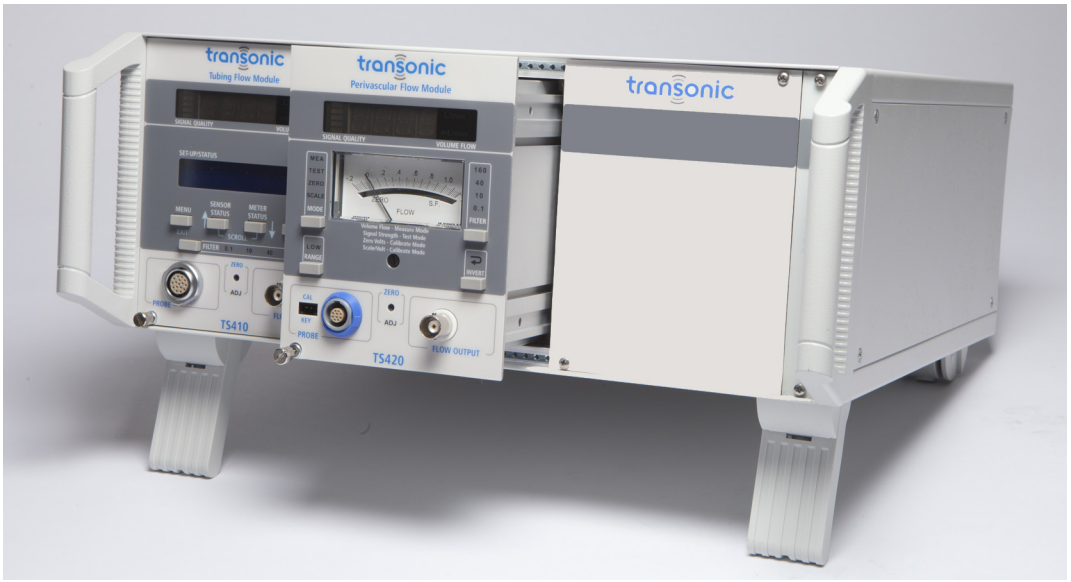
OPERATOR'S MANUAL



Transonic® 400-Series Consoles & Modules For Research Use

Models:

Consoles: T402, T403
Modules: TS410, TS420 & SP430

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THE MEASURE OF BETTER RESULTS.

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CE

AU-OPR-400Ser-EN, Rev D Last Updated 12/22/17

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Warnings & Precautions

√ Read this manual before use. Failure to follow the instructions and the Warnings and Precautions below may result in risk of fire or electric shock.

√ Research Consoles & Modules

- Transonic® Research Consoles and Modules, and compatible Probes, Sensors, Transducers and Catheters are designed only for investigative use with animals and are not for use in humans. Contact Transonic Systems Inc.® for alternative products for human use applications.
- Safe and effective use of the Transonic® Console with Flow Module(s) and/or Pressure Amplifier Module(s) depends on correct application technique, adequate precaution and readiness for emergencies. Prevent liquids and vapors from entering the device.
- The instrument Console and/or Modules are fragile electric equipment. They must be transported and stored at temperatures between -20°C to +60°C with humidity between 0 - 90% RH non-condensing. Rated altitude: 2000 meters. Operational temperatures must be between 0°C to +40°C with humidity between 20 - 90% RH non-condensing.

√ Perivascular Flowprobes

- Transonic® Perivascular Flowprobes are designed for acute use and/or chronic implantation in animals. Excessive vessel manipulation or constrictive Flowprobe fit may cause vessel spasm or damage and thus should be avoided.
- Recalibration of the Flowprobe is necessary if the Flowprobe is to be used at a different temperature or on a liquid other than the one for which it was calibrated.

√ Tubing Flowsensors

- Transonic® Flowsensors are designed for laboratory use only.
- Transonic® Tubing Flowsensors are designed for measuring non-aerated liquid flow in tubing and should not be applied to blood vessels or other internal ducts. They should be used only on tubings and for liquids for which they were calibrated.
- Tubing Flowsensors are not designed to measure non-liquid (gaseous) fluid flow.
- Clamp-on Flowsensors are not designed to measure liquid flow in metal or hard plastic pipes. Clamp-on Flowsensors should not be immersed in liquids for extended periods of time.
- Factory or on-site recalibration of Tubing Flowsensors is necessary if the Flowsensor is to be used on a different tubing, liquid or temperature other than for which it was calibrated.

√ Pressure Transducers

- Pressure Transducers compatible for use with the SP430 Transonic Scisense Pressure Amplifier Module must be used according to manufacturers' instructions and are only intended for use with animals or in laboratory models when connected to a SP430 Pressure Amplifier Module in a 400-Series Console, regardless of individual Pressure Transducer classification.
- Transonic Scisense Pressure Catheters contain metal and are not compatible with MRI.

√ Safe Electrical Use

- Use only with grounded power receptacle to reduce risk of shock.
- Position instrument so that rear panel switch and plug are accessible for quick disconnect.
- Install only Transonic® manufactured Modules in 400-Series Consoles. Do not use with alternative power supplies.
- Do not turn on Console unless Modules are installed and panel covers are in place for empty bays.
- Do not remove or replace Modules in the Console with power turned on.
- Keep flammable liquids and vapors away from the Console and Modules. They may cause a fire in the instrument.
- All repair on Consoles or Modules must be performed by qualified electrical technicians authorized by Transonic Systems Inc.®

√ For a list of possible warning symbols please refer to "Appendix C: Symbols & Signs"

I. Introduction

NOTE: In this manual, "Consoles" refer to T402 & T403 Multi-channel Consoles.
NOTE: "Modules" refer to the TS420 Perivascular Flow Modules, TS410 Tubing Flow Modules & SP430 Transonic Scisense Pressure Amplifier Modules.
NOTE: In this manual, "Probe" and "Flowprobe" refer to Transonic® Precision Perivascular Flowprobes.
NOTE: "Sensor" and "Flowsensor" refer to Transonic® Clamp-on and Inline Tubing Flowsensors.
NOTE: "Transducers" refer to Pressure Transducers including Transonic Scisense Pressure Catheters and/or Transpac® IV Pressure Transducers. "Catheters" refer to Transonic Scisense Pressure Catheters.

Mix and match the measurement capabilities you need in a single instrumentation Console. T402 and T403 line cord powered Consoles are multi-channel capacity cases with a shared universal power supply and back-panel analog outputs compatible with most data acquisition systems. The T402 and T403 Consoles accept any 400-Series Modules:

- TS420 Perivascular Flow Module: for in vivo arterial/ venous blood flow
- TS410 Tubing Flow Module: for volume flow of fluid in tubing
- SP430 Transonic Scisense Pressure Amplifier Module: for arterial/venous blood pressure

BOTH A CONSOLE AND A MODULE ARE REQUIRED TO TAKE MEASUREMENTS.

Fig. 1.1: T403 Console with TS410 Tubing Flow Module, TS420 Perivascular Flow Module and SP430 Transonic Scisense Pressure Amp

II. T402 & T403 Multi-channel Consoles

All 400-Series Consoles are line powered with convenient carrying handles and tiltable front feet. Consoles are not stand alone pieces of equipment; a properly connected, compatible Module is required to make measurements.

A. T402 Multi-Channel Bench-top Console

Four-Bay Console
Holds up to two double-bay wide Modules, one double-bay Module and two single-bay Modules or a combination.

B. T403 Multi-Channel Bench-top Console

Six-Bay Console
Holds up to three double-bay wide Modules, two double-bay Modules and two single-bay Modules or a combination.

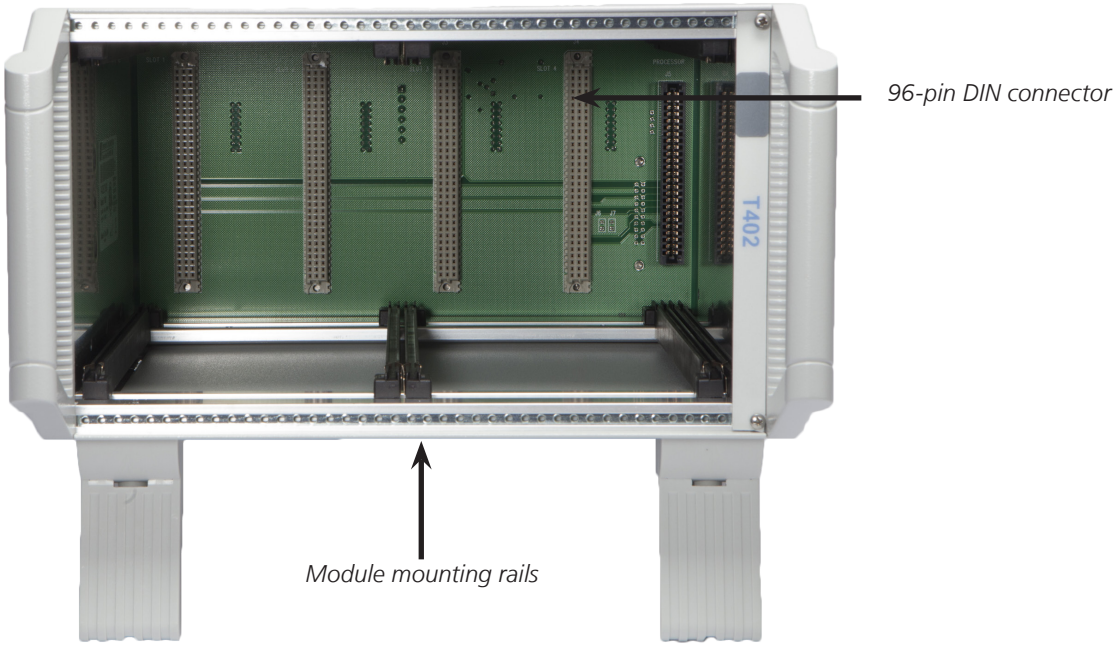


Fig. 2.1: T402 Console without any Modules

C. Console Care

It is recommended to keep all Console bays covered during use and storage. Those bays which are not filled by a Module may be covered with a blank panel cover (available in both single and double width). This will help keep dust and particulates out of the Console.

Turn the power off before cleaning the Console. Exterior surfaces can be cleaned using a cloth or brush dampened with soapy water, followed by damp wiping with clear water. For disinfection, the surface can be damp-wiped with 70% isopropyl alcohol. Do not drip or splash liquids into the Console.

Modules and Consoles exposed to accidental spillage should be unplugged immediately from the power source. Remove the Module(s). If the spilled fluid is potentially corrosive or may leave a residue, carefully wipe the area of the spill in the Console and the outside of the Module cabinets with a damp cloth taking care not to flood the internal electronic boards. Compressed air may be used to blow liquid off components, repeating the rinse and air-blowing as needed.

DO NOT OPERATE THE CONSOLE IN A WET CONDITION; KEEP IT IN A DRY ENVIRONMENT.

i. Consoles: Functions & Controls

B. Back Panel

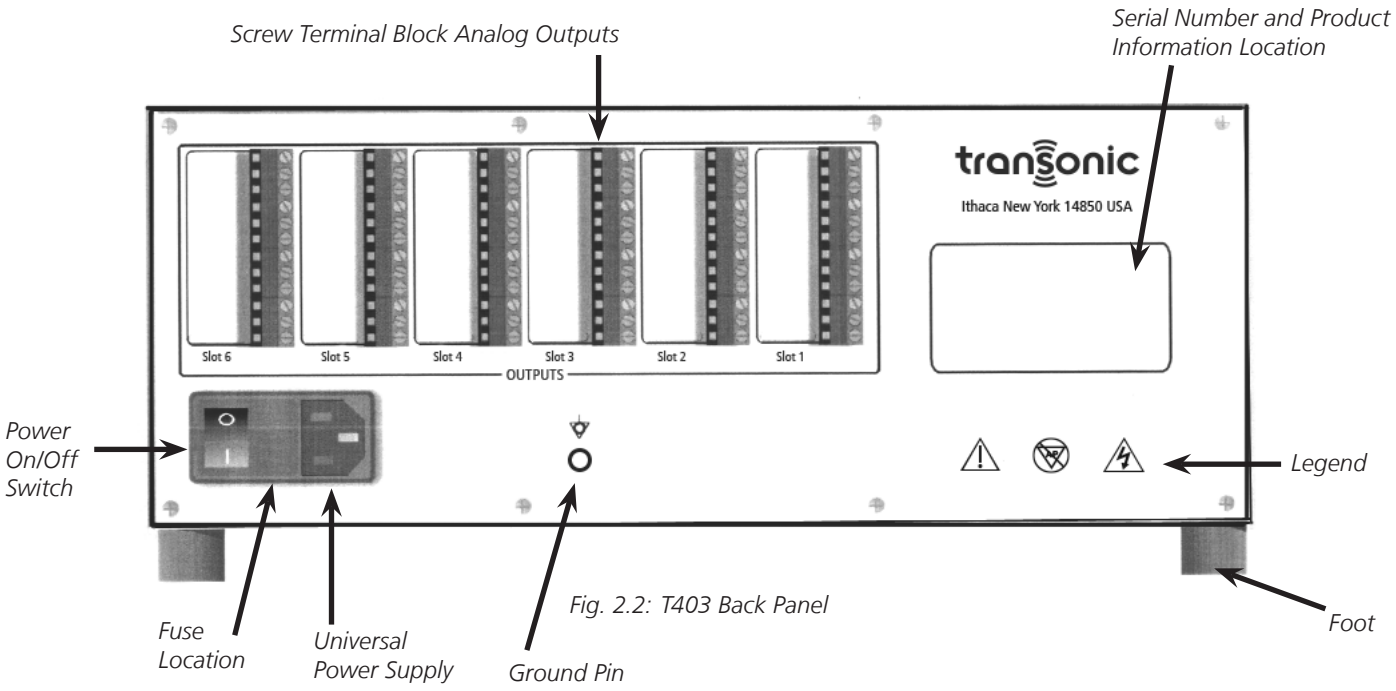


Fig. 2.2: T403 Back Panel

POWER ON/OFF SWITCH
Switch power On & Off for the Console and all connected Modules

FUSES
Two user replaceable fuses are located under a protective cover

SCREW TERMINAL BLOCK ANALOG OUTPUTS
12-screw terminal blocks. Outputs dependent on connected Module. Use general purpose stranded hookup wire to connect terminals with a data acquisition system.
NOTE: Double-bay wide Modules only use odd numbered slots.

CHANGING FUSES

The Universal Power Supply is protected from power surges by two replaceable fuses. These are located on the rear panel of the Console. Should the Console fail to power on, the fuses may need to be replaced.

- With the power cord unplugged, gently pry open the tab side of the black plastic frame to the left of the power switch with a flat screwdriver.
- The cover will open exposing two tabs with arrows. Lift up under the arrow tabs and pull out the fuse holder.
- If the fuses are blown, replace with 0.8 Amp fast blo fuses (Bussman # GMA0.8, 250 VAC).
- If the Console still does not power on, contact your local Transonic® representative.

WARNINGS/ LABELS

- Attention: Consult accompanying documents
- Not category AP equipment
- Dangerous Voltage: Service by trained technicians only
- CE Conformity Mark
- ETL Testing Mark: Electrical Safety Compliance Certification (Intertek 59018)
- Equipotentiality pin: Instrument ground
- RoHS Compliant

iii. Consoles: Specifications

WEIGHT/ SIZE
T402 Four Bay Console

- 5.21" h x 9.25" w x 12" d
- 5.8 lbs

T403 Six Bay Console

- 5.21" h x 13.46" w x 12" d
- 7.6 lbs

Consoles have side panel handles and tiltable front feet for easy viewing

MODULE COMPATIBILITY
Accepts 400-Series Flow and Pressure Amplifier Modules

ELECTRICAL
Console is grounded. If accidentally left ungrounded, line to isolation ground leakage current is less than 50 microamperes.

RoHS COMPLIANT

POWER
AC Input: 100-240 VAC; 50-60 Hz, 50 watts
Fuses: 0.8A fast blo, mfg bussman # GMA0.8, 250 VAC

POWER CORD
USA/Japan: Feller 458-H161 or equivalent
Europe: Feller 199-000 or equivalent
United Kingdom: Feller 209-000 or equivalent
Australia: Feller 198-000 or equivalent

AUDIBLE ALARM
Beeping alarm, non-adjustable volume. Trip level and on/off setting activated through TS410 program.

MODULE CAPACITY

- T402 Four Bay Console: Accepts 2 double-bay, wide Modules of 20 HP width or 4 single bay, narrow Modules of 10 HP width or a combination of wide and narrow Modules.
- T403 Six Bay Console: Accepts 3 double-bay, wide Modules of 20 HP width or 6 single bay, narrow Modules of 10 HP width or a combination of wide and narrow Modules.

CONSOLE TO MODULE CONNECTION
96-pin DIN connector on proprietary backplane. Thumb-screw to lock into front panel.

SIGNAL OUTPUTS
Back panel screw terminal block receives output signals from Module(s) via DIN 96-pin connection with Console; 12 output connections per Module, two dedicated for ground; See Module specifications for signal definition and voltage rating. Use with general purpose hookup wire; stranded wire is preferred.

- Wire: UL 1007 or equivalent; 24 - 14 gauge
- Minimum strip length: 6 mm (0.236 inches)

iv. Consoles: Directions For Use

A. Installing Modules

INSTALL ONLY MODULES THAT ARE COMPATIBLE WITH TRANSONIC'S 400-SERIES CONSOLES.

- Be sure the power on the Console is turned off.
- Align wide Flow Modules (TS410 & TS420) with right and left upper and lower rails.
- Align narrow Modules (SP430 Pressure Amplifier Modules) on either left or right set of upper and lower rails.

ALWAYS PLACE SP430 MODULES IN ONE OF THE BAYS (SLOT 3, 4, 5 OR 6) ON THE RIGHT SIDE OF THE CONSOLE TO ENSURE BEST SIGNAL QUALITY.*

- Slide Module into the Console and push gently on upper and lower portion of the front panel to engage the rear panel 96-pin connector. The Module will click into place so that the Module is slightly recessed in the Console.
- Lock into place by tightening the thumbscrew.
- Cover any empty Module slots with a blank panel cover from Transonic®. Align the cover holes with the console top and bottom horizontal rails and screw into place.

B. Removing Modules

Modules may be removed for transfer to another compatible Transonic® Console or for repair by a qualified electrical technician authorized by Transonic®.

- Turn power off on the back of the Console.
- Loosen the thumbscrew in the lower left corner of the Module until it is un-threaded and free from the Console, but not removed from the Module.
- Pull gently on the screw and BNC connector to disengage the rear panel 96-pin connector.
- Slide the Module out of the Console.
- It is recommended to cover any vacant Console bays with a blank panel cover to protect the Console.

C. Synchronization

The timing of ultrasonic signal bursts for Transonic® Flow Modules and other ultrasonic devices in the same frequency range should be synchronized to avoid interference between multiple Probes/Sensors that are within a 20 cm area. Cross-talk between Probe/Sensor signals causes unpredictable errors in flow measurement such as increases in zero offset and corrupt flow waveforms. No external synchronization is required for the SP430 Pressure Module.

1. SELF-TRIGGERING

   Connect Terminal block pin 11 "Synch Out" to pin 12 "Synch In" via jumper on same terminal block. This gives the lowest flow noise and is selected when a Flow Module runs by itself, or multiple Flowprobes/Flowsensors on multiple Modules run simultaneously with sufficient distance (>20 cm) between Probes/Sensors. **NOTE:** Flow Modules are shipped from the factory in self-trigger mode unless otherwise specified.

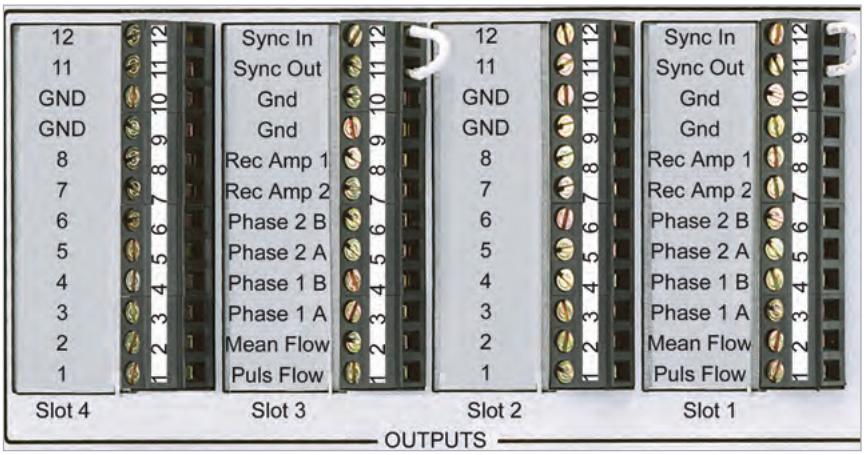


Fig. 2.3: Self-triggering Synchronization

2. SEQUENTIAL TRIGGERING

Interconnect 2 or 3 Flow Modules on the rear panel with jumpers between Modules (pins 11 & 12) from "Synch Out" to "Synch In" as shown (Fig. 2.4) & (Fig. 2.5). This wiring avoids the flow offsets that could result from ultrasonic cross-talk between adjacent Probes/Sensors. **NOTE:** Be careful to choose the active terminal connections that correspond to the installed Modules (TS410 & TS420 use the odd numbered terminal slots).

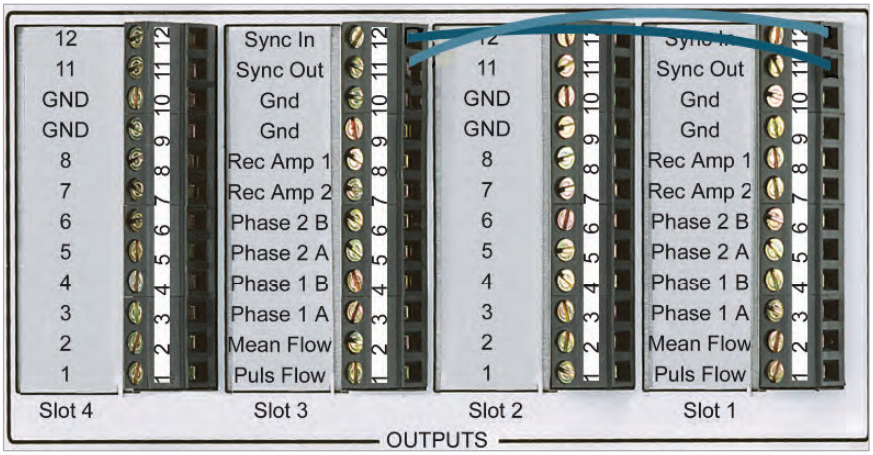


Fig. 2.4: Sequential Triggering with 2 Flow Modules

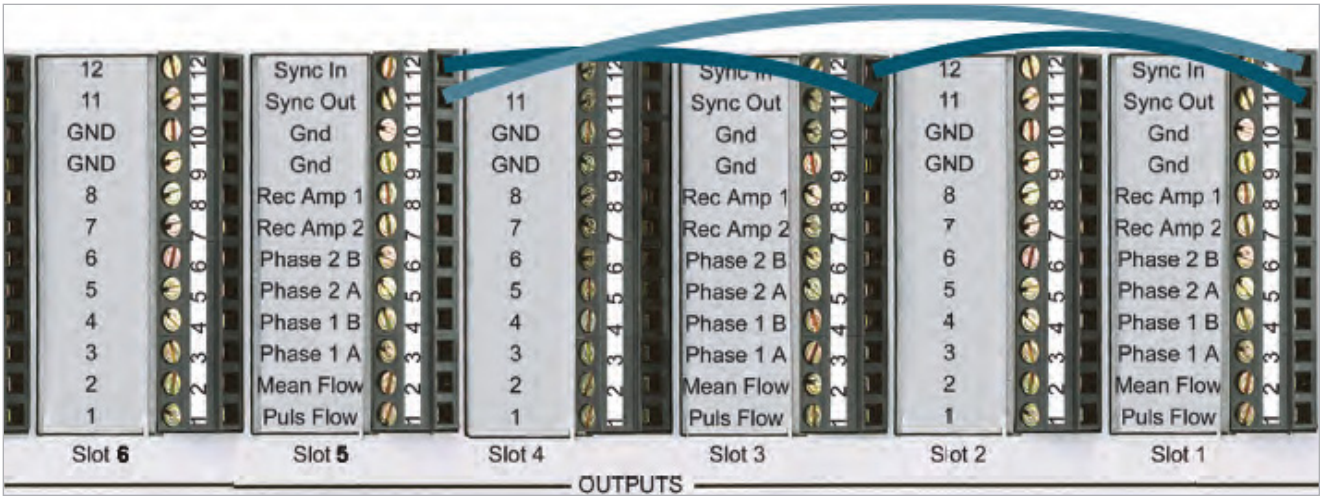


Fig. 2.5: Sequential Triggering with 3 Flow Modules

TEST FOR CROSS TALK

(To determine if Modules require sequential triggering)

- Place Flowprobes on vessels or Flowsensors on tubing as they will be used (when < 20 cm apart).
- Record both average and pulsatile flow from each Probe/Sensor simultaneously.
- Disconnect Probe/Sensor-1 from the Module connector leaving Probe/Sensor-2 in place.
- Observe any changes in average flow value or waveform of Probe/Sensor-2.
- Reconnect Probe/Sensor-1 and continue recording from both Probes/Sensors.
- Disconnect Probe/Sensor-2 from the Module leaving both Probes/Sensors in place.
- Observe any changes in Probe/Sensor-1 average flow value or waveform recording.
- If the following conditions occur, sequential-triggering for the Flow Modules is recommended:
  - Shift in average flow baseline when 2 Probes/Sensors are used together compared with each Probe/Sensor used separately.
  - Erratic flow wave pulses or shifts in baseline when both Probes/Sensors are used together.
  - Unnatural spikes in the waveform.
- Repeat test after sequential jumpers are in place to confirm synchronization (correction of previously determined issue).

III. TS410 Tubing Flow Module

The TS410 Tubing Flow Module measures a single channel of volume flow using ultrasonic transit-time technology. The Module operates both Inline and Clamp-on Flowsensors for measuring volume flow in flexible plastic tubing circuits. The Flowsensors can be calibrated for and used with most non-aerated liquids including but not limited to: blood, saline, water, cell culture, physiological buffers, and blood analogs such as glycerine/water solutions.

The TS410 Module allows the user to select preconfigured calibration options, change the gain to recalibrate the Flowsensor on-site, and set parameters and alarms. Acoustical velocity phase signals are also available for ultrasound dilution measurements.

The TS410 Tubing Flow Module must be properly installed in a compatible 400-Series Console to function. See"Installing Modules" on page 5 for installation instructions.

Fig. 3.1: T403 Console with two TS410 Tubing Flow Modules

A. Compatible Flowsensors

See Tubing Flowsensor flyer (RL-28-fly) for more detailed specifications.

ME-PXL CLAMP-ON TUBING FLOWSENSORS

Easy to operate, clip-on ME-PXL Flowsensors allow for sterility to be maintained in the flow system by attaching to the outside of the tubing while measuring flow within (Fig. 3.2). Sensors are sized by OD in 1/16" increments for tubing between 1/8" and 1-1/4" OD. Metric sizes are also available for metric tubing. PXL-Series Flowsensors can be calibrated and programmed for up to 4 different fluid, temperature, tubing, and flow rate combinations. User must specify calibration parameters at purchase.

ME-PXN INLINE TUBING FLOWSENSORS

Inline Flowsensors splice into the tubing circuit providing high sensitivity and independence from tubing type (Fig. 3.3). Sensors are sized by ID and are available for tubing between 3/64" to 1" ID. PXN Inline Sensors can be calibrated and pre-programmed for up to 4 fluid, temperature, and flow rate combinations. User must specify calibration parameters at purchase.

Fig. 3.2: ME-PXL Clamp-on Tubing Flowsensor on tubing.

Fig. 3.3: Small ME-PXN Inline Tubing Flowsensor with flexible tubing ends

Fig. 3.4: Large ME-PXN Inline Tubing Flowsensor with rigid barbed ends

i. TS410 Module: Functions & Controls

A. Front Panel

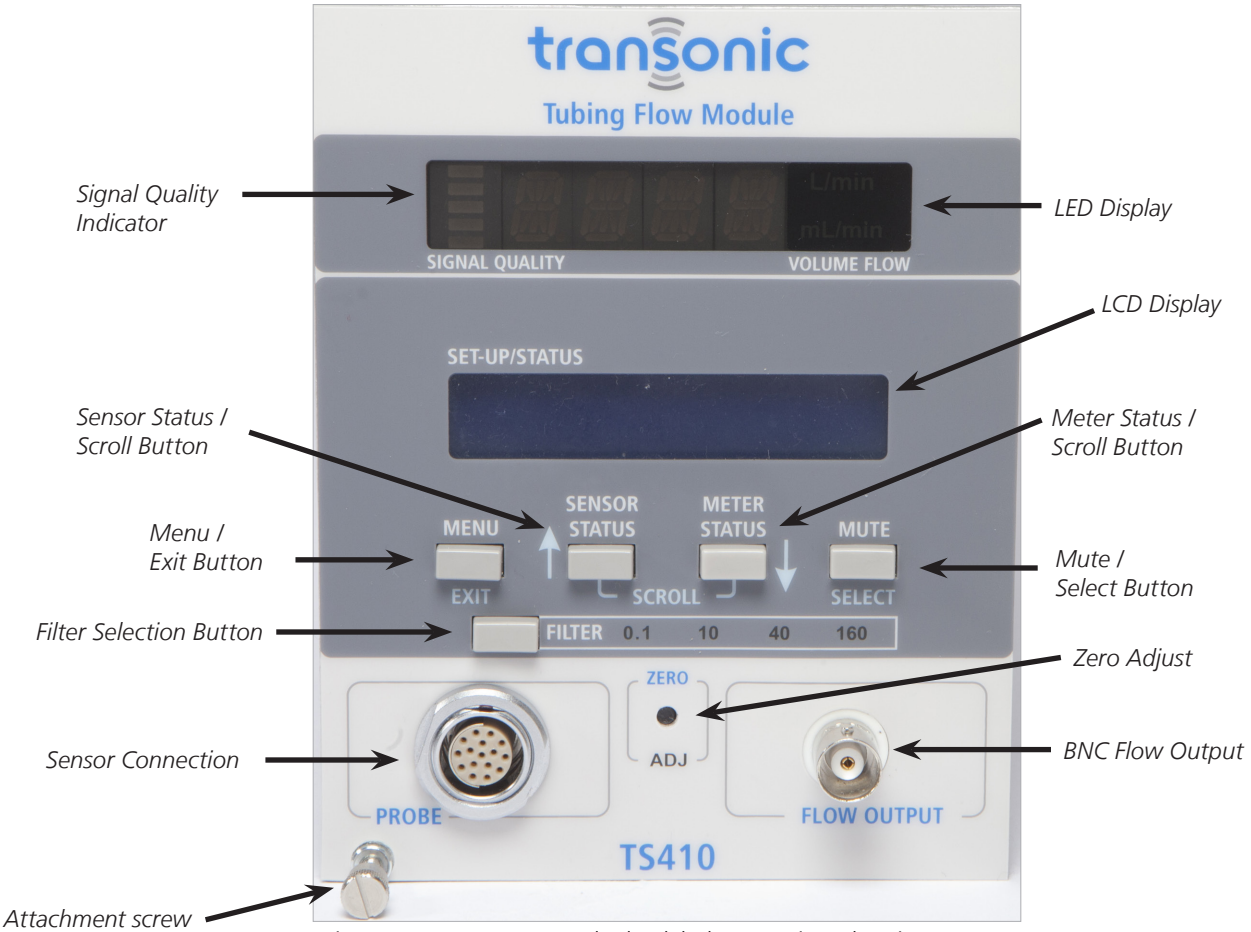


Fig. 3.5: TS410 Front Panel. Blue labels are active when in Menu mode. White labels are active in Measure and Status modes.

MENU/ EXIT BUTTON
Enter or exit Menu mode

SENSOR STATUS / SCROLL ↑ BUTTON
Displays Sensor calibration and gain
Scrolls up when in Menu mode

METER STATUS / SCROLL ↓ BUTTON
Display active Module settings
Scrolls down when in Menu mode

MUTE / SELECT BUTTON
Turns audible alarm on/off
Selects value or enters sub-menu in Menu mode

FILTER SELECTION BUTTON
Sets output filter to 0.1, 10, 40 or 160 Hz

ZERO ADJUST
Adjusts Module to read zero when flow is stopped

PROBE (SENSOR) CONNECTION
Connects Flowsensor or extension cable

BNC FLOW OUTPUT
BNC analog output for mean & pulsatile flow

LED DISPLAY
- Signal quality indicator
- Mean volume flow (mL/min or L/min)

LCD DISPLAY
Module and Sensor settings & Menu mode displays

TS410 Module: Functions & Controls

B. Modes of Operation

MODE	OUTPUTS		
	LCD DISPLAY Front Bottom	LED DISPLAY Front Top	MEAN & PULSATILE FLOW Front BNC/ Rear Analog
MEASURE	Flowsensor model & serial number	Bar indicator of signal quality	Flow = recorded voltage x scale factor
SENSOR STATUS	Flowsensor calibration parameters: Fluid type, temperature, tubing type, tubing dimensions & % gain if adjusted	Average flow in mL/min or L/min	Bidirectional flow output ± 5 V
METER STATUS	Module settings: Invert flow status, 1/4 scale status & active alarm values	Start-up & error messages	
MENU: SENSOR CONTROLS	Select & change calibration & gain		
MENU: METER CONTROLS	Alarm setup		
	1/4 flow scale	Increase flow resolution	Scale factor reduced by 1/4
	Invert	Change sign of flow	Reverse signal polarity
	Calibrate 0 volt scale	0 mL/min	0 V = 0 mL/min
	Calibrate 1 volt scale	Scale factor flow value	1 V = scale factor flow

C. Filter Settings

To record instantaneous flow: set the flow output **[Filter]** to a frequency at least 10 times the rate of flow pulsation. The digital sample rate for data recording should be set to a minimum of 3 times the application frequency.

HEART RATE OR APPLICATION FREQUENCY	LOW PASS FILTER SETTING	RECOMMENDED MINIMUM DIGITAL SAMPLE RATE FOR DATA ACQUISITION
Average Flow Recording	0.1 Hz	0.3 Hz
Pulsatile to 60 beats/minute	10 Hz	30 Hz
Pulsatile to 240 beats/minute	40 Hz	120 Hz
Pulsatile to 960 beats/minute	160 Hz	500 Hz

D. Analog Outputs

Transonic® Flow Modules output analog signals in the range of -5 volts to +5 volts that are compatible with most A/D (analog-to-digital) converters of Data Acquisition Systems. The back panel analog outputs generated by the TS410 Module are listed in the table below:

NUMBER	TERMINAL NAME	VOLTAGE	DESCRIPTION
12	Sync In		In/Out required for operation; Multi-Module synchronization
11	Sync Out		In/Out required for operation; Multi-Module synchronization
10	GND		Ground
9	GND		Ground
8	Rec Amp 1	0 - 4 V	Quality of ultrasound transmission for testing Sensor functionality, acoustic coupling or blockage of ultrasound by air or other impedance mismatch. Can be used in bubble detection by indicating a drop in signal as air passes through the Flowsensor. 2 V = 100%
7	Rec Amp 2	0 - 4 V	Same as Rec Amp 1 for the second pair of transducers. 2 V = 100%
6	Phase 2 B	± 5 V	Same as Phase 2 A but offset by +4.5 V or -4.5 V
5	Phase 2 A	± 5 V	Same as Phase 1 A but for the second pair of transducers
4	Phase 1 B	± 5 V	Same as Phase 1 A but offset by +4.5 V or -4.5 V
3	Phase 1 A	± 5 V	Acoustic velocity of fluid used in ultrasound indicator dilution studies
2	Mean Flow	± 5 V	Average volume flow output, filtered at 0.1 Hz
1	Puls Flow	± 5 V	Instantaneous pulsatile volume flow output, filtered at 10, 40, or 160 Hz depending on the Module front panel **[Filter]** setting. Output defaults to 160 Hz if 0.1 Hz button depressed.

All PXN and PXL Sensors have two pairs of transducers. Flow data is determined from the combination of both pairs while phase and received amplitude data are separated by transducer pair.

ii. TS410 Module: Specifications

GENERAL FEATURES
Size: 5.125" h x 4" w x 9.062" d
Weight: 2.3 lbs.
Module fits 2 Console bays (20HP) in T402 or T403 Consoles
Power: Derives input power from 400-Series Consoles. Installation in a Console is required.
RoHS compliant

OPERATIONAL TECHNOLOGY
Ultrasonic Transit-time

FLOWSENSOR COMPATIBILITY
ME-PXL-Series & ME-PXN-Series

SENSOR CONNECTOR
Front panel 16-pin connector. Accepts research Inline and Clamp-on Flowsensors and extension cables with male CC16 or CP16 connectors.

AUTOMATIC ADJUSTMENTS
Sensor size identification and corresponding flow output ranges. Volume flow calibration and serial number displayed of active Flowsensor.

LED DIGITAL DISPLAY
4-Digit (14 segment) LED displays Flow / Sensor data / Error Messages
Bar Indicator Light: Displays received signal for continuous monitoring of Sensor signal quality.

LCD DISPLAY
One line 16-character alpha numeric LCD displays program parameters, Sensor and Module status, alarm settings. Default displays Sensor serial number.

SET-UP/STATUS & PROGRAM PARAMETERS
STATUS MODE: (White labels) Status message displayed on LCD.

- Sensor Status: Sensor type & calibration
- Meter Status: Active Flow Module settings & alarm status
- Alarm Mute: Audible alarm on/off toggle

PROGRAM MODE: (Blue labels)

- Sensor Controls: Select pre-programmed factory calibration options; Adjust Flowsensor gain to change calibration on-site.
- 1/4 Flow Scale: Increases flow gain by factor of 4 for low flow measurements.
- Calibrate Scale: Sets output to 0 and 1 Volt to calibrate external recording devices with scale factor flow.
- Invert Flow: Inverts polarity of analog outputs & flow display
- Alarms Menu: 3 level program to select, set thresholds, and activate Alarms for "Low Flow", "High Flow" and "Received Signal" interruption

FILTER PROPERTIES

- 0.1, 10, 40 Hz: 2nd order Butterworth, with a third passive pole at 160 Hz
- 160 Hz: 3rd order Butterworth

ZERO FLOW ADJUST
Recessed momentary push button to zero flow reading at stopped flow.

FLOW OUTPUT
Front panel BNC output connector & rear panel terminal block:

- Pulsatile/Average Volume Flow
- Filtering controlled by front panel selectable filters
- Voltage range: -5 to + 5 volts
- Output resistance: 500 Ohm
- Full Range for Flow: -5 to +5 V (bidirectional flows, with range of 5 times scale factor flow)

AUTOMATIC DIGITAL SENSOR ID & CALIBRATION
TS410 reads operational data (size, scale & calibration) programmed in the Sensor's EPROM.

ULTRASONIC FREQUENCY RANGE
600 KHz to 14.4 MHz; Sensor size dependent

SIGNAL OUTPUTS
8 accessible signals via 400-Series Console's back-panel terminal block: Pulsatile Volume Flow; Mean Volume Flow; Received Signal Amplitude (2); Phase (4)

SYNCHRONIZATION
Rear panel jumpers select synchronization mode

- Self-Triggering Mode: "SYNC IN" to "SYNC OUT" jumper on each Module
- Sequential Triggering Mode: "SYNC IN" crossed to "SYNC OUT" between Modules

iii. TS410 Module: Functional Tests

These functional tests are suggested to acquaint a new user with Transonic® TS410 Flow Modules and Transonic® Tubing Flowsensors and to check for damage incurred during shipment. If the apparatus does not function as described during this initial operation, please call Transonic® customer service or your authorized Transonic® provider or sales representative.

A. Flow Module Set-up

1) Verify that the Console's rear panel synchronization terminals are properly connected (see Console synchronization instructions, page 5).
2) Connect Console power cord to grounded power receptacle. NOTE: Do not operate unless Console is electrically grounded via supplied power cable.
3) Turn on power switch on back panel of Console.
    a) Digital Display will scroll "TSI ✓" and display "NO.PR." The LCD will read "TS410 Flowmeter." Pressing **[Menu]** and **[Status]** buttons will change the LCD display to "No Sensor." NOTE: No parameters may be changed without a connected Sensor.
4) Connect a Tubing Flowsensor to the front panel mounted self-aligning 16-pin connector. The digital display will scroll Sensor size and series and signal coupling status "No Sig." (no signal) until liquid is present in the Flowsensor. The LCD will display Sensor serial number.
    a) When liquid is present in the Flowsensor, the digital display will report average volume flow in milliliters/minute or liters/minute. Acoustic signal quality is displayed by the number of illuminated bars on the digital display and can be continuously monitored for the presence of air, or change in Flowsensor performance.

SIGNAL STRENGTH	SIGNAL QUALITY	BAR DISPLAY	"REC AMP" VOLTAGE FROM REAR PANEL
over 80%	Good	5 bars lit	over 0.8 V
60% to 80%	Good	4 bars lit	proportional reading
30% to 60%	Good	3 bars lit	
20% to 30%	Low	2 bars lit	
10% to 20%	Low	1 bars lit	
under 10%	No Signal	no bars lit	under 0.1 V

B. Flowsensor Zero Offset

1) Connect a Flowsensor to the Tubing Flow Module and insert/clamp-on to the tubing circuit. Allow about 5 minutes for the Sensor to stabilize.
2) Press **[Sensor Status]** to view the active calibration parameters.
    a) If the calibration parameters on the display do not match the system conditions use the **[Menu]** to choose the correct calibration combination. Incorrect calibration parameters may result in a high or unstable zero offset.
3) With the tubing filled with fluid and the flow stopped the flow reading should be zero or close to zero. If there is zero offset, it may be nullified by depressing the **[Zero Adj]** button using a pointed instrument such as the tip of a pen or pencil. The LED Display will flash "Zero Adj" for about 10 seconds and the "Adj" light will be illuminated to indicate that the offset has been adjusted. NOTE: Once the zero offset has been adjusted, it cannot be adjusted again unless the Sensor is disconnected or the Module turned off. Unplugging the Sensor or turning off the Module will cause the zero offset to reset.

C. User Adjusted Gain

The user may adjust the calibration gain if using different fluids, temperatures or variables from the pre-programmed calibrations.

1) Set up the tubing calibration system with the desired parameters.
2) Choose the calibration setting which most closely matches the system setting.
3) Nullify the zero offset as described in “Flowsensor Zero Offset” on page 11.
4) Preform a multi-point calibration to create a calibration curve and determine the % correction required. Flowsensor calibration instructions are found in RL-34-tn.
5) **[Select]** “User Adj Gain” to alter the factory calibration by percent (%) according to the results from the previously performed calibration. NOTE: This new calibration gain will be stored in the Flowsensors EPROM and becomes the default calibration until reset to factory default of 100%. Calibration selections which have user adjusted gains have a % symbol next to them in the “Sensor Controls” menu and a * star indicating that they have been adjusted.

D. Calibrating a Data Acquisition System

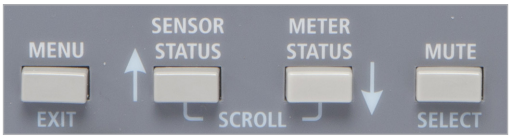
The calibration reference signals are located in the **[Menu]** (see ”Program Menu” on page 13 for Menu setup diagram). **[Select]** “Meter Controls” then **[Scroll]** to “Calibrate Scale” and press **[Select]**. The “0 Volt Scale” and “1 Volt Scale” settings are provided to generate 0 and 1 Volt reference scale signals for calibrating a data acquisition system.

1) Connect the data acquisition system to either the front or rear analog outputs.
2) Follow the data acquisition provider instructions for a 2-point calibration.
3) For reference point “zero” (0 volts), **[Select]** “0 Volt Scale” and record the output voltage. NOTE: A star (*) appear when the signal is active. NOTE: In the “Calibrate Scale” menu either “0 Volt Scale” or “1 Volt Scale” is always active. Exiting the menu deactivates the calibration signal.
4) For reference point “1 volt”, **[Scroll]** to “1 Volt Scale” and press **[Select]** and record the voltage. The value of the 1 volt reference signal is the Sensor scale factor that is displayed on the LED display of the Module. NOTE: The Flow Module can read up to five times the scale factor value.
5) If the scale is changed (Standard Flow vs. 1/4 Scale Flow) during the experiment, the 1 volt reference scale value in the data acquisition system must be reset. The voltage range for the Flow Module remains the same, but the scale factor changes. Repeat the calibration sequence above whenever the flow range setting has been changed.

iv. TS410 Module: Directions For Use

A. Program Menu

Press **[Menu]** to enter the program, this makes the blue button labels active. Use arrows ↑↓ to **[Scroll]** through menus and to set values for alarms and gain (pressing and holding scrolls faster). Press **[Select]** to enter menus or toggle settings on and off. A star (*) indicates that a selection is made/active. Return to Measure mode at any point using the **[Exit]** button.



METER CONTROLS → 1/4 FLOW SCALE *[Select] on**

CALIBRATE SCALE → 0 VOLT SCALE *[Select] on**

TO METER OPTIONS

1 VOLT SCALE *[Select] on**

INVERT FLOW *[Select] on**

ALARMS MENU → LOFLO ALARM → LO FLOW ↑↓ min *[Select] on**

HIFLO ALARM → HI FLOW ↑↓ max *[Select] on**

REC SIG ALARM → THRESHOLD ↑↓ % *[Select] on**

TO METER OPTIONS

SENSOR CONTROLS → "CALIBRATION CHOICES" (Up to 4 factory programmed) → Display selection & select as active calibration

USER ADJ. GAIN → SENSOR GAIN 100% ↑↓ *[Select] on**

B. Alarms Menu

The TS410 has 3 alarm settings: Low Flow, High Flow and Received Signal. Alarm threshold values are set in the Program mode. Use the **[Scroll]** buttons to adjust the threshold from the default value. Default values are scaled by Sensor size. Alarms are turned on/off in the Program mode using **[Select]**. NOTE: A star (*) indicates an alarm is set.

ALL ALARMS TURN OFF AND RESET TO DEFAULT VALUES WHEN SENSOR IS DISCONNECTED OR MODULE TURNED OFF.

When an alarm condition is met, the LCD will flash alarm messages for the specific condition. The LCD will continue to flash until the condition ends. The message will continue to be displayed on the LCD (not flashing) to show that the condition occurred. Clear the LCD by pressing any button. NOTE: The button pressed will also perform its regular function in addition to clearing the LCD screen.

NOTE: The alarm can be re-triggered if the condition is met again without having to reset the alarm in the program mode. If more than one alarm is set and triggered simultaneously (ie low flow and received signal) a joint alarm message is displayed. If more than one alarm is triggered sequentially only the most recent alarm message will be displayed.

If the audible alarm is turned on, an alarm will sound a non adjustable beeping when the condition is met. The audible alarm will stop if the condition ends. Press the **[Mute]** button to disable (or enable) the audible alarm.
NOTE: The mute button is a toggle ON/OFF and must be reset to sound if muted.

LOW FLOW ALARM "LOFLOW"

The low flow alarm is activated when the pulsatile flow signal is lower than the set threshold level. Default value is minimum flow value (negative flow not zero flow) that the Sensor is specified to detect.

HIGH FLOW ALARM "HIFLOW"

The high flow alarm is activated when the pulsatile flow signal is higher than the set threshold level. Default value is maximum flow value (positive flow) that the Sensor is specified to detect.

RECEIVED SIGNAL ALARM "REC SIG ALARM"

The Received Signal Alarm is activated when the acoustic signal falls below the set threshold. This alarm can be used as a gross bubble alarm or detector. The signal amplitude will fall or be interrupted by air or gas bubbles in the flow circuit. Default value is 0%.

C. Use of Clamp-on Flowsensors

SENSOR SELECTION

Flowsensor size and calibration is determined by the OD of the tubing on which it will be used. Each Transonic® Clamp-on Tubing Flowsensor is custom calibrated for use on particular tubing (silicone rubber, latex, polyurethane, or polyvinyl chloride {PVC}). Use on tubing other than specified generally yields inaccurate measurements and may cause erratic zero baseline drift.

SENSOR CALIBRATION

Flowsensors are precalibrated for a particular tubing and liquid at a certain temperature (see Flowsensor's calibration certificate). Recalibration is necessary for accurate measurements at other temperatures or in other liquids. If a more precise zero baseline than that specified is needed, the Module must be zeroed by stopping the flow momentarily.

TS410 Module: Directions For Use

SITE SELECTION

The Flowsensor should be applied on straight tubing segments, about 10X the ID from side branches to produce measurements within its accuracy specifications. The best application site for the Flowsensor is a point well below the highest elevation of the tubing (where gas bubbles might lodge). The Flowsensor will deform the tube slightly. If the tubing site becomes permanently deformed at one clamping position, choose another site to achieve better ultrasonic (acoustic) coupling.

TUBING PREPARATION

Apply a layer of petroleum jelly, or silicone grease over the tubing surface to enable ultrasonic transmission between tube and Sensor. NOTE: Water-based ultrasonic gels should not be used for coupling Clamp-on Tubing Sensors since they dry out and may build up on the transducer faces. This can cause additional offset in the measurement and decrease signal quality.

SENSOR APPLICATION

To apply the Flowsensor to tubing, open the Flowsensor's hinged lid, insert lubricated tubing into the sensing cavity, and close the lid. Fit should be tight, with the full tubing cross section contacting all inner surfaces of the sensing window. Once the tubing is filled with the liquid to be measured, Flowsensor operation and signal quality can be confirmed on the Module. Check that the signal quality bars are illuminated. Low signal quality may indicate that an air or gas bubble is lodged in the tube. Since gas bubbles block ultrasonic transmission, tilt the tubing and Flowsensor vertically before operating the Module to flush any bubbles from the sensing window.

FLOW MEASUREMENTS

If using a data acquisition system, calibrate the system prior to beginning measuring. The digital display presents the average volume flow value in mL/min or L/min. Choose the appropriate **[Filter]** setting for average or pulsatile applications.

INVERT FLOW

The arrow on the Sensor points in the direction of positive flow. If the Sensor is installed backwards the Invert function can change the polarity of the flow outputs without changing the Sensor position. Under the **[Menu]**, **[Select]** "Invert Flow" to change the display and outputs to the correct polarity.

LOW FLOW (1/4 SCALE)

Under the **[Menu]**, **[Select]** "1/4 Flow Scale" to increase the flow gain by a factor of four and increased sensitivity at low flow rates. The maximum value at the low flow scale is five times the 1 volt scale value. Before switching to "1/4 Flow Scale" check to ensure that peak pulsatile flows will not be cut off as this will cause inaccurate readings. NOTE: When changing the flow scale be sure to recalibrate the data acquisition system as the 1 volt scale value will change.

CLEANING & STERILIZATION

A Clamp-on Tubing Sensor may be cleaned by wiping with a solution of soap and water (60°C, 140°F). Because no physical contact is required between the liquid under observation and the Flowsensor, sterilization is not usually necessary. Standard cold (ethylene oxide) gas sterilization may be used (≤ 60°C, 140°F). The sterile-tubing Flowsensor can be damaged by saline immersion or wet storage and should not be boiled, autoclaved, or sterilized by cold liquid sterilization.

D. Use of Inline Flowsensors

SENSOR SELECTION
Flowsensor size is determined by the tubing with which it will be used. Inline Flowsensors are sized based on the ID of the system tubing.

SENSOR CALIBRATION
Flowsensors are precalibrated for a particular liquid at a certain temperature (see Flowsensor's calibration certificate). Recalibration is necessary for accurate measurements at other temperatures or in other liquids. If a more precise zero baseline than that specified is needed, the Module must be zeroed by stopping the flow momentarily.

SITE SELECTION
The Flowsensor should be inserted into straight tubing segments about 10X the ID from side branches to produce measurements within its accuracy specifications. The best application site for the Flowsensor is a point well below the highest elevation of the tubing (where gas bubbles might lodge).

SENSOR APPLICATION
Inline Flowsensors splice into flexible tubing circuits. Larger Sensors (4-25PXN) with barbed ends insert into the tubing. Tubing clamps may be used in high pressure applications to ensure a secure fit. Small Sensors (1-3PXN) with flexible tubing ends may be spliced in using a rigid piece of tubing or expanded over the circuit tubing (see RL-31-tn for PXN installation instructions).

Once the tubing & Sensor are filled with the liquid to be measured, Flowsensor operation and signal quality can be confirmed on the Module. Check that the signal quality bars are illuminated. Low signal quality may indicate that an air or gas bubble is lodged in the Sensor. Since gas bubbles block ultrasonic transmission, tilt the tubing and Flowsensor vertically before operating the Module to flush any bubbles from the sensing window.

FLOW MEASUREMENTS
If using a data acquisition system, calibrate the system prior to beginning measuring. The digital display presents the average volume flow value in mL/min or L/min. Choose the appropriate **[Filter]** setting for average or pulsatile applications.

INVERT FLOW
The arrow on the Sensor points in the direction of positive flow. If the Sensor is installed backwards the Invert function can change the polarity of the flow outputs without changing the Sensor position. Under the **[Menu]**, **[Select]** "Invert Flow" to change the display and outputs to the correct polarity.

LOW FLOW (1/4 SCALE)
Under the **[Menu]**, **[Select]** "1/4 Flow Scale" to increase the flow gain by a factor of four and increased sensitivity at low flow rates. The maximum value at the low flow scale is five times the 1 volt scale value. Before switching to "1/4 Flow Scale" check to ensure that peak pulsatile flows will not be cut off as this will cause inaccurate readings. **NOTE:** When changing the flow scale be sure to recalibrate the data acquisition system as the 1 volt scale value will change.

CLEANING & STERILIZATION
An Inline Tubing Sensor may be cleaned by wiping with a solution of soap and water (60°C, 140°F). The inside of PXN Flowsensors may be cleaned with a soft brush. Care should be taken to avoid scratching the inside surface of the tube. Standard cold (ethylene oxide) gas sterilization may be used (≤ 60°C, 140°F). The tubing Flowsensor can be damaged by wet storage and should not be boiled, autoclaved, or sterilized by cold liquid sterilization. **NOTE:** Do not use alcohol on small (1-3PXN) Flowsensors as it will damage the flexible tubing.

IV. TS420 Perivascular Flow Module

The TS420 Perivascular Flow Module measures a single channel of volume flow using ultrasonic transit-time technology. The Module operates a range of Perivascular Flowprobes for measuring volume flow in arteries, veins and ducts. Probes are available for both acute use and chronic implantation.

The TS420 Perivascular Flow Module must be properly installed in a compatible 400-Series Console to function. See"Installing Modules" on page 5 for installation instructions.

Fig. 4.1: T402 Console with two TS420 Modules and one Flowprobe with extension cable and calibration key

A. Compatible Flowprobes

PS-SERIES INCLUDING NANOPROBES
0.5-20mm Flowprobes with a range of customizable features including cable orientation, reflector style, cable length, connector type and calibration.

PR-SERIES
1 & 1.5mm Flowprobes offer a more robust alterative to the PS-Series Nanoprobes for acute and chronic use.

PAU-SERIES CONFIDENCE FLOWPROBES®
8-36mm COnfidence Flowprobes® come with Ultrafit Liners for acute or chronic use in cardiac output studies.

PMP-SERIES HANDLE PROBES
2-14mm Handle Flowprobes for acute surgical monitoring.

V-SERIES
0.5 & 0.7mm Microcirculation Flowprobes for acute use only for a more robust alternative to the PS-Series Nanoprobes.

Fig. 4.2: PS-Series Flowprobes

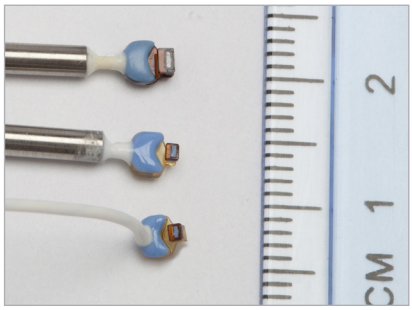


Fig. 4.3: PS-Series Nanoprobes

Fig. 4.4: PR-Series Probes

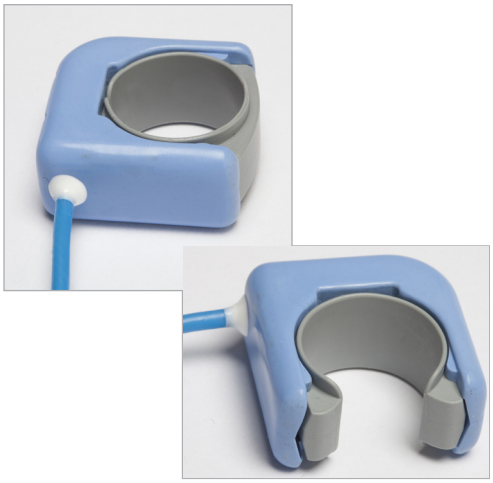


Fig. 4.5: PAU-Series COnfidence Flowprobes® with chronic liner (top) and acute liner (bottom)

Fig. 4.6: PMP-Series Handle Flowprobe

Fig. 4.7: V-Series Flowprobes

i. TS420 Module: Functions & Controls

A. Front Panel

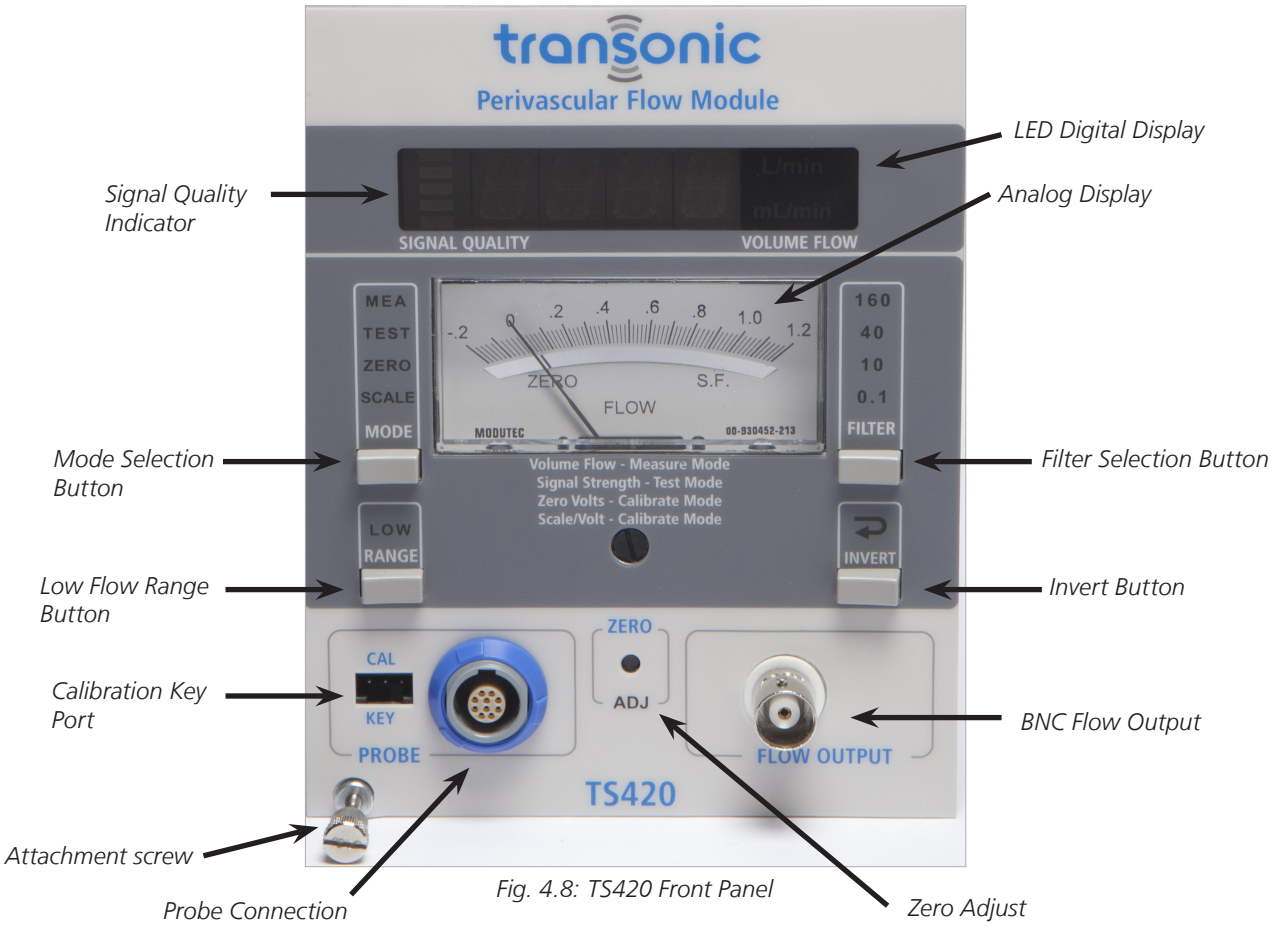


Fig. 4.8: TS420 Front Panel

MODE SELECTION BUTTON
Changes Module between Measure (MEA), Test, Zero and Scale modes

LOW FLOW RANGE BUTTON
Switches between low (1/4) flow and standard flow ranges (changing scale factor & sensitivity)

FILTER SELECTION BUTTON
Sets output filter to 0.1, 10, 40 or 160 Hz

INVERT BUTTON
Changes flow polarity of front panel display and analog outputs

ZERO ADJUST
Adjusts Module to read zero when flow is stopped

PROBE CONNECTION
Connects Flowprobe or extension cable

CALIBRATION KEY PORT
Connects calibration key for use with 4-pin Probes

FLOW OUTPUT
BNC analog output for mean & pulsatile flow

LED DIGITAL DISPLAY
- Signal quality indicator
- Mean volume flow (mL/min or L/min)
- Error messages

ANALOG DISPLAY
Instantaneous flow as a voltage (flow x scale factor)

TS420 Module: Functions & Controls

B. Modes of Operation

MODE	OUTPUTS		
	FRONT DIGITAL DISPLAY	FRONT ANALOG DISPLAY	MEAN & PULSATILE FLOW Front BNC/ Rear Analog
MEASURE	Bar indicator of signal quality Average flow in mL/min or L/min Start-up & error messages	Instantaneous volume flow= flow reading x scale factor	Flow = recorded voltage x scale factor Bidirectional flow output ± 5 V
TEST	Probe size and received signal quality	Proportional value of received signal amplitude 1 V = standard normalized level	
ZERO	0 mL/min	0 V = zero flow (calibration reference)	0 V = 0 mL/min
SCALE	Scale factor flow value	1 V = scale factor flow (calibration reference)	1 V = scale factor flow

C. Filter Settings

To record instantaneous flow: set the flow output **[Filter]** to a frequency at least 10 times the flow pulsation or heart rate. The digital sample rate should be set to a minimum of 3 times the application frequency.

HEART RATE OR APPLICATION FREQUENCY	LOW PASS FILTER SETTING	RECOMMENDED MINIMUM DIGITAL SAMPLE RATE FOR DATA ACQUISITION
Average Flow Recording	0.1 Hz	0.3 Hz
Pulsatile to 60 beats/minute	10 Hz	30 Hz
Pulsatile to 240 beats/minute	40 Hz	120 Hz
Pulsatile to 960 beats/minute	160 Hz	500 Hz

D. Analog Outputs

Transonic® Flow Modules output analog signals in the range of -5 volts to +5 volts that are compatible with most A/D (analog-to-digital) converters of Data Acquisition systems. The back panel analog outputs generated by the TS420 Module are listed in the table below:

NUMBER	TERMINAL NAME	VOLTAGE	DESCRIPTION
12	Sync In	N/A	In/Out Jumper required for operation; Multi-Module synchronization input
11	Sync Out	N/A	In/Out Jumper required for operation; Multi-Module synchronization output
10	GND		Ground
9	GND		Ground
8	Rec Amp 1	0 - 4 V	Quality of ultrasound transmission for testing Probe functionality, acoustic coupling or blockage of ultrasound by air or other impedance mismatch. 2 V = 100%
7	Rec Amp 2	0 - 4 V	Same as Rec Amp 1 for a second pair of transducers. 2 V = 100%
6	Phase 2 B	± 5 V	Same as Phase 2 A but offset by +4.5 V or -4.5 V
5	Phase 2 A	± 5 V	Same as Phase 1 A but for a second pair of transducers
4	Phase 1 B	± 5 V	Same as Phase 1 A but offset by +4.5 V or -4.5 V
3	Phase 1 A	± 5 V	Acoustic velocity of fluid used in ultrasound indicator dilution studies
2	Mean Flow	± 5 V	Average volume flow output, filtered at 0.1 Hz
1	Puls Flow	± 5 V	Instantaneous pulsatile volume flow output, filtered at 10, 40, or 160 Hz depending on the Module front panel **[Filter]** setting. Default to 160 Hz if 0.1 Hz filter is used.

Only PAU-Series Probes have two transducer pairs, all other Probe series have a single pair. For single pair Probes Phase 2 and Rec Amp 2 outputs are identical to Phase 1 and Rec Amp 1 outputs.

E. Calibration (Cal) Keys

The Calibration Keys store Probe specific calibration information normally located in the Probe's EPROM. Probes with small 4-pin connectors do not have a built in EPROM and require the matching Cal Key to function. **NOTE:** Cal Keys are Probe specific and should not be used with Probes other than the one for which they were programmed. Calibration keys will override a Probe connector EPROM if both are present.

ii. TS420 Module: Specifications

GENERAL FEATURES
Size 5.125" h x 4" w x 9.062" d
Weight: 2.2 lbs.
Module fits 2 Console bays (20HP) in T402 or T403
Power: Derives input power from 400-Series Consoles. Installation in a Console is required.
RoHS compliant

OPERATIONAL TECHNOLOGY
Ultrasonic Transit-time

FLOWPROBE COMPATIBILITY
PS-, V-, PR-, PMP- & PAU-Series

PROBE CONNECTOR
Front panel 10-pin connector. Accepts research perivascular Flowprobes and extension cables with male CRA 10-pin connectors. Conversion cables are available for other configurations.

AUTOMATIC ADJUSTMENTS
Probe size identification and corresponding flow output ranges. Volume flow calibration of applied Probe.

DIGITAL DISPLAY
4-Digit (14 segment) LED displays Flow / Probe data / Error Messages
Bar Indicator Light: Displays received signal amplitude for continuous monitoring of Probe signal quality

ANALOG DISPLAY
Taut-band needle (-0.2 volts to +1.2 volts) displays Flow / Received Signal Amplitude/Calibration information

MODE BUTTON CONTROLS
Select modes of operation of displays and outputs

- MEASURE MODE: Displays current volume flow values. Indicator light bar shows received signal strength
- TEST MODE: Displays Probe size & received signal amplitude
- ZERO MODE: Sets outputs to zero vlots to calibrate external recording device
- SCALE MODE: Sets outputs to scale factor flow (1 volt) to calibrate external recording device

FILTER PROPERTIES

- 0.1, 10, 40 Hz: 2nd order Butterworth, with a third passive pole at 160 Hz
- 160 Hz: 3rd order Butterworth

ZERO ADJUST
Recessed momentary push button to zero flow reading at stopped flow

LOW RANGE
Low Range increases flow gain by a factor of 4

INVERT
Invert the polarity of analog flow outputs and flow displays

SIGNAL OUTPUTS
Up to 8 accessible signals via 400-Series Console's back-panel terminal block: Pulsatile Volume Flow; Mean Volume Flow, Received Signal Amplitude (2); Phase (4)

ULTRASONIC FREQUENCY RANGE
600 KHz to 14.4 MHz; Probe size dependent.

FLOW OUTPUT
Front panel mounted BNC output connector & rear panel terminal block:

- Pulsatile/Average Volume Flow
- Filtering controlled by front panel selectable filter
- Voltage range: -5 to + 5 volts
- Output resistance: 500 Ohm
- Full Range for Flow: -5 to +5 V (bidirectional flows, with range of 5 x scale factor flow)

AUTOMATIC DIGITAL PROBE ID & CALIBRATION
TS420 circuitry reads Probe operational data (size, scale & calibration) programmed in the Probe's EPROM.

- Probes with 10 or 12-pin connectors: EPROM installed in the connector.
- 4-pin Probe connectors require separate EPROM calibration key

CAL KEY PORT: Front panel socket accepts 3-pin EPROM calibration keys for Flowprobes with 4-pin connectors. Flow Module reads and uses "CAL KEY" data if both a separate calibration key and connector EPROM are present.

SYNCHRONIZATION
Rear panel jumpers select synchronization mode

- Self-Triggering Mode: "SYNC IN" to "SYNC OUT" jumper on each Module
- Sequential Triggering Mode: "SYNC IN" crossed to "SYNC OUT" between Modules

iii. TS420 Module: Functional Tests

These functional tests are suggested to acquaint a new user with Transonic® 400-Series Flow Modules and Transonic® Perivascular Flowprobes and to check for damage incurred during shipment. If the apparatus does not function as described during this initial operation, please call Transonic® customer service or your authorized Transonic® provider or sales representative.

A. Flow Module Set-up

1) Verify that the Console's rear panel synchronization terminals are properly connected. (See Console synchronization instructions, page 5)

2) Connect Console power cord to grounded power receptacle.
NOTE: Do not operate unless Console is electrically grounded via supplied power cable.

3) Turn on power switch on back panel of Console.
   a) The TS420 starts up in Test Mode to encourage testing of the Flowprobe prior to use.
   b) Digital Display will scroll "TSI ✓" and display "NO.PR." NOTE: Module settings cannot be adjusted without a Flowprobe connected.

4) Connect a Flowprobe (or extension cable with a Flowprobe) to the front panel mounted self aligning 10-pin connector. If a 4-pin chronic connector is used, also insert the calibration key into the **[Cal Key]** socket on the front panel next to the Probe connector.
   a) Digital Display will scroll "No Sig" and Probe size.

B. Perivascular Flowprobe Signal Quality Test

1) Attach the Flowprobe to the Module and set the **[Mode]** to "Test."

2) Immerse the Probe in a soft plastic beaker filled with degassed water or saline.
NOTE: Hard containers reflect the ultrasound signals and will cause the Probe to appear to have high or drifting zero offset values. Sponge may be inserted in the container to absorb extraneous signal.

3) Dislodge any air bubbles from the surfaces of the Probe. Shaking the Probe under water may be sufficient. A fine gauge paint brush is useful especially with smaller Probes which can hold air bubbles.

4) Observe Flow Module's front panel indicators. The "No Sig" message will be replaced with "Good Sig" as good acoustic conduction is established with the Probe. A dry Probe may need to be immersed in water or saline for several minutes before this occurs. Swishing the Probe back and forth helps to speed up the process. The Probe's received signal stabilizes when the surfaces are sufficiently wetted and confirms acoustic transmission of the ultrasound signal.

5) The Signal Quality Indicator should be fully illuminated - all 5 bars will be lighted. NOTE: If the Flowprobe has less than 3 bars lit during the water/ saline test (without interruption from bubbles) do not use the Flowprobe for measurements. Contact your Transonic® representative for additional troubleshooting or repair return instructions.

SIGNAL STRENGTH	SIGNAL QUALITY	BAR DISPLAY	ANALOG DISPLAY	"REC AMP" VOLTAGE FROM REAR PANEL
over 80%	Good	5 bars lit	over 0.8 V	over 0.8 V
60% to 80%	Good	4 bars lit	proportional reading	proportional reading
30% to 60%	Good	3 bars lit		
20% to 30%	Low	2 bars lit		
10% to 20%	Low	1 bars lit		
under 10%	No Signal	no bars lit	under 0.1 V	under 0.1 V

C. Flowprobe Zero Offset

If there is any zero offset, it can be nulled using the **[Zero Adj]** button. Use a pointed instrument (such as the tip of a pen or stylus) to depress the button. Make sure the Probe is fully wetted before adjusting the zero offset as dry Probes display more signal drift. **NOTE:** Small zero offset is normal due to slight differences in the transducers and generally considered insignificant.

1) For applications where an absolute zero is required, nullify the zero offset on the vessel of interest. Temporarily occlude the vessel to stop flow and then depress the **[Zero Adj]** button. **NOTE:** Once the zero offset has been adjusted, it cannot be adjusted again unless the Probe is disconnected or the Module turned off. Turning off the Module or disconnecting the Probe will reset the zero offset.

D. Determining Scale Setting

The flow range of each Flowprobe is scaled according to Probe size (see Flowprobe Specification Table, RL-20-ds, for scale factor values). Each Flowprobe has two scale ranges: normal flow and low flow. Low flow range is 1/4 of normal range, however the signal is amplified to provide a four fold increase in sensitivity. The scale factor value is the flow at 1 volt output in mL/min or L/min. Probes measure bidirectional flow up to five times the scale factor value.

When determining which scale setting to use it is important to keep in mind that under normal physiological conditions for a given vessel size, mean blood flow values are generally near or below the 1 volt normal scale value for the appropriate Probe size for the vessel.

- Peak pulsatile flows may push the output to 5 volts.
- Beyond the 5 volt maximum range of the Module, “peak clipping” occurs and the complete wave form is not recorded and the mean flow may be underestimated.
- Use the low flow range setting ONLY when peak flow will not exceed 5 times the low flow scale factor. It is recommended to check peak flows using the normal flow mode before switching to low flow if there is concern about potential peak clipping.

Put the Flow Module in **[Scale]** mode to display the value of the Probe’s 1 volt reference signal in the normal or low flow range. This reference signal is used to calibrate the data acquisition system and does not change the factory calibration of the Flowprobe. All Transonic® Flowprobes are precalibrated at the factory for absolute volume flow measurement. (See Calibration Technical Note RL-5-tn).

E. Calibrating a Data Acquisition System

1) Connect the data acquisition system to either the front or back analog outputs.
2) Follow the data acquisition provider’s instructions for a 2-point calibration.
3) For reference point “zero” (0 volts), press **[Mode]** to select “Zero” and record the output voltage.
4) For reference point “1 volt”, press **[Mode]** to select “Scale” and record the voltage. The value of the 1 volt reference signal is displayed on the digital display of the Module while the analog display shows 1V.
5) If the scale is changed (Standard Flow vs. Low Flow) during the experiment, the 1 volt reference scale value in the data acquisition system must be reset. Repeat the above sequence whenever the flow range setting has been changed.

iv. TS420 Module: Directions For Use

FLOWPROBE PREPARATION
At least 10 minutes before acute use, submerge the Flowprobe in sterile saline. This "soaking" of the Probe eliminates random drift in zero offset which a dry Probe may exhibit when applied to a vessel. If only chronic measurements are needed, the 10 minute Probe soak may be omitted. The Flowprobe has been factory calibrated to meet Transonic® Flowprobe specifications when applied to a living vessel (see RL-20-ds). If a more precise zero baseline than that specified is needed, the Probe's zero must be obtained in situ by vessel occlusion. A zero reading in a beaker of liquid generally will differ from an "in situ" zero.

VESSEL SITE SELECTION
The Flowprobe is largely insensitive to turbulence and/or vessel-Probe alignment and may be applied effectively on straight segments or near side branches of the vessel. When applied on a curved segment of the vessel, the plane defined by the Probe's transducers and reflector bracket should be perpendicular to the plane defined by the curve of the vessel.

VESSEL PREPARATION
Use blunt dissection to free just that section of the vessel to which the Probe will be applied; you need not "clean" it for ultrasonic permeability, but carefully remove all fatty tissue in the Probe's acoustic pathway. Try not to deflect the vessel from its natural course. If absolute flow into or out of an organ is a study parameter, all unligated side branches between the measurement site and the organ must be occluded during flow measurements.

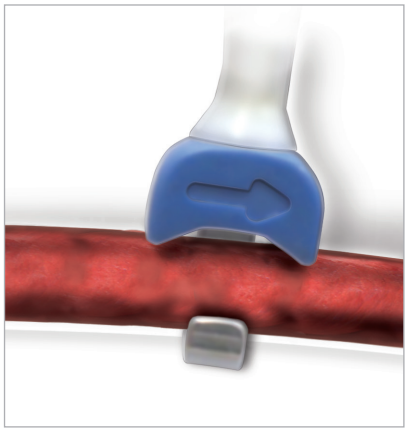


Fig. 4.9: Flowprobe placement

PROBE APPLICATION
The Flowprobe is applied so that the vessel under observation lies within the sensing window formed by the Probe's transducer body and the attached reflector bracket (Fig. 4.9). The optimal alignment is to have the vessel run perpendicularly through the Probe's window. The Flowprobe may be oriented in either direction relative to upstream/downstream flow; preferred orientation allows an easy exit for the cable.

ACUTE APPLICATION
Excessive vessel manipulation may cause vessel spasm and should be avoided. Often, securing the Flowprobe in place with a temporary suture is helpful for preventing vessel occlusion or twisting. For proper function, the space between the circular vessel and the rectangular reflector bracket must be filled with a suitable ultrasonic couplant.

STANDARD COUPLANTS
For acute applications, proper ultrasonic contact between Probe and vessel must be provided using an acoustically matched couplant (see Acoustical Couplants for Acute Measurements RL-9-tn). Surgilube & H-R Lubricating Jelly are recommended couplants. Banked blood (if the site's geometry is suitable) may be applied to provide this acoustic coupling between vessel and Flowprobe but should not be used for small vessels. At a highly pulsatile site, movement of a liquid couplant within the sensing window will be measured as flow and will affect net measurement. For accurate measurements, the vessel should fill 75% - 99% of the Flowprobe lumen. This will eliminate Probe positional sensitivity. It is also easier to maintain coupling with a close fitting Probe as less gel is required and surface tension will hold gel in place.

ACOUSTIC COUPLING
Proper coupling is verified by observing the Module's diagnostic messages in "TEST" mode. On the digital dispaly, the "(Probe size)-Gd" must be displayed. The analog display must indicate a Probe relative received signal strength which exceeds 60% of the Probe's reading in saline (e.g., a new Probe will show around 1.0 in saline; its acute reading must exceed 0.6.) A low signal strength reading indicates that air bubbles and/or fat particles are in the acoustic window. They must be removed before the Probe can attain its stated measurement accuracy.

TS420 Module: Directions For Use

CHRONIC APPLICATION

For chronic implants, the Probe must be secured in place to maintain its proper alignment with the vessel without impeding flow once the preparation is closed. Standard Probe/reflector combinations come factory-prepared with suture holes and eyelets to allow for this suturing. The proper method to secure a Probe in place depends on the application site: Transonic® Surgical and Technical Application Notes offer some tried and proven methods. Generally, three sutures suffice to secure a Probe's position and orientation (often for an PS-Series Probe with sliding cover, two sutures through the reflector brackets and one around the Probe cable). For Probes supplied with silicone sheathing, sutures also may be made through the silicone. If standard suture placements are not satisfactory for your application, contact Transonic® for a custom Probe modification. For only chronic measurements, no ultrasonic couplant is necessary during implantation. Fibrous encapsulation of the Probe within the first week of implant will yield a stable, air bubble-free coupling.

FLOW MEASUREMENTS

The digital display presents the average volume flow value in mL/min or L/min. The analog meter registers flow proportional to the Flowprobe scale (at low flow range the needle deflection will increase four fold). Choose the appropriate **[Filter]** setting for average or pulsatile applications.

INVERT FLOW

Use the **[Invert]** button to change the display and outputs to the correct polarity. Some Probes have arrows on the Probe head indicating the positive direction of flow. To determine direction of flow in unmarked Probes, place the Probe head in water and move the Probe back and forth noting when the Module reads positive and negative flow. It is recommended to place the Probe according to easiest surgical access and **[Invert]** the flow if necessary.

LOW FLOW RANGE

Use the **[Range]** button to switch to "Low Flow" for increased sensitivity at low flow rates. Before switching to "Low Flow" check to ensure that peak pulsatile flows will not be cut off as this will cause inaccurate readings. The maximum value at the low flow scale is five times the 1 volt scale value.

CLEANING AND STERILIZATION

For complete cleaning instructions see "Cleaning & Sterilization of Transonic® Research Flowprobes" (AU-IFU-RProbeSteril-EN) provided with each Probe.

Disassemble Probe before use, keeping all of the parts of each Probe together because parts are not interchangeable among Probes. Thoroughly wash the Flowprobe and its reflector bracket in soap and warm water (≤ 55°C, 130°F). Remove any visible foreign material with a soft-bristled brush. Reinstall the reflector bracket in the alignment groove recessed on either side of the Probe body taking care not to distort the shape of the groove or bracket. Proper reflector alignment is crucial for measurement accuracy. The CM4-style (4-pin) implantable connectors can be cleaned following standard scrubbing procedures but cannot be taken apart because it is hermetically sealed. The CRA10 (10-pin) connector should not be submerged but may be cleaned with alcohol-wipes. The Flowprobe should never be boiled or autoclaved. STERRAD® or standard cold (≤ 60°C, 140°F) ethylene oxide gas sterilization is acceptable. The Probe may be rinsed and wiped in 70% isopropyl alcohol before sterilization.

- If a connector becomes wet, drying overnight in an incubator oven (≤ 60°C, 140°F) is recommended.
- Inspect cables routinely for damage.
- Store the dry Probe at room temperature.

PAU Ultrafit Liners are single use and should be properly disposed of according to local regulations.

V. SP430 Pressure Amp Module

The SP430 Transonic Scisense Pressure Amplifier Module is a specialized amplifier for compatible Pressure Catheters and Transducers to measure arterial or venous blood pressure in the research setting. The Module accepts two Pressure Transducers for simultaneous measurement of two channels of pressure with separate controls for zero offset balance of each Transducer. This Module incorporates an internal barometric pressure reference for use with fully sealed chronic pressure implants. Analog output signals may be recorded via front panel BNC connectors or the Console's rear terminal block.

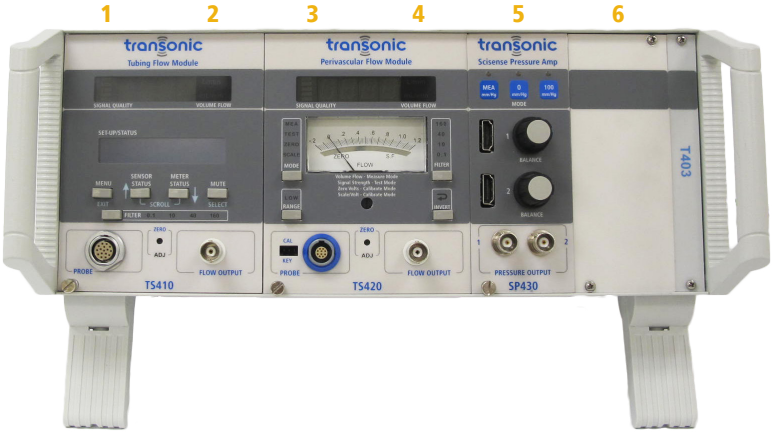


Fig. 5.1: Transonic T403 with TS410, TS420 and SP430 modules installed
** Note: Power Supply circuitry could interfere with pressure output signal quality if the SP430 Module is placed in slot 1 or 2, the bay farthest to the left (from the front).*

A. Compatible Pressure Catheters and Transducers

The SP430 Pressure Module is equipped to work with Transonic Scisense solid-state Pressure Catheters. The Module is also compatible with Transpac IV pressure transducers Transonic PART # YS100 when used with the YS100-ADPT.

1. TRANSONIC SCISENSE PRESSURE CATHETERS

Transonic Scisense solid-state Pressure Catheters provide high fidelity pressure measurements directly at the source. Their high frequency response makes them suitable for physiological measurements in animal sizes ranging from mice to cows. These Catheters are available in catheter sizes ranging from 1.2F to 7.0F and can be connected directly to the SP430 Module using the supplied HDMI style cable.

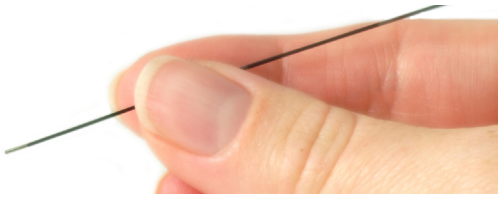


Fig. 5.2: Transonic Scisense 1.6F FTH Pressure Catheter

FTH-SERIES: SMALL ANIMAL PRESSURE CATHETERS
1.2F, 1.6F, Single and Dual Sensor Catheters
1.9F (available as PV catheter only)
3.5F for large animals
NOTE: The SP430 Pressure Module will operate only the pressure sensor of PV catheters.

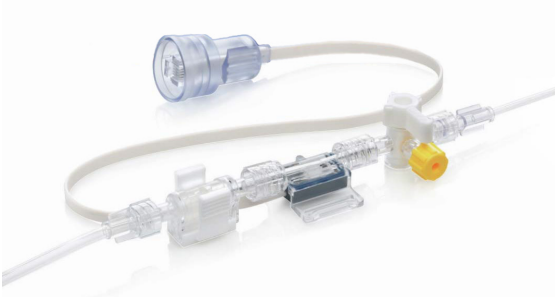


Fig. 5.3: Transpac® IV Pressure Transducer

FDH-SERIES: LARGE ANIMAL PRESSURE CATHETERS
Sizes: 5F, 7F Single and Dual Sensor Catheters, Straight or Pigtail
NOTE: The SP430 Pressure Module will operate only the pressure sensor of PV catheters.

2. TRANSPAC® IV PRESSURE TRANSDUCER (TRANSONIC® PART # YS100)

The Transpac® IV Pressure Transducer provides a measurement of arterial or venous blood pressure by Luer Lock connection to an indwelling fluid-filled catheter or inline connection for in vitro applications. The Transpac® connects to the SP430 Module using the RJ11-HDMI connector adaptor (Transonic® part YS100-ADPT). The disposable Transpac® IV is supplied in sterile packaging and may be reordered. See http://www.icumed.com/products/critical-care/blood-pressure-monitoring/transpac-iv.aspx for more information and specification. Transpac® IV is a registered trademark of ICU Medical, Inc.

i. SP430 Module: Functions & Controls

A. Front Panel

Fig. 5.4: SP430 Transonic Scisense Pressure Amp Module

MEA (MEASURE) MODE BUTTON
Press to engage pulsatile pressure measurement mode. Light indicates activation.

0 MMHG CALIBRATION BUTTON
Outputs calibration voltage (-2.857 V ±2%) corresponding to 0 mmHg. Light indicates activation.

100 MMHG CALIBRATION BUTTON
Outputs calibration voltage (-0.571 V ±2%) corresponding to 100 mmHg. Light indicates activation.

HDMI CONNECTORS FOR PRESSURE INPUTS
Pressure Catheter extension cable or YS100-ADPT adaptor with extension cable. Two channels available. Use only Transonic® approved HDMI cables.

BALANCE CONTROL KNOBS
Adjusts the pressure output voltage for nullifying zero offset. Each channel is adjusted separately.
NOTE: KNOBS ADJUST EASILY - BEWARE OF UNINTENDED ADJUSTMENTS.

BNC ANALOG OUTPUTS
Pulsatile pressure as a voltage. One output for each channel.

B. Modes of Operation

MODE	OUTPUTS	
	FRONT ANALOG BNC	REAR ANALOG TERMINAL BLOCK
MEA MMHG (MEASURE)	Pulsatile pressure in volts	Pulsatile pressure in volts
0 MMHG	-2.857 V ±2% (corresponds to 0 mmHg) Acceptable range: -2.800 V to -2.914 V	-2.857 V ±2% (corresponds to 0 mmHg) Acceptable range: -2.800 V to -2.914 V
100 MMHG	-0.571 V ±2% (corresponds to 100 mmHg) Acceptable range: -0.560 V to -0.582 V	-0.571 V ±2% (corresponds to 100 mmHg) Acceptable range: -0.560 V to -0.582 V

C. Analog Outputs

Transonic® Pressure Amp Modules output analog signals in the range of -5 volts to +5 volts that are compatible with most A/D (analog-to-digital) converters of data acquisition systems. The back panel analog outputs generated by the SP430 Module are listed in the table below:

NUMBER	TERMINAL NAME	VOLTAGE	DESCRIPTION
12	Inactive		Inactive
11	Inactive		Inactive
10	GND		Ground
9	GND		Ground
8	Inactive		Inactive
7	Inactive		Inactive
6	Inactive		Inactive
5	Barometric Pressure	± 5 V	Barometric Air Pressure
4	Inactive		Inactive
3	Pulse Pressure 2	± 5 V	Pulsatile pressure from Sensor 2
2	Inactive		Inactive
1	Pulse Pressure 1	± 5 V	Pulsatile pressure from Sensor 1

ii. SP430 Module: Specifications

GENERAL FEATURES
Weight/Size Dimensions: 5.125" h x 2" w x 9.062" d
Weight: 1.9 lbs
Module is 1 Console bay (10HP) wide
Console Compatibility: 400-Series Flowmeter Consoles (T402 and T403).
Power: Derives input power from 400-Series Console 12Vdc ±5% input voltage.
RoHS compliant
Installation in a Console is required. The SP430 module must be installed in one of the bays on the far right in the T402 or T403 console (slot, 3, 4, 5 or 6) to meet specifications for best performance. Location in slot 1 or 2 may result in excessive noise in the signal.

CATHETER/TRANSDUCER COMPATIBILITY
Accepts Pressure input in 2 front panel HDMI connectors. Each channel has separate controls and outputs.

- Transonic Scisense solid-state Pressure Catheters with HDMI connectors
- Transpac® IV from ICU Medical using the YS100-ADPT RJ11 TO HDMI adaptor

ANALOG OUTPUT SIGNALS

- Front panel BNC: 2 analog pressure signals filtered to 800 Hz
- Rear Panel Terminal Connector: 2 analog pressure signals filtered to 800 Hz;
- Internal atmospheric pressure reference filtered to 1 Hz

ACCURACY
Refer to individual Pressure Transducer specifications

INPUT FILTER
3.5 kHz low pass

OUTPUT FILTER
800 Hz low pass

AMPLIFIER GAIN
1143

NOISE
±10 mv or 1 mmHg

RANGE
-50 to + 300 mmHg (2.286 V/100 mmHg)

BAROMETRIC PRESSURE REFERENCE
Infineon KP236 Analog absolute Pressure Sensor
Accuracy: ±1 kPa.
Sensitivity: 53.3 mV/kPa
Operating range: 40-115 kPa

iii. SP430 Module: Functional Tests

For installation of the SP430 module into the T402 or T403 Console, see "T402 & T403 Multi-channel Consoles" section A. Installing Modules on page 5 or follow the instructions on the IFU provided with the module.

A. Transducer Calibration Check

The SP430 Pressure Module does not require any calibration prior to use. However, it is advisable to check the calibrations on individual Pressure Transducers before use. The calibration check verifies the voltage gain of the Transducer channel to be 2.286 V/100 mmHg and requires that a known pressure is applied from a calibrated source.

1) Press the **[MEA]** mode button; the indicator light will switch to MEA mode
2) Open the stopcock attached to the Transducer to air for zero pressure
3) The analog output should be at -2.857 V ±2%. If not, adjust the balance control knob. This serves to correct any zero offset.

   NOTE: KNOBS ADJUST EASILY - BEWARE OF UNINTENDED ADJUSTMENTS.
4) Close the stopcock and apply a known pressure of 100 mmHg from a calibrated source such as a sphygmomanometer or graduated column of fluid set at the appropriate height.
5) The analog output should be at -0.571 V (Do not adjust the balance control knob). **NOTE:** If the output at 100 mmHg is significantly different, do not use the Pressure Transducer and contact your local Transonic® representative for troubleshooting or repair return instructions.

B. Calibrating a Data Acquisition System

The SP430 Pressure Amplifier Module will interface with any data acquisition system that accepts an analog output in the range of -5 volts to +5 volts. Two hardware connector choices are provided with front panel BNC and rear panel screw terminals.

1) The sampling rate on the acquisition software should be 1 KHz for rodents and 200Hz for larger animals
2) Follow the data acquisition system's protocol for a 2-point calibration.
3) Press the **[0 mmHg]** button on the SP430 Module. The green light above the button will illuminate to confirm selection.
   a) Voltages (-2.857 V ±2%) corresponding to 0 mmHg are output on both BNC output channels and rear terminals. Use as 0 mmHg reference point.
4) Press the **[100 mmHg]** button on the SP430 Module. The green light above the button will illuminate to confirm selection.
   a) Voltages (-0.571 V ±2%) corresponding to 100 mmHg are output on both BNC and rear terminals. Use as 100 mmHg reference point.

iv. SP430 Module: Directions For Use

A. Transonic Scisense Pressure Catheters

Unpack the Catheter from its original packaging (keep the packaging for storing the Catheter after use). Care must be taken to avoid kinking the Catheter tubing. Be careful not to apply direct pressure to the sensor membrane.

Fig. 5.5: Transonic Scisense 5F FDH Pressure Catheter

1) In order to minimize signal drift, immerse the sensing tip in saline (i.e. a saline filled syringe) and allow a warm up time of 30 minutes while preparing the animal for surgery.
2) Connect the Catheter to the channel 1 input using the supplied HDMI cable.
3) Immediately before using the Catheter, the pressure signal offset must be adjusted to zero using the balance control knob for channel 1 on the SP430 Module (see "Transducer Calibration Check" on page 29 for directions). Use caution not to bump the balance knob once adjusted.
4) If using a second Pressure Catheter, follow the directions above using channel 2.
5) Make sure the Module is in **[MEA]** mode prior to taking measurements.

B. Dual Pressure Catheters

A Dual Pressure Catheter must be plugged into channel 1 to provide two pressure measurements instead of using two separate Catheters. The primary pressure will be output as "Pressure 1" and the secondary pressure value will be output as "Pressure 2". **NOTE:** With Transonic Scisense Dual Pressure Catheters the distal (tip)pressure sensor is primary and the proximal pressure sensor, secondary.

- If a second Catheter is plugged into channel 2 it will override the secondary pressure value of the first Catheter. **NOTE:** There will only be two pressure outputs regardless of the number of transducers.
- If a Dual Pressure Catheter is plugged into channel 2 it will only provide a single pressure signal regardless of the presence of a Catheter in channel 1. The primary pressure signal will be output as "Pressure 2."
- If Dual Pressure Catheters are plugged into both channels then the primary pressure signal from each Catheter will be output as the respective pressure signal.

C. Catheter Cleaning & Care

ALWAYS CLEAN PRESSURE CATHETERS IMMEDIATELY AFTER USE.
FAILURE TO PROPERLY AND PROMPTLY CLEAN CATHETERS MAY CAUSE SENSOR FAILURE AND VOID ANY AND ALL WARRANTIES. DO NOT USE ULTRASONIC CLEANERS FOR THE CATHETERS.

For complete cleaning instructions see "Catheter Cleaning & Disinfecting Guide" provided with each Catheter.

1) Immediately after use, immerse the Catheter in distilled water or saline.
2) Soak the Catheter in a pH neutral enzymatic cleaning solution (i.e. Endozime®).
3) Optional: Disinfect in Cidex® (Not: Cidex® 7, Cidex® Plus or Cidex® PA) or similar solution. Do not use glutaraldehyde solutions containing surfactants or solutions containing hydrogen peroxide.
4) Rinse the Catheter by soaking in distilled water to remove all traces of cleaning agents.
5) Dry the Catheter by placing on a paper towel or gauze. Do not air dry or use alternative drying methods. **NOTE:** Never apply direct pressure to the pressure sensor membrane.

6) Before returning the Pressure Catheter to its original packaging for storage, use magnification to check for blood or tissue residue. If any is found, repeat the cleaning process.

7) Store the dry Catheter in it's original box. Position the pressure sensor within the foam cutout to prevent damage.

Single use Catheters should be disposed of after use according to local waste disposal regulations.

D. Transpac® IV Pressure Transducers

A disposable Transpac® IV Pressure Transducer for a fluid-filled arterial or venous catheter can be connected to the Module using a RJ11 to HDMI adaptor (Transonic® part YS100-ADPT). **NOTE:** Use of the Transpac® IV Pressure Transducer from ICU Medical with the SP430 Module is intended for animal use only and is not intended for clinical use on human subjects.

1) Open the package and remove the Transducer with cable.

2) To allow the use of the Transpac IV with the SP430 and adapter, use a blade to cut through the plastic hood over the RJ11 connector to expose the phone jack connector. Be careful not to cut through the white ribbon wire lead. A slit on either side of the hood works well see Fig. 5.6.

3) Plug the phone jack connector into the RJ11 connector on the HDMI adapter. Connect this adapter to the channel 1 input using the supplied HDMI cable.

4) Assemble the Transducer for testing.

5) Immediately before using the Transducer, the pressure signal offset must be adjusted to zero using the balance control knob for channel 1 on the SP430 Module (see "Transducer Calibration Check" on page 29 for directions).

Transpac® IV Transducers are single use devices. Dispose of Transpac® IV Pressure Transducers according to local waste disposal regulations.

Fig. 5.6: Transonic® RJ11 to HDMI adaptor (part number YS100-ADPT) next to Transpac® IV transducer

VI. Guarantee, Service and Warranty

A. Limited Warranty

Transonic® warrants that the 400-Series Multi-channel Research System components are free from defects which are the result of faulty material or workmanship by Transonic® for a limited period according to the following schedule:

- Consoles & Modules are warranted for a period of 12 months after date of shipment
- Flowprobes & Flowsensors are warranted for a period of 6 months after date of shipment
- Transonic Scisense Pressure Catheters less than two French (<2F) are warranted for a period of 12 months after date of shipment
- Transonic Scisense Pressure Catheters greater than two French (>2F) are warranted for a period of 3 months after date of shipment

The warranty shall not apply to:

1) Defects caused by abuse, neglect or misuse (e.g. cut cable, pulled cable, Probe, Catheter or Sensor damage from improper cleaning or sterilization)
2) Damage or loss due to accident or casualty or interruption of electrical power
3) Unauthorized alterations or repairs made by anyone other than Transonic® or its appointed repair or licensed representative.

The 400-Series System warranty is valid only if equipment is purchased through Transonic® or its duly appointed distributor or licensed representative. The obligations of Transonic® under this warranty are limited to repairing or, at its option, replacing any components goods determined to be defective. The Buyer must notify Transonic® in writing within the warranty period of the reason the Buyer believes that warranty repairs are required. The Buyer must then, upon the request of Transonic®, return the goods to the Transonic® manufacturing plant or to the designated service agent. The Buyer pays shipping charges to Transonic® or designated service agent. Any goods repaired or replaced by Transonic® shall be warranted for the period of time remaining on the original limited warranty.

No other warranty oral or written, expressed or implied. Transonic® is not liable for incidental or consequential damages.

VII. Equipment Return Instructions

A. Consoles & Modules

1) Call your Transonic® representative or contact your regional office, listed below, with a description of the problem. The representative will refer you to the nearest Service Technician. The Service Technician will issue a Return Merchandise Authorization (RMA) number.

2) Thoroughly clean and sterilize all equipment prior to packing and shipping. Any equipment that has not been cleaned will be immediately returned without repair.

3) If possible, use the original shipping carton for returning the Console and Module for repair. Include with your shipment:
   a) The Repair Return Form
   b) Power cord
   c) Additional Probes, Sensors, cables or other equipment if requested by the Service Technician

B. Flowprobes, Flowsensors & Transonic Scisense Pressure Catheters

1) Call your Transonic® representative or contact your regional office, listed below, with a description of the problem with the Probe, Sensor or Catheter. You will be referred to the nearest Service Technician and a Return Merchandise Authorization (RMA) number will be issued.

2) Thoroughly clean and sterilize all Probes, Sensors and Catheters. Any Probes, Sensors or Catheters that have not been cleaned will be immediately returned without repair.

3) Package all parts of the Probes, Sensors and Catheters in the original packaging along with:
   a) The Repair Return Form
   b) Any correspondence you wish to include

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Appendix A: Theory of Operation

Transit-Time Ultrasound

A Transonic® Perivascular Flowprobe (Fig. D.1) consists of a Probe body which houses ultrasonic transducers and a fixed acoustic reflector. The transducers are positioned on one side of the vessel or tube under study and the reflector is positioned at a fixed position between the two transducers on the opposite side. Electronic ultrasonic circuitry directs a Flowprobe through the following cycles:

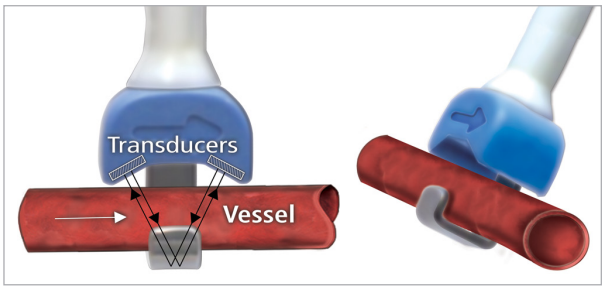


Fig. D.1: Schematic views of a Transonic® perivascular ultrasonic volume Flowsensor. Using wide beam illumination, two transducers pass ultrasonic signals back and forth, alternately intersecting the flowing liquid in upstream and downstream directions. The Flowmeter derives an accurate measure of the "transit time" it takes for the wave of ultrasound to travel from one transducer to the other. The difference between the upstream and downstream integrated transit times is a measure of volume flow rather than velocity.

UPSTREAM TRANSIT-TIME MEASUREMENT CYCLE

An electrical excitation causes the downstream transducer to emit a plane wave of ultrasound. This ultrasonic wave intersects the vessel or tubing under study in the upstream direction, then bounces off the fixed "acoustic reflector." It again intersects the vessel and is received by the upstream transducer where it is converted into electrical signals. From these signals, the Flowmeter derives an accurate measure of the "transit time" it takes for the wave of ultrasound to travel from one transducer to the other.

DOWNSTREAM TRANSIT-TIME MEASUREMENT CYCLE

The same transmit-receive sequence is repeated, but with the transmitting and receiving functions of the transducers reversed so that the flow under study is bisected by an ultrasonic wave in the downstream direction. The Flowmeter again derives and records from this transmit-receive sequence an accurate measure of transit time it takes for the wave of ultrasound to travel from one transducer to the other.

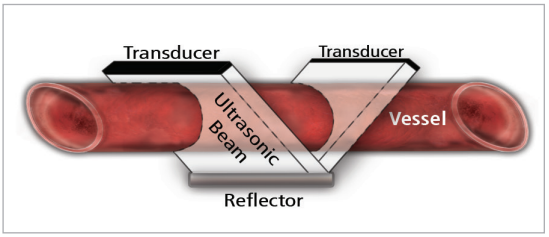


Fig. D.2: The vessel is placed within a beam that fully and evenly illuminates the entire blood vessel. The transit time of the wide beam then becomes a function of the volume flow intersecting the beam, independent of vessel dimensions.

Just as the speed of a swimmer depends, in part, on water currents, the transit time of ultrasound passing through a conduit is affected by the motion of liquid flowing through that vessel. During the upstream cycle, the sound wave travels against flow and total transit time is increased by a flow-dependent amount. During the downstream cycle, the sound wave travels with the flow and total transit time is decreased by the same flow-dependent amount. Using wide beam ultrasonic illumination, the Flowmeter subtracts the downstream transit times from the upstream transit times. This difference in the integrated transit times is a measure of true volume flow.

WIDE BEAM ILLUMINATION

One ray of the ultrasonic beam undergoes a phase shift in transit time proportional to the average velocity of the liquid times the path length over which this velocity is encountered. With wide-beam ultrasonic illumination (Fig. D.2), the receiving transducer integrates these velocity-chord products over the vessel's full width and yields volume flow: average velocity times the vessel's cross sectional area. Since the transit time is sampled at all points across the vessel diameter, volume flow measurement is independent of the flow velocity profile. Ultrasonic beams which cross the acoustic window without intersecting the vessel do not contribute to the volume flow integral. Volume flow is therefore sensed by perivascular Probes even when the vessel is smaller than the acoustic window (Fig. D.3).

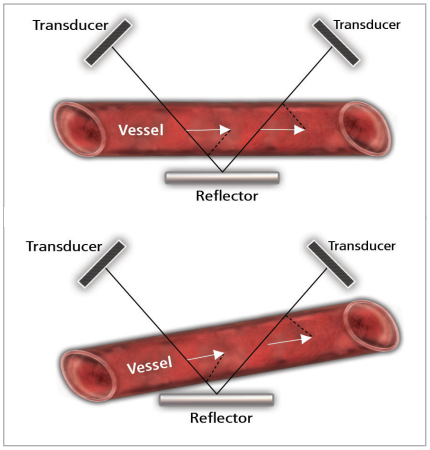


Fig. D.3: The ultrasonic beam intersects the vessel twice on its reflective path. With each intersection, the transit time through the vessel is modified by a vector component of flow. The full transit time of the ultrasonic beam senses the sum of these two vector components, or flow. With misalignment (bottom), one vector component of flow increases as the other decreases, with little consequence to their sum.

Drost, C.J., "Vessel Diameter-Independent Volume Flow Measurements Using Ultrasound", Proceedings San Diego Biomedical Symposium, 17, p.299-302, 1978. ***U.S. PATENT 4,227,407, 1980.***

Appendix B: EMC Tables

The 400-Series System complies to the Standard for Safety Electrical Measurement and Test Equipment Part 1: General Requirements UL 3111-1 and Safety Requirements for Measurement, Control and Laboratory Use Part 1: General Requirements CSA C22.2 No. 1001.1-92 in accordance with UL 61010A-1 Electrical Equipment for Laboratory Use, Part 1: General Requirements.

In accordance with EN 61326:1997 Electrical Equipment for Measurement, Control and Laboratory Use, the following tables provide information regarding the EMC characteristics of this Electrical Equipment.

MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

The 400-Series System is intended for use in the electromagnetic environment specified below. The customer or user of the 400-Series System should ensure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE
Radiated emissions EN 61326	Class A
Conducted emissions EN 61326	Class A

MANUFACTURER'S DECLARATION - IMMUNITY

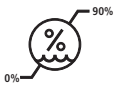
The 400-Series System is intended for use in the electromagnetic environment specified below. The customer or user of the 400-Series System should ensure that it is used in such an environment.

IMMUNITY TEST	EN 61326 TEST LEVEL	COMPLIANCE LEVEL
ESD IEC 1000-4-2	±2kV Contact ±4kV Contact ±2kV Air ±4kV Air ±4kV Indirect via HCP ±4kV Indirect via VCP	Pass: Performance criteria B
RF Electromagnetic Field IEC 1000-4-3	80-1000 MHz, 3 V/m, 80% AM (1kHz)	Pass: Performance criteria A
BFT IEC 1000-4-4	±0.5kV, 5/50 Tr/Th ±5kHz I/O	Pass: Performance criteria B
EFT EN 61000-4-4	±2kV Mains	Pass: Performance criteria B
Surge IEC 1000-4-5	±0.5kV Differential ±1kV Common	Pass: Performance criteria B
Conducted RF IEC 1000-4-6	3 Vrms, 80% AM (1 kHz) 0.15-80 MHz to Main & I/O	Pass: Performance criteria A
Voltage Dips/Dropout IEC 1000-4-11	Reduction 100%, 1 Cycle	Pass: Performance criteria B

Appendix C: Symbols & Signs

The following table contains a list of the possible symbols with accompanying definitions. Not all symbols are applicable to all products.

FAILURE TO COMPLY WITH ALL WARNINGS BOTH WRITTEN AND SYMBOLIC COULD RESULT IN PATIENT INJURY OR EQUIPMENT DAMAGE, AND VOID ANY AND ALL WARRANTIES.

LEGEND SYMBOL	DEFINITION	TRANSONIC NOTATION
	**Attention, Consult Accompanying Documents**	The specific directions in this manual and in the package inserts included with each device must be observed. Periodic testing of devices must be performed to assure the validity of flow measurements.
	**Dangerous Voltage**	The device must not be modified or serviced except by qualified Transonic® repair personnel.
	**Not Category AP Equipment**	Danger-Explosion risk if used with flammable anaesthetics.
	**Equipotentiality**	This ground pin is connected to the metal cabinet of the monitor. It provides the User with a means to equalize the electrical potential when connecting the device to other equipment.
	**Waste Electrical and Electronic Equipment**	This device contains material that requires special waste handling procedures for disposal. Contact Transonic® Customer Service to arrange for disposal.
	**CE Conformity Mark**	This device conforms to the requirements of applicable EU directives. See the Declaration of Conformity accompanying this device for specific directives.
	**ETL Testing Mark**	Electrical Safety Compliance Certification
	**Authorized Representative**	Transonic Systems Europe is an authorized representative in the European Community
	**TUV Testing Mark**	Electrical Safety Compliance Certification
	**RoHS Compliant**	This device was manufactured in accordance with RoHS requirements for applicable hazardous material content.
	**Keep Dry**	Do not expose the device to excessive liquids. Dry immediately if exposed to any liquids.
	**Temperature Limits**	Do not expose the device to temperatures above or below those listed. Different temperature limits may apply to transportation, storage and use of the device.
	**Use By Date**	Do not use this device after the end of the day, month or year shown.
	**Manufacture Date**	This device was manufactured on the date listed.
	**Manufacture Location**	This device was manufactured by the company listed; at the location listed.
LOT	**Batch Code**	The number listed is the lot number/batch code for the device.
REF	**Reference Number**	The number listed is the catalog, reorder or reference # for the device.
SN	**Serial Number**	The number listed is the serial number for the device.
	**Humidity**	Do not expose the device to humidities above or below those listed. Different humidity limits may apply to transportation, storage and use of the device.