20 Series Transmitters
User Manual

20 Series Transmitters User Manual

Printed in U.S.A.
Issued January 2002

Part Number: 390-0083-001 Revision A

Data Sciences International
4211 Lexington Ave. N. Suite 2244
St. Paul, MN 55126-6164 U.S.A.
Telephone: 1(651) 481-7400
Fax: 1 (651) 481-7404

www.datasci.com

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Functional Specifications

All statements about transmitter accuracy assume data is collected using the Dataquest system software, an OpenART partner system, UA10 Universal Analog adaptor, or another approved analog adapter that uses factory or custom calibrations. Transmitters may contain recycled electronic components. Recycled components must pass the same final inspection and tests as new components.

TX FCC ID MHA20DSI
These devices comply with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must except any interference that my cause undesired operation.

Caution
Changes or modifications not expressly approved by the party responsible for compliance could void the users authority to operate the equipment.

PA-C20

General Specifications	
Parameters measured	Pressure and physical activity
Outer material	Silicone elastomer
Nominal weight	3.9 g
Temperature operating range	
Operating range	34-41 °C
Exposure range	-20 to 55 °C
Shelf life	
Battery	12 months
Sterility	12 months
Battery life (warranted/nominal)	1.5 months/2 months
Turn-off mechanism	Magnetically activated
Modes available	Off, On
Receiver compatibility	Any PhysioTel receiver except RL1000
Sensor burst pressure	1000 mmHg gauge pressure (sea level) 1750 mmHg absolute
Pressure Measurement Specifications	
Pressure range	-20 to 300 mmHg
Ambient pressure range	670 to 800 mmHg
Maximum altitude above sea level	625 meters*
Bandwidth (3dB, maximum catheter length)	>70 Hz
Initial accuracy	± 3 mmHg
Offset Stability	
First month after implantation	< 5 mmHg
Second month	< 4 mmHg
Third month and after	< 3 mmHg
Scale Stability	
Maximum drift with time	1% of gauge pressure reading per three months
Temperature (37.5 +/-3.5 ° C)	± 1%

*This altitude is based on factory calibration values. Higher altitudes can be accommodated using custom calibration values.

TA-F20

General Specifications	
Parameters measured	Temperature and physical activity
Outer material	Silicone elastomer
Temperature operating range	33-43 °C
Shelf life	
Battery	12 months
Sterility	12 months
Battery life (warranted/nominal)	6 months/9 months
Turn-off mechanism	Magnetically activated
Modes available	Off, On
Receiver compatibility	Any PhysioTel receiver
Temperature Measurement Specifications	
Initial accuracy	0.1 °C
Resolution	0.01 °C
Maximum drift over Warranted battery life	0.05 °C first two weeks on 0.05 °C per 6 months thereafter

EA-F20/ETA-F20

General Specifications	
Parameters measured	
EA-F20	Biopotential and physical activity
ETA-F20	Biopotential, temperature, and physical activity
Outer material	Silicone elastomer
Temperature operating range	33-40 °C
Shelf life	
Battery	12 months
Sterility	12 months
Battery life (warranted/nominal)	
EA-F20	4 months/6 months
ETA-F20	4 months/6 months
Turn-off mechanism	Magnetically activated
Modes available	Off, On
Receiver compatibility	Any PhysioTel receiver
Biopotential Measurement Specifications	
Input impedance	≥ 300 kOhm
Maximum recommended electrode Impedance	15 kOhm
Bandwidth (3 dB points)	1-200 Hz with factory calibrations 1-100 Hz (receiver analog output)
Maximum peak input voltage	2.5 mV
Maximum noise floor	10 μV peak-to-peak
System gain stability	± 5% over warranted battery life
Temperature Measurement Specifications	
Initial accuracy	0.1 °C
Resolution	0.01 °C
Maximum drift over Warranted battery life	0.1 °C first two weeks on 0.05 °C thereafter

Device Operation

All 20 series transmitters have two operational modes: On and Off. Transmitters are shipped in the Off mode, with the batteries not activated. When switched to the On mode, the transmitters begin to sense and transmit data. The switch to change modes is magnetically activated.
All transmitters should be turned on 24 hours before use to allow the electronics to stabilize. The data from the transmitters may not be completely accurate until this has occurred. For pressure implants, this can have an effect on the pressure offset measurement; please see the section "Checking Accuracy Prior to Implantation" for more information. For details on switching operational modes, please refer to the appropriate section of your surgical manual.

Storage of Transmitters

It is crucial that the transmitters be stored properly to avoid damage to the transmitter or unnecessary loss of battery life. These instructions include the proper storage technique for both new and resterilized transmitters.
All transmitters should be carefully examined when they arrive at your facility. Remove the packages containing the transmitters from the shipping boxes. Save the shipping boxes and foam liners for returning used transmitters. Inspect the transmitter package for signs of damage. Using your AM radio, confirm that the transmitter is turned off. Although each unit is checked just before shipping, it is possible that the transmitter may have been exposed to stray magnetic fields during shipment. This can cause the unit to be turned on unintentionally. New and refurbished units are sterile upon arrival. If the package remains undamaged, this sterility is warranted according to the information on the package label. Transmitters in the Off mode may lose up to 10% of the battery life within 12 months after the manufacture date.
The transmitters should be stored in a cool (between 10 and 25 degrees Celsius), dry area away from exposure to static discharge and magnetic fields. They should never be exposed 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. Storage in a refrigerator does not provide significant benefit in terms of battery life. If the implants are to be stored for an extended period of time, Data Sciences recommends periodic checks with an AM radio to ensure the transmitters are still turned off.
The transmitters should be turned on 24 hours before use to allow the electronics to stabilize. Zero offset should be checked on all pressure transmitters just prior to use to verify stability.

Storage of Resterilized Transmitters

Data Sciences supports a method for on-site resterilization of transmitters. For transmitters used in short-term studies, this allows multiple uses from a single unit before it is necessary to return it to Data Sciences for refurbishment. This provides convenience for the investigator as well as reducing the overall cost of the transmitters. Occasionally there may be a delay between when the unit is removed from the first animal and the next implantation. Proper storage of the resterilized transmitter is necessary to assure that the unit will perform normally. Following explantation, each transmitter should be thoroughly cleaned and resterilized according to Data Sciences' resterilization procedure (please see the section on resterilization). Using your AM radio, each transmitter should be checked to assure that it is properly turned off before storage. If the original transmitter package was saved, place the transmitter into the plastic packaging. This will help to identify the transmitter and the calibration values associated with it. There is no effective way to maintain unit sterility during storage, therefore each unit will require sterilization again at the time of use. Sterilization prior to storage is necessary to prevent spread of bacteria during handling.

Handling of Pressure Transmitters

When measuring blood pressure telemetrically, it is essential to verify that the measurements are accurate, since a small percentage of these devices exhibit long-term drift. Verification can be done in a variety of ways, including pressure chambers, arterial cannulation, comparison to a mercury manometer, etc. Arterial cannulation is normally used only if it is necessary to check the accuracy of the device at a time other than at implantation or explantation. For most protocols this is not necessary. Since those devices that exhibit long-term drift while implanted almost always drift toward lower pressure, validation of accuracy at implantation and explantation can provide a simple and reliable method for assuring that the measurements obtained during the course of the study are accurate. The following procedure will determine if the pressure transmitter is reading zero prior to implantation or if there is a deviation (zero offset).

Checking Accuracy Prior to Implantation

All Data Sciences transmitters are carefully calibrated and tested prior to being shipped to the customer. However, we strongly recommend that all pressure devices be checked again immediately prior to surgery. The following protocol will allow you to verify that the pressure transmitter is functioning normally prior to surgical placement in an animal.

To check offset, turn the transmitter on approximately 24 hours prior to surgery. This will allow the electronics time to stabilize. The calibration information from each transmitter should be entered into the Configuration Program of Dataquest and each transmitter should be assigned to a receiver. It is important that the Dataquest Acquisition Program be running and that at least one ambient pressure sample is recorded prior to checking zero offsets.

Just prior to surgery the transmitter should be placed on its assigned receiver in the sterile pack. It is very important that the catheter tip be level with the body of the transmitter. If the catheter is above or below the level of the transmitter body, the measured values will be affected by this "head pressure" and will not be accurate. Usually, if the transmitter is checked while it is still in the sterile pack, the unit is held in the proper position for zero offset.

The value being measured by the transmitter can now be visualized using Waveform Trace in the Acquisition Program. By right-clicking the mouse you can select tracking. This will bring up a dialogue box that shows x values and y values. By moving the mouse on the waveform, you will be able to see where the offset lies. For units manufactured within the previous three months, this value should be within 3 mmHg of zero to comply with manufacturer specifications. Units older than three months may experience a larger offset. If desired, right clicking the mouse and selecting Print can make a hard copy of a trace. This should be kept with the lab data for the project as verification of initial accuracy. Another accuracy verification option is to collect the pressure "waveform" or offset in the same way you would sample from the animal, using the Save and Trace option in the Acquisition Program. This procedure would save the pressure offset data in the same file with the animal's data, permanently associating the offset value to the animal.

If the value of offset is outside ±3mmHg, contact your Data Sciences Service Representative for further instructions. If your transmitters have been on the shelf for an extended period of time and they have an unacceptable zero offset, it may be possible to adjust calibration values to compensate for the offset. If you are routinely experiencing offsets prior to implantation greater than ±1.5 mmHg, your ambient pressure monitor (APR-1) may require recalibration.

If your experimental protocol or quality standards (such as FDA GLP) require that transmitter accuracy be checked more thoroughly, we recommend placing the transmitter in a chamber that can be pressurized using a mercury manometer and verifying the accuracy of the device at several pressures (e.g., 0, 100, and 200 mmHg). Such a chamber can be fabricated by your mechanical shop or purchased from Data Sciences.

Checking Accuracy at Explantation

It is also valuable to check the zero offset of the transmitter at the end of the experiment. If the device was accurate prior to implantation and at explantation, it is safe to assume that the measurements were also accurate in between. To do a post implantation offset, the transmitter should be carefully removed from the animal. If it is necessary to cut the catheter, this should be ONLY done using a new scalpel blade at a 45° angle to the catheter. Using scissors to cut the catheter will ruin the sensor.

Gently clean the catheter to remove any blood or tissue debris from the tip. It is essential that the temperature of the transmitter be stable while the offset is checked. This can be done by placing it in a beaker of 37° Celsius water immediately upon removal from the animal. The water in the beaker should be just barely deep enough to cover the body of the implant to avoid any affect of head pressure on the offset measurement. Alternately, the transmitter may be left at room temperature for 1 to 2 hours, but maintaining the temperature close to 37° is preferable.
Once the temperature of the transmitter has stabilized, the unit should be placed on its receiver and the value recorded as described above. The manufacturer specification for electronic drift is less than 5 mmHg per month. Generally speaking, however, transmitters show much less than the specified drift. If you are experiencing excessive drift, please contact your Data Sciences Service Representative for assistance.
By checking the zero offset before and after implantation, you can be confident that the data being collected are accurate. If accuracy needs to be verified during the experiment, there are various methods for achieving this. Contact Data Sciences for more information on these techniques.

Regelling the PA-C20

Because of the small diameter of the catheter tip, these units are particularly difficult to reuse in the event that the first implantation is not successful. As with the rat-sized transmitters, try to insert as much of the catheter into the vessel as possible. This will allow it to be reused by leaving the residual glue outside of the vessel with each successive use. Cleaning the tip of the catheter and replacing lost gel is somewhat more difficult with the PA-C20. However, the following guidelines will greatly increase your success with this procedure.
The tip of the catheter will probably need to be re-gelled in the event that the animal dies while the transmitter is still implanted. When the transmitter cools from body temperature to ambient temperature while the catheter tip is still in the blood stream, the fluid in the catheter recedes due to thermal expansion and typically blood products are drawn into catheter tip. The most important factor in removing this material is to flush it out before it solidifies. A stream of warm saline from a syringe can be used to gently flush debris out of the catheter tip prior to regelling.
Make sure the transmitter is turned on and you have your AM radio close by. This allows you to audibly monitor the amount of pressure you are exerting during the procedure. Expel a small amount of gel before entering the catheter tip to prevent introduction of air bubbles into the catheter tip. With the radio turned on to monitor applied pressure, carefully insert the tip of the gel syringe into the lumen of the catheter tip past the foreign material. Be sure not to insert the gel syringe tip beyond the interface of the distal gel plug and the catheter fluid. This interface is sometimes difficult to see, but the gel plug never extends beyond 1.5 mm from the distal tip of the catheter.
With the gel syringe in place, firmly apply pressure to the plunger of the syringe, which will back-fill the catheter tip and slowly force the foreign material out the distal tip. Don't rush this procedure, it is a slow process due to the viscosity of the gel and the small ID of the syringe needle.
In the event that you are unable to remove all foreign material from the catheter tip using the above method, there is a more risky maneuver. *If performed incorrectly, excessive pressure can be applied to the internal pressure sensor and destroy the transmitter! Do not attempt this procedure without monitoring applied pressure with an AM radio!*
As a last resort, you can gently squeeze the catheter tip with clean, gloved, fingers to expel contaminants from the distal end. Start by grasping the stem material at the proximal aspect of the thin walled section. Pressure can then be progressively applied in a proximal to distal direction. This motion will expel tip contents without applying excessive pressure to the transmitter. The pitch emitted by the transmitter will change is you squeeze the catheter; if the pitch is changing rapidly, relax your grip on the catheter and proceed more slowly. The expelled material can be wiped away with wet gauze. Before releasing the pressure, apply a drop of gel to the distal tip and allow the gel to be drawn into the catheter tip as finger pressure is slowly released. Gently clean the tip and sterilize the transmitter for implantation.
The gel is sterile, but the syringe tip may become contaminated after use. The gel syringe may be reused by expelling a small amount of gel, then disinfecting the tip.

Precautions Against Blown Sensors

The pressure sensors in Data Sciences' blood pressure implants are extremely sensitive; and can be easily damaged. Therefore, it is necessary to use proper care when handling the transmitters. Here are some preventative measures to take when handling the blood pressure transmitters to reduce the possibility of a blown sensor.

Handle the device with care and make sure not to drop it.

Try not to produce any situations whereby more than 20 lbs per square inch of gauge pressure (approx. 1000 mmHg) are applied to the sensor.

Take care to grasp the catheter with a proper tool so that the lumen of the catheter does not collapse. Data Sciences recommends the use of vessel cannulation forceps.

If it is necessary to cut the catheter, do not use a pair of scissors. Catheters should always be cut with a new scalpel blade at a 45° angle at no less than 3cm from the body of the transmitter. Data Sciences recommends removing the entire implant and catheter assembly intact whenever possible to avoid damage.

Make sure to notice where you are gripping the protective tip cover of the catheter. If the protective cover is gripped too close to the catheter, it could collapse the lumen of the catheter. This causes a sharp increase in pressure. Snapping the protective tip cover off can cause a sharp change in pressure as well.

Be sure to monitor the amount of pressure being applied with an AM radio while regelling the implant. For further instructions on regelling, contact Data Sciences Technical Support or see the section on Regelling the PA-C20.

When shipping the transmitters for refurbishment, make sure to properly package the implant to reduce the chance of damage during shipping. Data Sciences recommends using the original shipping container to return the transmitters.

Replacement of a blown pressure sensor may require a fee in addition to the standard implant refurbishment charge.

On-Site Resterilization of Transmitters

This procedure will increase the number of times an investigator can use each transmitter before returning it to Data Sciences for refurbishment, helping to reduce overall costs per study.

Supplies Needed:

1. Bio- or enzymatic detergent
These are available from most hospital supply companies. They are generally labeled for use on fabrics or surgical equipment/instruments; check to be sure they are considered safe for these applications. The purpose of the detergent is to remove blood, serum proteins, and tissue debris from the surface of the transmitter. Some brand names that have been used successfully are: Kleer-o® (Ulmer Pharmaceuticals), Haemo-sol® (Curtin Matheson), Medizyme® (Whitley Chemical), and Terg-A-Zyme® (Alconox, Inc.). If you are unsure that your current enzymatic detergent is safe for use on your transmitters, please contact Data Sciences' Technical Support for assistance.
2. 2% Activated Glutaraldehyde
This is also available from most hospital supply companies. It is considered a chemical disinfectant. It is effective against most agents commonly encountered in a research environment. One commonly found brand is Cidex (Surgikos). Glutaraldehyde is also available in concentrate. This solution can be diluted to 2%. It is important to note that 2% glutaraldehyde is an unstable solution. It has a shelf life of 14 days following activation or dilution.
3. Sterile Saline
Provides a rinse for the sterilized transmitter to remove all traces of the glutaraldehyde prior to implantation. Also can be used to temporarily store (< 4 hours) the transmitter aseptically until surgical implantation. See section on transmitter storage if you need to store the transmitters for longer than a few hours.

TA-F20 Transmitters

Following removal from the animal, the transmitter should be rinsed to remove gross contamination from blood and tissue. The transmitter can then be placed into the enzymatic detergent. The transmitter should be allowed to soak in the detergent for at least 30 minutes to allow breakdown of the surface contaminants. The transmitter should be removed and examined. If traces of blood or tissue remain, use gauze to wipe the surface until it is clean. Rinse the transmitter in tap water thoroughly.
Place the transmitter into fresh 2% activated glutaraldehyde (shelf life of 14 days). The transmitter should be left in the glutaraldehyde for at least 4 hours. For the best results, we recommend overnight (12 hours).
Place the transmitter into sterile saline for 15-30 minutes to rinse away the glutaraldehyde. We recommend at least two separate rinses. Following the final rinse, the transmitter can be left in the saline until ready for implantation.

EA-F20 and ETA-F20 Transmitters

Following removal from the animal, the transmitter should be rinsed to remove gross contamination from blood and tissue. Care should be taken to clean the suture ribs and remove any suture material that may be present. The transmitter can then be placed into the enzymatic detergent. The transmitter should be allowed to soak in the detergent for at least 30 minutes to allow breakdown of the surface contaminants. The transmitter should be removed and examined. If traces of blood or tissue remain, use gauze to wipe the surface until it is clean. Rinse the transmitter in tap water thoroughly. Prior to cold sterilization, use a piece of suture to tie off the ends of the biopotential leads. This will prevent any leakage of the gluteraldehyde into the lead, where it could cause tissue damage in the next implanted animal.
Place the transmitter into fresh 2% activated glutaraldehyde (shelf life 14 days). The transmitter should be left in the glutaraldehyde for at least 4 hours. For the best results, we recommend overnight (12 hours).
Place the transmitter into sterile saline for 30-60 minutes to rinse away the glutaraldehyde. We recommend at least two separate rinses. Following the final rinse, the transmitter can be left in the saline until ready for implantation. Prior to implantation the suture sealing the lead material should be cut off.

PA-C20 Transmitters

Following removal from the animal, the transmitter should be rinsed to remove gross contamination from blood and tissue. Carefully remove any residual tissue adhesive from the surface of the catheter. Remove any suture material present. If there is blood in the tip of the catheter, remove as much as possible by directing a stream of saline at the tip to flush it out. The transmitter can then be placed into the enzymatic detergent. The transmitter should be allowed to soak in the detergent for at least 30 minutes to allow breakdown of the surface contaminants. The transmitter should be removed and examined. If traces of blood or tissue remain, use gauze to wipe the surface until it is clean. The catheter should be wiped very carefully using wet gauze. Do not try to wipe the thin-walled section, however. Rinse the transmitter in tap water thoroughly.
Place the transmitter into fresh 2% activated glutaraldehyde (shelf life of 14 days). The transmitter should be left in the glutaraldehyde for at least 4 hours. For the best results, we recommend overnight (12 hours). Place the transmitter into sterile saline for 15-30 minutes to rinse away the glutaraldehyde. We recommend at least two separate rinses. Following the final rinse, the transmitter can be left in the saline until ready for implantation. The tip of the catheter should be filled with replacement gel at the time of surgery. This should be done aseptically to prevent contamination

Refurbishment of Transmitters

The following instructions are provided to answer any questions you have about returning any items to Data Sciences. If you follow these procedures, we will know the exact reason the products are being returned as soon as they arrive and can begin processing them immediately. Please contact your Data Sciences representative if you have any additional questions.

1) **Explanted transmitters may constitute a biohazard!** To prevent delays, follow cleaning & disinfection instructions carefully.
   a. **Clean explanted transmitter** using an enzymatic detergent to remove **ALL** blood, tissue debris, suture material, etc.
   b. **Soak clean transmitters** in a 2% solution of hospital disinfectant such as glutaraldehyde for at least 20 minutes. **Rinse and allow to air dry**.
   c. **Place disinfected transmitters into the zip-lock bag** provided by DSI before shipping as indicated in number five (5) below.
   d. Shipments that have obviously not been cleaned and disinfected will be rejected and sent back to the user at their expense plus a $25 handling fee.

2) **Obtain a purchase order** prior to returning the goods. Many companies and institutions will issue blanket purchase orders that will cover several shipments. One of the most common reasons for delays in returning devices is the lack of a purchase order. Having a blanket purchase order will save you time and the difficulty of having to obtain a new purchase order each time you return implants for refurbishment and allow us to serve you better.

3) **Fill in the Returned Materials Form** you received with your implants and fax the form to Data Sciences at (1-651) 481-7404 prior to returning any products to us for refurbishment, repair, or return of items on loan. A copy of the RMA form **MUST** accompany your shipment.

4) **Please indicate** on the RMA form the serial number of any device that exhibited performance problems and the type of problems you noticed. Please also identify any products that had been loaned to you.

5) **Pack the products carefully** for return shipment in the foam-lined box you received with your implants. Place implants in the original package or in the zip-lock bags provided in the RMA kit you received with your implants. Please do not place implants alone in a box full of packing material since small implants can easily be lost. Place the zip-lock bags or packaged implants in a box with adequate packing material to prevent

damage during shipment. Return your products to the USA shipping address listed on the RMA form. **Include your name, Customer Service Number and telephone number on the RMA form.** Check the contents of the box to assure that it matches the information you provided on the RMA form.

6) **Make a copy of the RMA form** for your own records, and put the original in the pouch on the zip-lock bag with the goods being returned.

Benefits of Refurbishment During Warranty Period

When an implant is refurbished, the warranty period for that implant is automatically renewed. This renewal warrants all F-series and C-series transmitters for an additional 18 months from the time of refurbishment. Transmitter circuitry is typically not repairable. If a transmitter is returned for refurbishment *within the warranty period* and fails to perform within specification, it is replaced with a new unit. If a transmitter is returned *outside of the warranty period* and does not pass our quality assurance tests the transmitter cannot be refurbished. The transmitter can, however, be replaced by purchasing a new unit. Replacement of damaged sensors incurs a charge that is in addition to normal refurbishment charges.