Tami™

Trans-air method of investigation

Instructions for Use

Device Description

The Tami Trans-Air Method of Investigation is a wireless urodynamic measurement system that receives signals from T-DOC® Air-Charged Urodynamic Catheters and transmits them to the urodynamic equipment.

This wireless telemetry system consists of a battery-operated (rechargeable) portable transmitter, a stationary receiver with connector cables, and a battery charger. These components work together to record accurate urodynamic pressures without water and without wires.

Because it is wireless, TAMI facilitates mobility, including standing and ambulatory studies, allowing the patient to sit, stand, walk or heel bounce without concerns of transducer location, rectal balloon adjustments or artifact, or excessive instrumentation.

Indications

For use in urodynamic recording studies.

T-DOC® AIR-CHARGED CATHETERS

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Urodynamic Procedure

Study Preparation

Connect receiver cables to urodynamic equipment.
Check that the cables are connected in proper order, aligning the numbers on the cable with the corresponding receiver port. (See Figure 1)

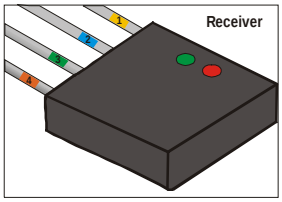


Figure 1

Check TAMI rechargeable battery.
Press the blue button on the portable transmitter once. If a green blinking light is observed, the battery power is adequate. If a red light is observed, the battery needs to be recharged. (See Figure 2)

Figure 2

Recharge TAMI battery (when necessary).
Attach battery charger connector to the side of the portable transmitter. Then, plug the battery charger into an electrical outlet. When the green light is lit without blinking, the battery is recharged. (See Figure 3) **Note:** TAMI cannot be used when charging.

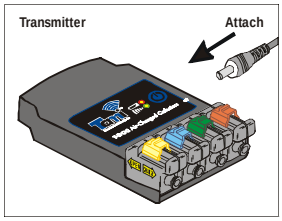


Figure 3

Equipment Check and Setup

Check receiver signal.
Check the receiver signal by pressing the blue button on the portable transmitter once to get a green blinking light. Then, observe the lights on the stationary receiver connected to the monitoring system.

A green light blinking three times means a strong signal. A green light blinking two times means a medium signal. A green light blinking once means a weak signal. A red light means no signal. A green blinking light, quickly followed by a red light means another transmission device might be interfering. (See Figures 1 & 2)

Attach catheter(s).
Attach the catheter(s) to the portable transmitter by twisting the colored luer cap(s) onto the transducer connector of the same color. Be sure to completely tighten the luer fittings. (See Figure 4)

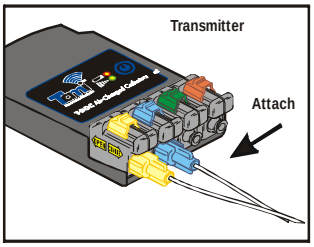


Figure 4

2.

Procedure

Attach EMG wire assembly (optional).
If recording EMG signals, connect EMG wire assembly to transmitter. Attach electrodes to the EMG wires and position on patient. (See Figure 5)

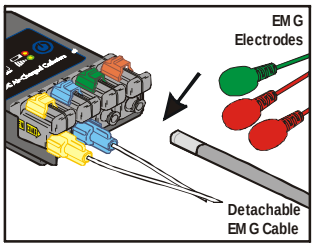


Figure 5

Insert catheter(s).
Place cable neck holder around the patient's neck. Insert the catheter(s) and perform the procedure according to hospital protocol.

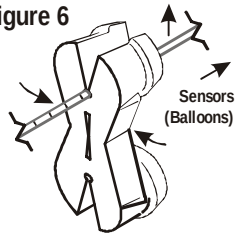
When the procedure is complete, uncharge the sensor(s) by sliding the colored switch(es)to the open position on the portable transmitter. Remove catheter(s) and discard.

Turn off Portable Transmitter after use.
Turn off portable transmitter by holding down the blue button for 5 seconds until the green LED light stops blinking.

System Calibration

Calibration is recommended before initial use of TAMI system and/or when transducer cables are changed.

Figure 6



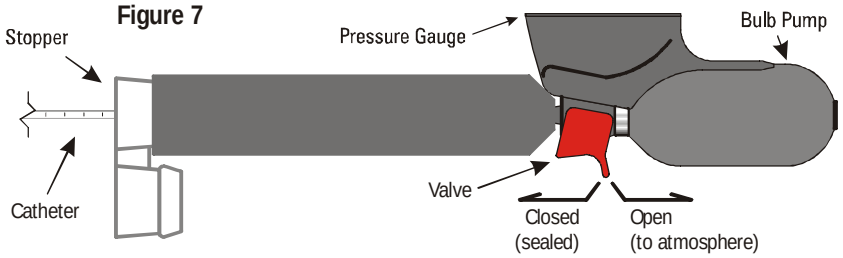
Calibrate catheter to system as follows:

Attach catheter(s) to transmitter.

Remove stopper from the end of calibrator, open stopper by pinching tabs, place catheter in slot with sensor(s) below the stopper, and release tabs. (See Figure 6)

Insert catheter into the calibrator until each sensor is inside, and then seal calibrator by pushing stopper into the end of the tube. (See Figure 7)

Figure 7



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Charge calibrator to pressure above 50 cmH20 by pumping bulb with valve closed. Adjust pressure by lightly pulling back on valve. (See Figure 8)

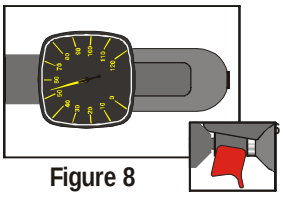

Figure 8

Charge sensor(s) by sliding the colored transducer switch(es) forward on the portable transmitter. (See Figure 9)

Calibrate according to the urodynamic equipment manufacturer's instructions.

Release pressure from calibrator by pulling valve back until it snaps into place, and remove stopper from calibrator.

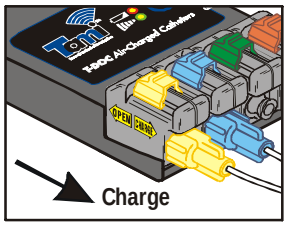

Figure 9

INSTRUCTION TO THE USER

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

* Reorient or relocate the receiving antenna.
* Increase the separation between the equipment and receiver.
* Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
* Consult the dealer or an experienced radio/TV technician for help.

This equipment has been certified to comply with the limits for a class B computing device, pursuant to FCC Rules. In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception. The user is cautioned that changes and modifications made to the equipment without the approval of manufacturer could void the user's authority to operate this equipment.

This Class B digital apparatus meets all of the Canadian Interference-Causing Equipment Regulations.

This device complies with Part 15 of the FCC Rules.
Operation is subject to the following two conditions:
(1) This device may not cause harmful interference and
(2) this device must accept any interference received, including interference that may cause undesired operation.

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