offset value taken at room temperature will compromise the integrity of the calibrations from DSI. If technical support has recommended it, or if the above criteria are met, use the method below to get the most accurate pressure offset:

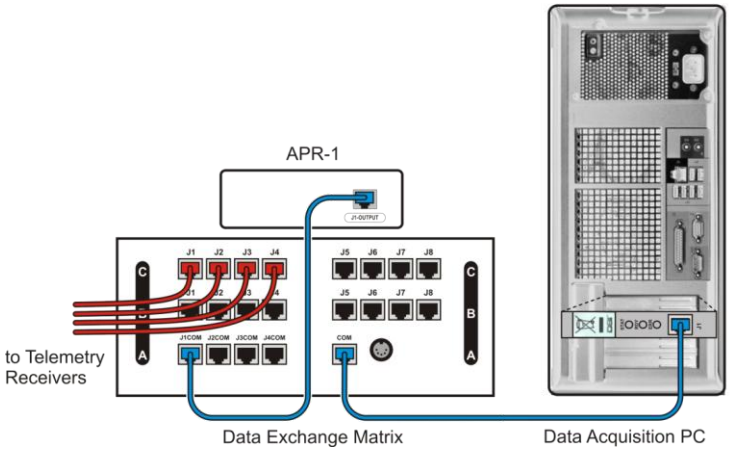
Determining actual pressure offset when hydrated at body temperature before implantation:

1. Ensure the lab has a calibration schedule to ensure all measurement equipment is up to date on its maintenance. For example, temperature probes may require calibration every year.
2. Ensure that the APR-1 is connected to the system and has been calibrated within the last 2 years.
3. Create a rudimentary water bath:
    a. Heat sterile saline (or distilled water if saline is unavailable) in a beaker on a hot plate. Stir the liquid to create a homogeneous medium.

   b. Bring the liquid temperature to the calibrated temperature range of the device (see specifications in Appendix C) to simulate animal body temperature for the most accurate offset reading.
   c. Place a calibrated temperature probe or thermometer in the liquid with the device.
   d. Hydrate the entire implant, including the catheter, to properly acclimate the device to the simulated *in vivo* environment. **NOTE: DSI <u>always</u> recommends that the catheter be hydrated in heated sterile saline for at least 15-30 minutes before every implantation for optimum patency and for signal accuracy.**
4. Turn on the implant.
5. Start Acquisition of the pressure signal. This assumes the device and study has already been set-up properly.
6. Watch the pressure and temperature parameters and wait for stabilization. This may take a minimum of 1 hour to let the electrical components stabilize and acclimate to temperature. If the device has been sitting on a shelf for a long period of time, it may take up to 4 hours to stabilize (as in the above procedure).
7. Compare the calibrated APR-1 recording to the implant's pressure reading at body temperature. This is the pressure offset for the implant.
8. Record this value for tracking purposes.
9. **Enter the pressure offset in the software only if it has been verified at temperature and after closely examining the warranted DSI specifications, otherwise the adjustment may actually cause the offset error to be greater once it is implanted.** If there is any doubt about the accuracy of the system, note the offset and account for it outside of the software in a lab notebook. To enter it in the software follow the steps below:
   a. Go to the "Hardware Configuration" window.
   b. Expand the matrix, receiver and implant of interest to see the associated physiologic channels.
   c. Right click on the pressure channel of interest and go to "Properties".
   d. Go to the "Advanced" tab and enter in the numerical offset in the offset field at the bottom of the calibration table.

DSI SYSTEM SETUP

There are several components needed to monitor from the new DSI system. There are four main components of the PhysioTel Hybrid Digital (HD) telemetry system; the data acquisition computer, the Data Exchange Matrix (DEM), the receivers, and the HD implants. The DEM receives information from the implants through the receiver. Using a hardware configuration wizard in the data acquisition software, the user chooses a set of implants and assigns them each to a particular receiver. Up to sixteen receivers can be assigned to one DEM. All DEM's operate on the same communication frequency. How to connect the separate pieces is shown in the diagram below and the following sections will explain the function of each piece of hardware:



If conducting a pair housing study, the Data Exchange Matrix is replaced with the MX2 device which allows researchers to acquire data from eight animals simultaneously. More information regarding the MX2 device can be found here.

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TELEMETRY RECEIVERS

Multiple receiver options exist and selection depends on the implant model and the caging setup. Listed below are the receivers that support this implant's transmission frequency (455 kHz or 18MHz). Check the implant's transmission range listed as the cage requirement in the product specifications (Appendix B). If space is an issue, if a non-standard cage is being used, or if there is a lot of signal drop out, skip to the shielding section in this document to learn more.

DSI receiver options for HD implants are listed below to assist researchers determine the appropriate telemetry receiver for specific study needs. Information about maximum receiver range, DRA capability, antenna capability, application and frequency is detailed for each receiver. DSI does offer servicing for receivers when they are not working properly. Contact your sales representative to learn more.

Receiver	Maximum Signal Range*	DRA Capability	Antenna Capability	Frequency	Application
RPC-1	Sufficient coverage for up to 16 in (or 41cm)	X	Single Internal	455kHz	Typical Cage Setup
RPC-3		X	Dual Internal	455kHz & 18MHz	Multiple implants in the same animal or paired housing use cases
RSC-1		X	Single Internal **or** Auxiliary External	455kHz	Supplementary for larger cage sizes or for unique cage configurations

RLA3000	Axis dependent		Single Internal	455kHz	Operating Room or Special Caging

*Range is highly dependent on telemetry model. The miniature implant size typically has a 20cm range, the small animal implant size typically has a 25cm range, and the large animal implant size typically has a 1.5m range.

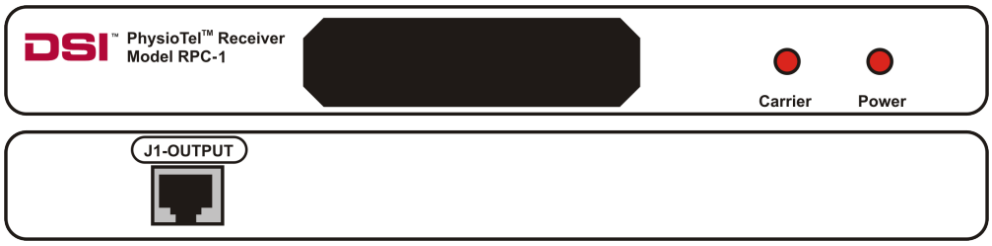
RPC-1

The Receiver Plastic Cage (RPC-1) is used to collect data from any 455 kHz associated PhysioTel implant. The RPC-1 can pick up the signal from the implant or from a neighboring cage so it is important to put enough distance between them so the signals do not interfere. PhysioTel 455 kHz implants can be read up to 40-45cm away from the receiver because of the dual axis antenna located inside the RPC-1 housing. Skip to the shielding section in this document to learn more about cage requirements. See the schematic of the RPC-1 below to see what the reciever looks like up close.

The RPC-1 specifications are as follows:

Pickup Frequency	455kHz
Size	12.9 x 8.9 x 1.3 inches (328 x 227 x 33 mm)
Power Requirements	Powered by the DEM

Photo of an RPC-1



Front (top) and back (bottom) of the RPC-1

RPC-3

The RPC-3 was designed for DSI's Sympathetic Nerve Activity (SNA) monitoring product the F50-W-F2 to be used in conjunction with a 455 kHz PhysioTel implant (most commonly the PA-C40). However it can be used with HD products and with the 4ET as well. It contains two antennas and is used to collect signals from 2 animals simultaneously which are pair housed or from two implants in one animal. One of the signals must be from an 18 MHz PhysioTel implant and the other from a 455 kHz PhysioTel implant. This is important if the system will use 18MHz frequencies in the future such as the 4ET or the F50-W-F2.

The RPC-3 can still pick up the signal from the implant or from a neighboring cage so it is important to put enough distance between them so the signals do not interfere. This receiver is different from the RPC-1 because has additional antennas that enable it to monitor from two separate frequencies. See the schematic below to see view the front and back profiles of the RPC-3. The RPC-3 looks similar to the RPC-1 (photo depicted above).

The RPC-3 specifications are as follows:

Pickup Frequency	18MHz and 455kHz
Size	12.9 x 8.9 x 1.3 inches (328 x 227 x 33 mm)
Power Requirements	Powered by the DEM

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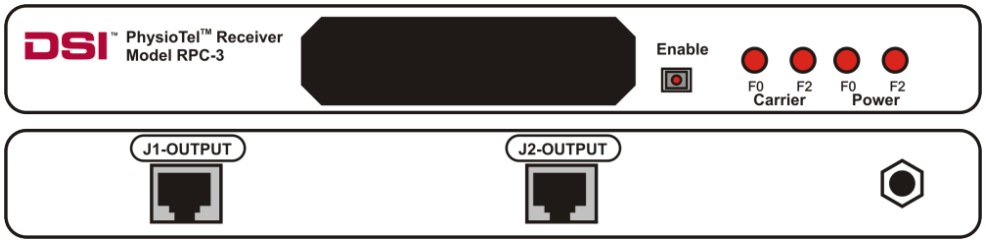


Front (top) and back (bottom) of the RPC-3

RSC-1

The Receiver Special Cage (RSC-1) contains the same antenna as the RPC-1 but has a much smaller profile. The RSC-1 is used in special situations where the RPC-1 is too large or will not fit close to the animal. Applications that are considered special situations could be adding a running wheel to the existing cage setup, using a metabolic cage or a large maze. The RSC-1 can be used to supplement an existing system. This device also has been used in larger caging setups with the DRA function (explained in the software manuals and briefly described below). The RSC-1 also has the function to attach any external antenna (for example 272-7002-001 "Tether Antenna"). Speak to DSI technical support if to learn more about this option for a specific use case. Some researchers may have interest in developing their own custom antenna. An engineering based manual is available by request to instruct users on how to interface their design to the RSC-1. The images below are photos of an actual RSC-1.

Photo of RSC-1 as viewed from the front

Photo of back of RSC-1

The RSC-1 specifications are as follows:

Pickup Frequency	455Hz
Size	3.3 x 1.2 x 5.25 inches (84 x 30 x 132 mm)
Power Requirements	Powered by the DEM

RLA3000

The RLA3000 is ideal for an operation room system as it works with all DSI small animal implants, is very portable and can be easily cleaned. Special situations where the RPC-1 is too large or will not fit close to the anesthetized animal the RLA3000 or the RSC-1 may be used. This works for short range applications where a wand-like receiver is useful. The portability of this receiver makes it ideal for spot checking animals and for surgical applications as it can easily be placed in a sterile filed and cleaned after surgery. It can be used to supplement an existing system, for example it has been used in marmoset studies to expand the range in a cage as it could be placed on a perch or platform.

The RLA3000 contains a single antenna (so one less than the RPC-1) and has a much different profile from the other receivers. However because of the single antenna this receiver has better reception depending on the orientation of the device to the receiver. The RLA3000 is ideal in anesthetized animal use because of this orientation limitation. Because the RLA3000 is an older receiver model it is not automatically recognized by the system like the other receivers so it must be configured when it is attached to the DEM. The RLA3000 also cannot calculate activity like the other receivers because of the single antenna. While the receiver can easily be cleaned, **please do not submerge it completely** as it is not water tight. Use disinfecting wipes or a cloth instead. This receiver also does not have any indicator lights to notify the users of its function like the other DSI receivers.

Limitations do apply with this receiver but it can be very useful in specific use cases. Speak to DSI technical support to learn more about this receiver for a specific use case. The images below are photos of an actual RLA3000.

Photo of RLA3000

The RLA3000 specifications are as follows:

Pickup Frequency	455Hz
Size	Length: 8 inches Diameter: 1.7 inches
Power Requirements	Powered by the DEM

RECEIVER FUNCTIONALITY

The receivers are always powered by the connection with the DEM. When connected, the DSI Dataquest or Ponemah software will detect the model and serial number and configure the software appropriately for all DSI hardware. All receivers have similar jacks and indicator lights. This section describes these and what they mean for each receiver.

Jacks

Plug the "J" output jacks into the DEM to establish a power and data connection. The RPC-3 has two "J" output jacks while the RPC-1 and RSC-1 have only one. The RSC-1 also has an "AUX" and an "ANT" jack on the back. The "AUX" is used in DSI manufacturing to test the product. The "ANT" is where customers can plug in a custom antenna made by DSI or by their own engineers.

Indicator Lights

The ***power*** light indicates that the receiver is connected to the DEM and powered appropriately. The light is either on or off.

The ***carrier*** light indicates when the receiver can detect an implant signal. The light is either on or off, so depending on the quality of the signal users may observe what appears to be blinking if the quality of the signal is poor.

The ***signa***l light is available on the RSC-1 only. It has a more gradual transition from off to on which is designed to indicate when the implant enters the reception range and the strength of the signal. This is useful in tuning remote antennas for custom antenna work.

Enable Button

The enable button on the front of the RPC-3 allows the user to turn off the receiver. Power will still be provided to the receiver, it just severs the connection between the receiver and the DEM. This is useful in situations when using a PhysioTel implant that is not of the HD platform. This feature prevents the receiver from detecting information when an animal or cage is removed from a rack. Because the receiver is so sensitive, sometimes it will pick up data from other sources that look physiologic in cases where it is not watching for an encrypted signal like the HD implants use. The signal is "enabled" when the button is pressed in and the LED light is on. To "disable" or disconnect from the DEM press the button again and it should pop out with the LED light turned off. The carrier lights will both turn off as well indicating that the signal cannot be read by the acquisition system.

DRA FUNCTIONALITY

If a cage is being used that is larger than a single RPC-1, the receivers can be arranged in a Distributed Receiver Array (DRA) mode to cover a larger area. The DRA feature allows groups of 2, 4, 8, or 16 receivers to be used with a single animal to expand the coverage area and improve signal quality. A single data stream is passed back to the data acquisition computer based on instantaneous switching to the receiver that has the strongest signal strength. Unfortunately, the DRA function requires that all receivers within a group are the same receiver model. Please refer to the software user manual for more information on configuring a DRA setup. The DRA function is also only supported by Dataquest A.R.T. or Dataquest OpenART versions 4.31 and later.

DATA EXCHANGE MATRIX (DEM)

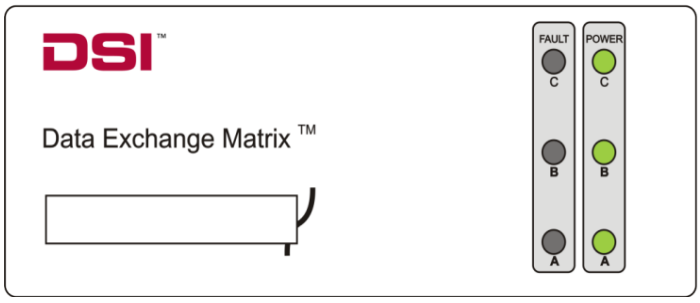
The Data Exchange Matrix is hardwired and connected to the receivers to deliver the transmitted signal to the computer. The matrix has 4 channels and can transmit data from 4 receivers simultaneously, or it can be configured to transmit from all 16 RPC's in a scheduled sampling mode that rotates between groups. The Data Exchange Matrix performs two tasks:

1) It multiplexes the signals fed into it from any combination of several receivers and sensors and sends this signal stream to the computer via a Local Area Network (LAN) type cable.
2) It routes power from the power supply to the connected receivers and analog-to-digital adapters

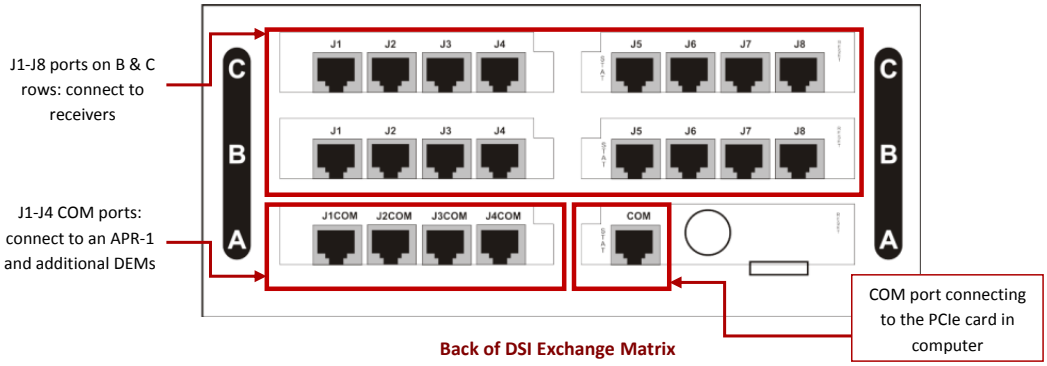
The Data Exchange Matrix also detects changes in signal strength that indicate movement in the animal, and provides one or more digital pulses to the computer upon each movement. The DEM's basic specifications are listed to the right. If additional specifications are of interest, please contact technical support.

Size	10.0 x 7.0 x 4.25 inches (254 x 178 x 108 mm)
Weight	6.05 lbs.
Power Requirements	5 Volts DC @ 1.5A 12 Volts DC @ 35mA
Maximum Receivers Daisy Chained	7
Operating Temperature	0-38°C
Operating Humidity	< 70% R.H. non-condensing

A Data Exchange Matrix is comprised of 3 circuit boards contained in a steel housing. The bottom circuit board (labeled "A" on the rear of the Data Exchange Matrix) is always a MCC-1 Communications Controller. The remaining circuit boards (labeled "B" and "C") are MMX-1 Receiver Multiplexors. On the front of the DEM there are two columns of lights, a green indicating power and a red indicating fault for each card. The green light indicates power to each card and should be continuously lit for all rows in a normally operating DEM.



Front of DSI Exchange Matrix



Back of DSI Exchange Matrix

The back of the Data Exchange Matrix has 20 available input jacks. The jacks on card A (MCC card) labeled J1COM through J4COM can be connected to an APR-1 and additional DEMs. Card A also has a COM port that connects to the Dataquest Acquisition card in the computer and a round plug for the DEM power supply. Jacks J1 through J8 on cards B and C are used to connect DSI's receivers and converters. Each Data Exchange Matrix has a unique serial ID number assigned at the factory that the data acquisition software recognizes when verifying the hardware configuration.

Blinking (Errors)

Blinking red lights indicate a fault or hardware error. There is one light per card. It also lights during system startup and when the card is reset. Blinking green lights indicate a power failure.

What to look for	What it means
"A" Red light blinks quickly on the front panel and then is off for a short time, and the pattern repeats. The red led light next to the COM port on the back panel is also blinking in the same pattern.	No communication from the DEM to the computer
Blinking Green Light	Power Failure

How to fix it?

Try these few steps as these are the most common failure modes:

1. Make sure the computer is powered on
2. Replace the cable between the Data Exchange matrix (DEM) and the computer with a spare or from a neighboring DEM that is functioning correctly. If the new cable works, the older one is bad and will need to be replaced.
3. Re-connect and re-start the system.

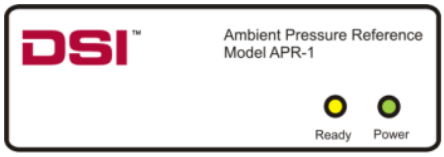
If these steps do not fix the issue, please contact technical support. Technical support can answer any questions about abnormal system behavior.

AMBIENT PRESSURE REFERENCE (APR)

The Ambient Pressure Reference, APR-1, is important because it is a special type of barometer that measures atmospheric pressure providing dynamic corrections via a digital signal to the computer. All local environmental pressure fluctuations and changes in ambient barometric pressure are automatically corrected against measurements obtained by the Dataquest A.R.T. system. Since the PhysioTel implants measure absolute pressure, an APR-1 is necessary for accurate pressure recordings as it provides dynamic adjustment to changes in ambient pressure.

The APR-1 requires routine calibration to ensure the accuracy of the data. Other pressure monitoring hardware systems may come with the ambient pressure reference built in to the acquisition hardware. DSI values accuracy and knows that all sensing equipment will drift over time. Calibrating the system is much more difficult when it is in the hardware and prefers to have it in its own smaller box for ease of calibration frequency and minimal system downtime. To learn more about the APR-1 refer to the user manual (to order a new one for free use part number 391-0047-001).

Pressure Accuracy	+/- 1 mmHg
Pressure Range	650-800 mmHg
Pressure Drift	< 1.0 mmHg per year at 20°C-30°C
Size	14 cm x 10.5 cm x 4 cm
Weight	510g
Suggested Calibration Frequency	Every two years
Power Requirements	Powered via DEM connection



Front of APR-1

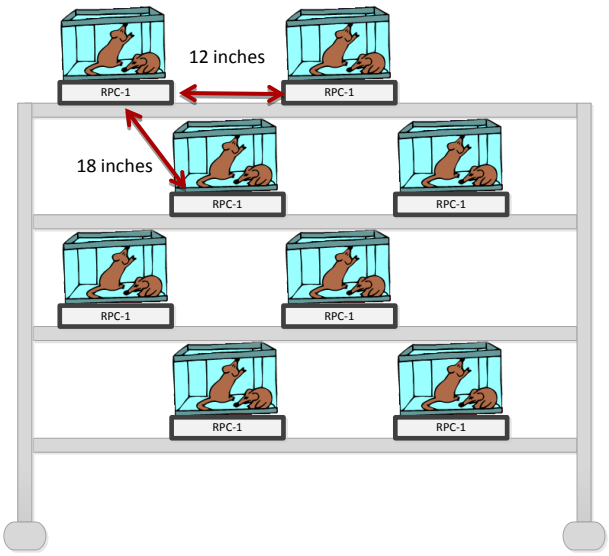
Back of APR-1

Lights

The green power light means the APR-1 is receiving power from the DEM. The ready light means the device has connected to the system, has passed the self-test and is actively monitoring pressure. **If the ready light does not turn on** the APR-1 should be checked for proper operation. Refer to the APR-1 user manual for more troubleshooting information.

CAGING AND SHIELDING RECOMMENDATIONS

DSI has experience using the typical shoe box sized cages but more and more customers are finding that lab space is difficult to come by. Many different configurations are possible depending on the animal model and space available. As a rule of thumb, always leave at a minimum the distance of one RPC-1 (~12 inches or 31cm) between cages. The best case situation would be placing each cage two receiver widths (18 inches or 45 cm) away from each other. Excluding pair housing studies, below is an example of the minimum recommended small animal configuration without any shielding:



As shown above, stagger the cages on a shelf to conserve the most space with this single frequency device. This illustration represents one implanted animal in each cage paired with another animal that is not implanted. With the HD-S11-F2 device, it is possible to pair two implanted animals with different frequency implants in the same cage and gather data simultaneously. The RPC-3 receiver is mandatory for pair housing studies and requires the same amount of distance between cages as that of the RSC-1 (~12 inches or 31cm).

If the receivers need to be closer together and data loss is prevalent (>5%) implement electromagnetic shielding. Shielding comes in many forms from sheet metal and chicken wire to high tech clear specifically designed metal mesh. Locate the source of the noise and enclose that with shielding if possible. For example, the DEM or another implant can be a source of noise if it is placed too close to the receivers. If problems arise or if you require a list of acceptable shielding options, technical support is equipped to help determine the best shielding method either remotely or onsite if necessary.

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SOFTWARE COMPATIBILITY WITH HD DEVICES

This matrix below explains the Dataquest ART, Ponemah and OpenART software versions (and service packs (SP) if necessary) required for each implant in the HD platform.

Software Platform	Version	Implant					
		HD-S21	HD-S11-F0	HD-S11-F2	HD-S10	HD-X11	HD-X10
Ponemah	5.0	●				● (SP2)	
	5.1	●	● (SP1)			●	
	5.2	●	●	●	● (SP5)	●	● (SP5)
	5.6	●	●		●	●	●
	6.1		●	●			
OpenART & Dataquest ART	4.31	●					
	4.32	●				●	
	4.33	●	●			●	
	4.34	●	●			●	
	4.36	●	●		●	●	●

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GLP REQUIREMENTS

If the lab is GLP certified, or if it aspires to be, DSI implants will work within this environment. However, Ponemah is the only DSI software that can be validated for GLP compliant labs. Because of the HD device's digitally transmitted animal ID, it is easier to track *in vivo* and verify that the correct animal is being used. Contact Scientific Services for more information on software validation services and how our experienced team can help save time and reduce costs associated with computer system validation.

APPENDIX A: CARE AFTER FIRST IMPLANTATION

EXPLANTATION

For complete information on device explantation, visit www.datasci.com or contact Technical Support (Support@datasci.com). When explanting DSI implants that are implanted intra-peritoneally or subcutaneously, consider the following:

1. Carefully remove the implant body first.
2. Be careful not to drop the implant.
3. **Never** cut a catheter if the intention is to re-use the implant.
    - If cutting the catheter is necessary, use only a new scalpel blade to cut the catheter at a 45-degree angle away from the device body and approximately 3 cm from the implant body.
    - Do not use any instrument other than a scalpel blade to cut the catheter. Cutting the catheter with a pair of scissors or any other instrument could cause damage to the pressure sensor and void the warranty.
    - **If the catheter must be cut, the implant cannot be reused in another animal model.** Please send the device back to DSI for participation in the Exchange Program and the standard Exchange discount on a new device will apply.
4. Leads can be cut as there are lead coupler kits available for purchase to extend the length of the leads. Lead coupler kits may make the leads less flexible over time so try to save as much length as possible during explantation.
5. Clean and sterilize the implant with an approved enzyme detergent and sterilant before returning the implant to DSI or re-using in another animal.
6. If the animal should die unexpectedly and the implant cannot be explanted immediately, the animal can be placed in a refrigerator or freezer until the explant can take place. The refrigerator or freezer will not damage the device, however; storage in a refrigerator will allow for an easier retrieval.

ON-SITE CLEANING AND RE-STERILIZATION

All new and exchanged implants shipped to an investigator are sterile and ready for implantation. In studies where devices are implanted for short periods at a time, significant battery life may remain at the end of the study allowing reuse of the implant. DSI has published specifications on the minimum guaranteed hours of battery life. Record the amount of time the device is on to track use and to calculate the battery life left. The PhysioTel HD platform allows this tracking to be much easier as the battery voltage and approximate on time is transmitted from the implant when it is in the ON mode.

DSI has developed detailed procedures for cleaning and sterilizing telemetry implants. These procedures will increase the number of times an investigator can use each implant before returning it to DSI via the Exchange Program, helping to reduce overall costs per study. Sterilization procedures are available online at www.datasci.com.

SHELF-LIFE AND STORAGE

New Implants direct from Manufacturing

1. Carefully examine all implants when they arrive at the facility.
2. Remove the sterile packages containing the implants from the shipping boxes. All implants are sterile upon arrival.

3. Save the shipping boxes to use when returning used implants for the Exchange Program.
4. Inspect each implant's sterile packaging for signs of damage. If the package remains undamaged, this sterility is warranted according to the information on the package label.
5. Confirm that each implant is turned off before storing.
    a. Using the AM radio on the low frequency setting, turn each implant on and off by scanning a magnet across the implant to ensure that none of the implants were damaged during shipping.
    b. Although each unit is checked just before shipping, the implant may have been exposed to stray magnetic fields during shipment. This can cause the unit to be turned on unintentionally.
    c. Implants in the OFF mode may lose up to 10% of the battery life within 12 months after the manufacture date.

Storage of Sterilized Implants

Occasionally there may be a delay between the implant removal from the animal and the beginning of the next study. Proper storage of the on-site sterilized implant is necessary to ensure that the unit will perform normally during the next study.

1. Using the AM radio on the low frequency setting, check each implant to ensure that it is properly turned off.
2. Thoroughly clean and sterilize each implant according to DSI's On-Site Re-sterilization procedure. www.datasci.com
3. If the original implant sterile package was saved, place the implant into the plastic packaging. This will help to identify the implant and the calibration values associated with it.
    a. **Do not** store implants in saline or other liquid.
4. Sterilization before storage is necessary to prevent the spread of bacteria during handling.
5. Each implant will require sterilization again at the time of use as there is not an effective way to maintain sterility after the sterile package has been opened.

STORAGE LOCATION REQUIREMENTS

The implants should be stored in a cool (between 10 and 25 degrees Celsius), dry area away from exposure to static discharge and magnetic fields. **Never** expose them to temperatures above 60 degrees Celsius, as this will void all warranties. It is also important to store them in an area where they will not be accidentally dropped or have items placed on top of them as the catheter could be crushed and the senor damaged. Storage in a refrigerator **does not** provide significant benefit in terms of battery life. By following the procedure for storage, the implants should perform just as well as the day they were shipped.

APPENDIX B: QUICK REFERENCE SPECIFICATIONS

Telemetry implants may operate over wider pressure and temperature ranges with reduced accuracy. Please contact technical support (Support@datasci.com) if the study requires use of products outside the specified range. Specifications and product performance is only valid for the warranted battery life and when the data is recorded using DSI Software platforms. Use of alternate software platforms or homemade calibration systems may compromise the integrity of the study.

HD-S10 PART NUMBER: 270-0180-XXX

Total Configuration Possibilities: 5

Measures: Pressure, Temperature & Activity

DIGITAL DATA

- Stored Factory Calibrations
- Animal ID
- Battery ON Time
- Battery Voltage

BATTERY LIFE

Min. Warranted Battery Life Period: 5 months
Battery Data Displayed:
Battery Voltage and ON time
ON time accuracy: ± 1 day at 37°C

OPERATING SPECIFICATIONS

Ambient Pressure Range (mmHg): 670 to 800
Maximum Altitude (meters): 625
RF Transmission Frequency (Hz): 455 kHz ± 10

PRESSURE SPECIFICATIONS

Pressure Accurate within Temperatures (°C): 34-41
***In vivo*:**
Range (mmHg): -20 to 300
Initial Accuracy (mmHg): ± 3
Drift (mmHg/month):
< 2.0 Maximum (< 0.25 Average)
In Package:
Pressure Drift over time
At Dry Heat of 37°C (mmHg / per month): ± 1

Pressure Catheter Properties:

Catheter Length	Tip Length	Diameter	Frequency Response**
8 cm	6 mm*	0.7 mm	Min 40Hz
8 cm	4.5 mm	0.7 mm	Min 40Hz
8 cm	3 mm	0.7 mm	Min 40Hz
10 cm	6 mm	0.7 mm	Min 40Hz
15 cm	6 mm	0.7 mm	Min 20Hz

No S10 catheter is to be used for dP/dT calculations
*Most common
**With default 50Hz software filter

ANIMAL RECOMMENDATIONS

Min. Animal Weight (g): 175
Max Cage Size (cm): 42 x 42 x 18

PACKAGING

Sterile Shelf Life: 12 months
Sterile Barrier Type: Single Layer

IMPLANT BODY DIMENSIONS

Excluding Suture Ribs:
Shape: Round with flat bottom
Length (mm): 23.4
Width (mm): 13.8
Height (mm): 13.2
Weight (g): 4.3
Volume (cc): 3.0
Outer Material: Silicone Elastomer
Suture Ribs: See configuration table

TEMPERATURE ACCURACY

Calibrated Range (°C): 34-41
Initial Accuracy (°C): 0.1
Resolution (°C): 0.05
Temperature Drift (°C)
Per 6 months: 0.2

WARRANTY INFORMATION

Maximum Warranty Period: 18 months
Warranted Implant Period: 9 months

HD-S11-F0/-F2 PART NUMBER: -F0: 270-0193-XXX; -F2: 270-0196-XXX

Total Configuration Possibilities: 10

Measures: Pressure, Biopotential, Temperature & Activity

DIGITAL DATA

- Stored Factory Calibrations
- Animal ID
- Battery ON Time
- Battery Voltage

BATTERY LIFE

Min. Warranted Battery Life Period: 2 months
Battery Data Displayed:
Battery Voltage and ON time
ON time accuracy: ± 1 day at 37°C

OPERATING SPECIFICATIONS

Ambient Pressure Range (mmHg): 670 to 800
Maximum Altitude (meters): 625
RF Transmission Frequency:
455 kHz (HD-S11-F0)
18 MHz (HD-S11-F2)

PRESSURE SPECIFICATIONS

Pressure Accurate within Temperatures (°C): 34-41
***In vivo*:**
Range (mmHg): -20 to 300
Initial Accuracy (mmHg): ± 3
Drift (mmHg/month):
< 2.0 Maximum (< 0.25 Average)
In Package:
Pressure Drift over time
At Dry Heat of 37°C (mmHg / per month): ± 1

Pressure Catheter Properties:

Catheter Length	Tip Length	Diameter	Frequency Response
8 cm	6 mm*	0.7 mm	Min 100Hz
8 cm	4.5 mm	0.7 mm	Min 100Hz
8 cm	3 mm	0.7 mm	Min 100Hz
10 cm	6 mm	0.7 mm	Min 50Hz
15 cm	6 mm	0.7 mm	Min 20Hz

*Most common and is only catheter recommended for dP/dt calculation

ANIMAL RECOMMENDATIONS

Min. Animal Weight (g): 175
Max Cage Size (cm): 42 x 42 x 18

PACKAGING

Sterile Shelf Life: 12 months
Sterile Barrier Type: Single Layer

IMPLANT BODY DIMENSIONS

Excluding Suture Ribs:
Shape: Flat with rounded edges
Length (mm): 34.8
Width (mm): 17.6
Height (mm): 12.0
Weight (g): 8
Volume (cc): 5.9
Outer Material: Silicone Elastomer
Suture Ribs: See configuration table

TEMPERATURE ACCURACY

Calibrated Range (°C): 34-41
Initial Accuracy (°C): 0.15
Resolution (°C): 0.05
Temperature Drift (°C)
First two weeks: 0.1
Per 6 months after: 0.1

BIOPOTENTIAL SPECIFICATIONS

Bandwidth Range (Hz): 0.1 - 145
Input Voltage Range (mV): ± 5
Biopotential Lead Dimensions
Length (cm): 30cm or 60cm
Outer Diameter (mm): 0.94
Coil Diameter (mm): 0.46

WARRANTY INFORMATION

Maximum Warranty Period: 18 months
Warranted Implant Period: 9 months

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HD-S21 PART NUMBER: 270-0192-XXX

Total Configuration Possibilities: 17

Measures: Pressure (2), Biopotential, Temperature & Activity

DIGITAL DATA

- Stored Factory Calibrations
- Animal ID
- Battery ON Time
- Battery Voltage

BATTERY LIFE

Min. Warranted Battery Life Period: 2 months
Battery Data Displayed:
Battery Voltage and ON time
ON time accuracy: ± 1 day at 37°C

OPERATING SPECIFICATIONS

Ambient Pressure Range (mmHg): 670 to 800
Maximum Altitude (meters): 625
RF Transmission Frequency (Hz): 455 kHz ± 10

PRESSURE SPECIFICATIONS

Pressure Accurate within Temperatures (°C): 34-41
***In vivo*:**
Range (mmHg): -20 to 300
Initial Accuracy (mmHg): ± 3
Drift (mmHg/month):
< 2.0 Maximum (< 0.25 Average)
In Package:
Pressure Drift over time
At Dry Heat of 37°C (mmHg / per month): ± 1

Pressure Catheter Properties:

Catheter Length	Tip Length	Diameter	Frequency Response
8 cm	6 mm*	0.7 mm	Min 100Hz
8 cm	4.5 mm	0.7 mm	Min 100Hz
8 cm	3 mm	0.7 mm	Min 100Hz
10 cm	6 mm	0.7 mm	Min 50Hz
15 cm	6 mm	0.7 mm	Min 20Hz

*Most common and is only catheter recommended for dP/dt calculation

ANIMAL RECOMMENDATIONS

Min. Animal Weight (g): 175
Max Cage Size (cm): 42 x 42 x 18

PACKAGING

Sterile Shelf Life: 12 months
Sterile Barrier Type: Single Layer

IMPLANT BODY DIMENSIONS

Excluding Suture Ribs:
Shape: Flat with rounded edges
Length (mm): 34.8
Width (mm): 17.6
Height (mm): 12.0
Weight (g): 8
Volume (cc): 5.9
Outer Material: Silicone Elastomer
Suture Ribs: See configuration table

TEMPERATURE ACCURACY

Calibrated Range (°C): 34-41
Initial Accuracy (°C): 0.15
Resolution (°C): 0.05
Temperature Drift (°C)
First two weeks: 0.1
Per 6 months after: 0.1

BIOPOTENTIAL SPECIFICATIONS

Bandwidth Range (Hz): 0.1 - 145
Input Voltage Range (mV): ± 5
Biopotential Lead Dimensions
Length (cm): 30cm or 60cm
Outer Diameter (mm): 0.94
Coil Diameter (mm): 0.46

WARRANTY INFORMATION

Maximum Warranty Period: 18 months
Warranted Implant Period: 9 months

HD-X10 PART NUMBER: 270-0171-XXX

Total Configuration Possibilities: 4

Measures: Pressure, Temperature & Activity

DIGITAL DATA

- Stored Factory Calibrations
- Animal ID
- Battery ON Time
- Battery Voltage

BATTERY LIFE

Min. Warranted Battery Life Period: 6 weeks
Battery Data Displayed:
Battery Voltage and ON time
ON time accuracy: ± 1 day at 37°C

OPERATING SPECIFICATIONS

Ambient Pressure Range (mmHg): 670 to 800
Maximum Altitude (meters): 625
RF Transmission Frequency (Hz): 455 kHz ± 10

PRESSURE SPECIFICATIONS

Pressure Accurate within Temperatures (°C): 34-41
***In vivo*:**
Range (mmHg): -20 to 300
Initial Accuracy (mmHg): ± 3
Drift (mmHg/month):
< 2.0 Maximum (< 0.25 Average)
In Package:
Pressure Drift over time
At Dry Heat of 37°C (mmHg / per month): ± 1

Pressure Catheter Properties:

Catheter Length	Tip Length	Diameter	Frequency Response
5 cm	4.5 mm	0.4 mm	Min 60Hz
7 cm	4.5 mm	0.4 mm	Min 40Hz

No mouse catheters are recommended for dP/dt calculations.

ANIMAL RECOMMENDATIONS

Min. Animal Weight (g): 19
Max Cage Size (cm): 33 x 33 x 14

PACKAGING

Sterile Shelf Life: 12 months
Sterile Barrier Type: Single Layer

IMPLANT BODY DIMENSIONS

Excluding Suture Ribs:
Shape: Tear Drop / Cylindrical
Length (mm): 19.58
Width (mm): 10.67
Diameter (mm): 9.65
Weight (g): 2.2
Volume (cc): 1.4
Outer Material: Silicone Elastomer
Suture Ribs: See configuration table

TEMPERATURE ACCURACY

Calibrated Range (°C): 34-41
Initial Accuracy (°C): 0.15
Resolution (°C): 0.05
Temperature Drift (°C)
First two weeks: 0.1
Per 6 months after: 0.1

WARRANTY INFORMATION

Maximum Warranty Period: 12 months
Warranted Implant Period: 6 months

HD-X11 PART NUMBER: 270-0170-XXX

Total Configuration Possibilities: 4

Measures: Pressure, Biopotential, Temperature & Activity

DIGITAL DATA

- Stored Factory Calibrations
- Animal ID
- Battery ON Time
- Battery Voltage

BATTERY LIFE

Min. Warranted Battery Life Period: 1 month
Battery Data Displayed:
Battery Voltage and ON time
ON time accuracy: ± 1 day at 37°C

OPERATING SPECIFICATIONS

Ambient Pressure Range (mmHg): 670 to 800
Maximum Altitude (meters): 625
RF Transmission Frequency (Hz): 455 kHz ± 10

PRESSURE SPECIFICATIONS

Pressure Accurate within Temperatures (°C): 34-41
***In vivo*:**
Range (mmHg): -20 to 300
Initial Accuracy (mmHg): ± 3
Drift (mmHg/month):
< 2.0 Maximum (< 0.25 Average)
In Package:
Pressure Drift over time
At Dry Heat of 37°C (mmHg / per month): ± 1

Pressure Catheter Properties:

Catheter Length	Gel Tip Length	Diameter	Frequency Response
5 cm	4.5 mm	0.4 mm	Min 60Hz
7 cm	4.5 mm	0.4 mm	Min 40Hz

No mouse catheters are recommended for dP/dt calculations.

ANIMAL RECOMMENDATIONS

Min. Animal Weight (g): 19
Max Cage Size (cm): 33 x 33 x 14

PACKAGING

Sterile Shelf Life: 12 months
Sterile Barrier Type: Single Layer

IMPLANT BODY DIMENSIONS

Excluding Suture Ribs:
Shape: Tear Drop / Cylindrical
Length (mm): 19.58
Width (mm): 10.67
Diameter (mm): 9.65
Weight (g): 2.2
Volume (cc): 1.4
Outer Material: Silicone Elastomer
Suture Ribs: See configuration table

TEMPERATURE ACCURACY

Calibrated Range (°C): 34-41
Initial Accuracy (°C): 0.15
Resolution (°C): 0.05
Temperature Drift (°C)
First two weeks: 0.1
Per 6 months after: 0.1

BIOPOTENTIAL SPECIFICATIONS

Bandwidth Range (Hz): 0.1 - 200
Input Voltage Range (mV): ± 2.5
Biopotential Lead Dimensions
Length (cm): 20cm
Outer Diameter (mm): 0.94
Coil Diameter (mm): 0.46

WARRANTY INFORMATION

Maximum Warranty Period: 12 months
Warranted Implant Period: 6 months

APPENDIX C: CATHETER & LEAD CONFIGURATION OPTIONS

Many configurations are available to enable flexibility between studies. Configurations that are more common and therefore have faster lead times are highlighted for convenience. Part numbers may change over time as more options become available and as more surgical methods are validated due to customer demand.

All listed surgical approaches are endorsed by DSI's surgical support staff and therefore training is available for these methods on-site or at DSI headquarters. The surgical placement may vary depending on the animal model and experimentation with a non-functional training device is recommended before attempting a survival surgery. Surgical manuals and videos for each implant are available.

Papers or posters verifying these surgical methods are available via DSI's bibliography system found on the website. In unique applications, DSI may also be able to connect researchers together for further surgical or scientific development.

HD-S10

The "X" after the Part Number means the pricing reflects participation in the Exchange Program.

270-0180-XXX	Catheter		Lead Length	Suture Rib?	DSI Endorsed Surgical Approach		
	Length / Tip	Ligation Aide?			Animal Model	Device Placement	Catheter Placement Options
-001	8cm / 6mm tip		30cm	●	Rat	Intra-peritoneal Subcutaneous	• Systemic BP from the Descending Aorta • Intra-Pleural Pressure • Systemic BP from the Femoral Artery
-002	10cm / 6mm tip		30cm	●	Rat	Intra-peritoneal	Systemic BP from the Femoral Artery
						Intra-peritoneal	Pulmonary Artery Pressure
					Rabbit	Intra-peritoneal	Right Ventricular Pressure
-003	15cm / 6mm tip		30cm	●	Rabbit	Subcutaneous	Systemic BP from the Femoral Artery
-007	8cm / 3mm tip	●	30cm	●	Rat	Intra-peritoneal	Bladder Pressure
-008	8cm / 4.5mm tip		30cm	●	Rat	Intra-peritoneal	Intra-Cavernosal Pressure

*** WARNING: The HD-S10 is NOT recommended for dP/dt analysis**

HD-S11-F0/-F2

All catheters are High Frequency catheters. They have been redesigned and improved upon from other DSI PhysioTel models. The "X" after the Part Number means the pricing reflects participation in the Exchange Program.

270-0193-XXX -F0: 270-0196-XXX -F2:	Catheter		Lead Length	Suture Rib?	DSI Endorsed Surgical Approach		
	Length / Tip	Ligation Aide?			Animal Model	Device Placement	Catheter Placement Options
-001	8cm / 6mm tip		30cm	●	Rat	Intra-peritoneal	• Systemic BP from the Descending Aorta • Intra-Pleural Pressure
-002	10cm / 6mm tip		30cm	●	Rat	Intra-peritoneal	Systemic BP from the Femoral Artery
						Intra-peritoneal	Pulmonary Artery Pressure
					Rabbit	Intra-peritoneal	Right Ventricular Pressure*
-003	8cm / 6mm tip		30cm		Rat	Subcutaneous	Systemic BP from the Femoral Artery
-004	8cm / 6mm tip	●	30cm	●	Rat	Intra-peritoneal	• Left Ventricular Pressure • Right Ventricular Pressure
-005	10cm / 6mm tip	●	30cm	●	Rabbit	Intra-peritoneal	Right Ventricular Pressure*
-006	8cm / 4.5mm tip		30cm	●	Rat	Intra-peritoneal	Intra-Cavernosal Pressure
-007	8cm / 3mm tip	●	30cm	●	Rat	Intra-peritoneal	Bladder Pressure
-008	10cm / 6mm tip		60cm	●	Ferret Rabbit G. Pig	Intra-peritoneal	Numerous Applications
-009	15cm / 6mm tip		60cm	●	Ferret Rabbit G. Pig	Intra-peritoneal	Numerous Applications
-010	8cm / 6mm tip	●	30cm		Rat	Subcutaneous	Numerous Applications

*** WARNING: Not recommended for dP/dt analysis in rats**

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HD-S21

All catheters are High Frequency catheters. They have been redesigned and improved upon from other DSI PhysioTel models. **For any pulse wave velocity analysis the catheter lengths must be equal.** The X after the Part Number means the pricing reflects participation in the Exchange Program. The L after the Part Number is a level pricing option offered on this product alone. Contact your sales representative to learn more**. WARNING: Only the 8cm catheter with a 6mm tip and ligation aide is recommended for dP/dt analysis in rodents.**

270-0192-XXX	Catheter 1		Catheter 2		Biopotential Lead Length	Suture Rib?	DSI Endorsed Surgical Approach		
	Length / Tip	Ligation Aide	Length / Tip	Ligation Aide			Animal Model		Catheter Placement Options
-001	8cm / 6mm		8cm / 6mm		30 cm	●	Rat	1 2	Two stomach pressures
-002	8cm / 4.5mm		8cm / 6mm		30 cm	●	Rat	1	Cavernosal pressure
								2	Blood pressure via descending aorta
-003	8cm / 3mm	●	8cm / 6mm		30 cm	●	Rat	1	Bladder Pressure
								2	Blood pressure via descending aorta
-004	8cm / 6mm		10cm / 6mm		30 cm	●	Rat	1	PAP or RVP
								2	Blood pressure via descending aorta
-005	8cm / 6mm	●	10cm / 6mm		30 cm	●	Rat	1	LVP
								2	Blood pressure via descending aorta
-006	10cm / 6mm	●	10cm / 6mm		30 cm	●	Rat	1	RVP
								2	Blood pressure via descending aorta
-007	10cm / 6mm		10cm / 6mm		30 cm	●	Rat	1	PAP or RVP or Intra-Pleural Pressure (IPP)
								2	Blood pressure via descending aorta
-008	8cm / 6mm		15cm / 6mm		60 cm	●	Rabbit	1	LVP (if no suture aid is desired)
								2	Blood Pressure via femoral artery
-009	10cm / 6mm	●	15cm / 6mm		60 cm	●	Ferret G. Pig Rabbit	1	LVP
								2	Blood pressure via descending aorta
-010	10cm / 6mm		15cm / 6mm		60 cm	●	Ferret G. Pig Rabbit	1	PAP or RVP
								2	Blood pressure via descending aorta
							Rat	1	PAP
								2	Blood pressure via femoral
-011	8cm / 6mm	●	15cm / 6mm		60 cm	●	Rabbit	1	LVP
								2	Blood pressure via femoral
-012	8cm / 3mm	●	8cm / 4.5 mm		30 cm	●	Rat	1	Bladder pressures
								2	Cavernosal pressures
-013	8cm / 6mm	●	8cm / 6mm	●	30 cm	●	Rat	1 2	LVP & RVP
-014	15cm / 6mm		15cm / 6mm		60 cm	●	Rat Rabbit	1 2	Pulse Wave Velocity (equal catheter lengths required)

270-0192-XXX	Catheter 1		Catheter 2				DSI Endorsed Surgical Approach		
	Length / Tip	Ligation Aide	Length / Tip	Ligation Aide	Biopotential Lead Length	Suture Rib?	Animal Model	Catheter Placement Options	
									Numerous surgical applications in rabbits
-015	8cm / 3mm	●	8cm / 3mm	●	30 cm	●	Rat	1 2	Intra-ocular & intra-cranial pressures
-017	10cm / 6mm		8cm / 3mm	●	30 cm	●	Rat	1	Blood Pressure via femoral artery
								2	Bladder Pressure

HD-X10

The 5cm catheter is the same as the one on the PhysioTel PA-C10 model. The 7cm catheter was developed for this product to enable carotid artery surgery while obtaining core temperature via IP placement of the device body. The "X" after the Part Number means the pricing reflects participation in the Exchange Program.

270-0171-XXX	Catheter	Suture Rib?	DSI Endorsed Surgical Approach		
			Animal Model	Device Placement	Catheter Placement
-001	5 cm		Mouse	Subcutaneous	Systemic BP from the Carotid Artery
-002	5 cm	•	Mouse	Intra-peritoneal	Systemic BP from the Descending Aorta
-007	7 cm	•	Mouse	Intra-peritoneal	Systemic BP from the Carotid Artery
-008	7 cm		Mouse/Juvenile Rat	Subcutaneous	Numerous Applications

HD-X11

The 5cm catheter is the same as the one on the PhysioTel PA-C10 model. The 7cm catheter was developed for this product to enable carotid artery surgery while obtaining core temperature via IP placement of the device body. The "X" after the Part Number means the pricing reflects participation in the Exchange Program.

270-0170-XXX	Catheter	Biopotential Lead Length	Suture Rib?	DSI Endorsed Surgical Approach		
				Animal Model	Device Placement	Catheter Placement
-001	5 cm	20 cm		Mouse	Subcutaneous	Systemic BP from the Carotid Artery
-002	5 cm	20 cm	•	Mouse	Intra-peritoneal	Systemic BP from the Descending Aorta
-007	7 cm	20 cm	•	Mouse	Intra-peritoneal	Systemic BP from the Carotid Artery
-008	7 cm	20 cm		Mouse/Juvenile Rat	Subcutaneous	Numerous Applications

APPENDIX D: RECOMMENDED SUPPLEMENTARY PRODUCTS AND SYSTEM COMPONENTS

It is important to practice the surgery with the new implants before the study begins. Every product is different and each surgical method is different. No matter how experienced the surgeon or researcher may be, it is always a good idea to review the new methods in DSI's surgical manual. A complete list of all recommended products for a DSI certified surgery is included in the surgical manual.

DSI's surgical team is always improving the recommended methods with feedback received from all over the world. DSI surgeons are available for individualized on-site training at your facility or at DSI's facility.

The tools listed below are not required by DSI but are offered as supplementary to complete DSI's solution for physiologic monitoring. The highlighted tools are highly recommended for all researchers, while the rest are replacement products or only useful in some applications. Speak with your sales representative to learn more.

Part Number	HD-S21	HD-S11-F0/-F2	HD-S10	HD-X10	HD-X11	Item Type	Distributor	Use Notes
00608-11	X	X	X	X	X	Vessel Cannulation Forceps	Fine Science Tools	Single most important surgical tool. Required to properly handle the catheter.
370-0193-0XX (10 options)		X				Non-Functional Training Module	DSI	Identical to the corresponding implant part numbers (replaces the beginning 270 with 370). Used to practice surgical techniques
370-0192-0XX (17 options)	X							
370-0180-0XX			X					
370-01XX-0XX								
370-0170-0XX (4 options)					X			
276-0038-001	X	X	X	X	X	SA Catheter Regel Syringe		500+ uses possible. See DSI's regel procedure online for implant reuse.
276-0103-001	X	X	X			Starter Kit		(1) HD Getting Started Guide (1) Surgical Manual (2) Surgical Video (1) 3ml bottle tissue adhesive (Vetbond) (1) Trocar/sleeves (1) Radio w/ batteries (1) Suture kit 5-0 silk (1) Magnet (1) Fiber patch 5x5cm (2) Needle hypo 14ga 1.5" (2) Needle hypo 22ga 1.5" (2) Needle hypo 20ga 1.5"

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Part Number	HD-S21	HD-S11-F0/-F2	HD-S10	HD-X10	HD-X11	Item Type	Distributor	Use Notes
276-0104-001				X	X	Starter Kit	DSI	(1) HD Getting Started Guide (1) Surgical Manual (1) Surgical Video (1) 3ml bottle tissue adhesive (Vetbond) (1) Trocar/sleeves (1) Radio w/ batteries (1) Suture kit 5-0 silk (1) Magnet (1) Fiber patch 5x5cm (2) Needle hypo 18ga 1.5” (2) Needle hypo 25ga 5/8” (4) Practice catheters
276-0019-001	X	X				Crimp Tool		For use with the lead coupler kit(s) which is used to crimp leads together. Must be ordered separately.
276-0019-002					X			
276-0031-001	X	X				Lead Coupler Kit		Used to extend existing leads or add a custom lead design. Requires a Crimp Tool (order separately. Includes: (5) Extra Pins/Sheaths (6) Tip Covers (276-0031-001 only) (2) Prepared leads ready to attach (60 or 20cm) (1) User Manual
276-0065-001					X			
370-0104-001	X	X				Extra Pins/Sheaths		Comes in packs of 5 and are included in the lead coupler kits.
370-0104-002					X			
370-0034-001	X	X	X	X	X	Extra Magnet		Used to turn on and off the device
391-0303-001	X	X	X	X	X	HD Getting Started Guide		This System Setup Guide has all necessary information including hardware, supplemental tools and specifications for all HD Implants.
391-1007-001	X	X	X			Surgical Implantation Manual		Surgical Manual on a CD for Specific Implants
391-1008-001				X	X			
390-0099-001	X	X	X			Surgical Video		Surgical Video which shows common techniques for device implantation with DSI surgical technicians voice over
390-1000-001				X	X			

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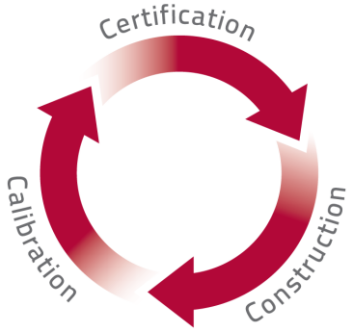
Typical Hardware Acquisition System Part Numbers

Hardware Description	Part Number
RPC-1	272-6001-001
RPC-3	272-6008-001
RSC-1	272-6012-001
RLA3000	272-5007-002
DEM	271-0117-001
DEM Power Supply	Depends on Geography Contact Sales for details
APR-1	275-0020-001
Computer System: • Computer • Monitor • Power Cables	 271-0112-005 271-0113-001 Depends on Geography Contact Sales for details

APPENDIX E: EXCHANGE PROGRAM

DSI Exchange allows customers to exchange their used telemetry implants for replacement implants at a fraction of the original purchase price.

We ensure that each implant manufactured as part of DSI Exchange meets or exceeds design expectations for guaranteed performance and quality. Participating in DSI Exchange contributes to a decrease in the overall cost of each customer's study.



Construction

Each implant is hand assembled by DSI's highly skilled technicians and receives 100% inspection to ensure that all components meet our quality standards

- A new battery is installed to guarantee functionality over the warranty period

Several steps ensure that a biocompatible device guaranteed to perform to specifications IN VIVO is delivered:

- Packaging in a biocompatible housing
- Attachment of biopotential leads and catheters to provide signal fidelity
- Pre-shipment sterilization

Calibration

- Mechanical and electrical testing of all components to guarantee optimal functionality
- Full calibration of each physiologic signal followed by testing to ensure accuracy specifications are met or exceeded when used as intended. Signals include: temperature, pressure, biopotential, and respiratory impedance
- Each implant includes a calibrations label on the sterile package to document that the device has been calibrated for accuracy

Certification

Each implant shipped from DSI has the same warranty policy and is guaranteed to operate exactly the same every time. Implants that are received through the exchange program are like a new product. Exchanged implants are purchased for a fraction of the cost of new devices, which reduces ongoing study costs while maintaining data quality and accuracy.

Already Participating?

DSI now has the option for researchers to pre-pay for their exchanges ahead of time and send implants back to DSI for exchange right away. This can shorten the internal purchasing order process and ensure that budget dollars are retained for future telemetry studies. Just give Customer Service a call when the devices are needed and we will maintain inventory for you. This enables customer's internal processing and lead time to become separate from the DSI product lead time so studies can get up and running faster. Giving DSI advanced notice may also decrease lead times on

special device configurations. Consider using the **Pre-pay Exchange Program** or the new **Exchange Manager** to help manage telemetry studies.

APPENDIX F: RETURNING PRODUCT TO DSI

A detailed updated procedure for properly returning telemetry products to DSI for product investigation is provided on our website, www.datasci.com. The following additional considerations should be made:

- To be covered under the manufacturer's warranty, the implants must be returned for exchange within the warranty period (listed in the implant specifications).
- Ensure that the implants are well packed, preferably in their original packaging and boxes.
- Return the implants via a traceable shipping method to prevent losses in transit.

Exchange forms are available on our website www.datasci.com

- 001465-001: DSI Exchange Form USA
- 001549-001: DSI Exchange Form Europe
- 004540-001: DSI Exchange Form International

Contact DSI Technical Services with any concerns or comments regarding the performance of the devices upon receipt and after the first use.

Forms needed for returning products for investigation:

- Product Investigation Form (PIF) – printed email sent from Technical Support

APPENDIX G: DEVICE WARRANTY

The most up to date DSI Telemetry Products Official Warranty is on the website. A summary is provided here.

Overview

DSI has a broad range of implants for application from mouse to large animal models, and warranty periods vary based on the implant model and its intended application. DSI also offers warranties on our non-implanted hardware products, typically of one year duration. This version of the warranty policy will be in effect as of December 1, 2009 and will supersede any previous warranty policies or references to the warranty in other printed materials.

DSI Implant "Exchange" Program Warranty Details

When sent back to DSI, each implant's catheters, leads, batteries, and housing are replaced. The savings is in the re-use of the electronics which are thoroughly tested and calibrated to the same standards as a brand new module. Even the electronics are replaced (DSI absorbs the cost) if it does not meet DSI specifications. The result is a "good as new" implant with the same warranty coverage as a new implant – but at a much lower price.

The Exchange Program pricing remains available until the implant model goes out of production. The only restriction is that implants must be carefully handled and returned in visually good condition. Implants with significantly damaged housings (i.e. beyond normal wear and tear such as animal chewing) will not be available for the Exchange Program.

Implant Warranty Duration Details

DSI warrants to customers that, for each of the warranty periods, DSI implanted implants and other products shall conform to DSI's applicable published specifications in effect at the time of shipment, and shall be free from defects in materials and workmanship.

For implanted implants, the **"Warranted Battery Life Period"** shall be the aggregate of the periods of battery "on time". For example, if the battery is turned on for use on January 1 and turned off on March 1 of the same year, the individual period of battery on time would be two (2) months. If all periods of battery on time exceed the Warranted Battery Life Period when added together, the device is no longer under warranty. The Warranted Battery Life Period is specified per implant model.

The **"Warranted Implant Period"** is the period of time over which DSI warrants the device to perform in-vivo in accordance with specifications. For example, if a device is implanted in a research subject on January 1 and later removed on March 1 of the same year, the individual period of in-vivo use would be two (2) months. If the cumulative total of all periods of in-vivo use exceed the Warranted Implant Period, the device is no longer under warranty. If customers implant DSI implantable telemetry devices for longer periods of time than the Warranted Implant Period, the customers assume all risk of device failure, compromised data quality or other adverse effects. This is because DSI does not warrant the performance to DSI's published specifications for devices that have been implanted longer than the Warranted Implant Period.

The **"Maximum Warranty Period"** is the continuous period commencing on the date that each product is shipped to the customer and shall continue for the specified number of months. If implants are returned to DSI beyond this date for any reason, the product is no longer covered free of charge under warranty and the customer will be charged for a new device if replacement is required. Even if it is out of warranty it can still be used in the Exchange Program as long as the product is still in production, but it will not be replaced for free.

DSI's applicable published specifications such as accuracy and other performance parameters are valid only within the shorter of (a) the Warranted Battery Life Period (b) the Warranted Implant Period and (c) the Maximum Warranty Period. Device operation and data collection outside of warranty is done at the sole discretion and risk of the customer.