REPORT ON THE SAFETY OF ULTRASONIC MEDICAL DIAGNOSTIC EQUIPMENT

PLANE-WAVE SEQUENCES IN THE VERASONICS VANTAGE 256 RESEARCH PLATFORM AND GE 9L-D PROBE

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SUMMARY

This report studies the compliance of the safety requirements stated in the international standard IEC606014-2-37 [1] for the use of Plane-Wave modalities in the Verasonics Vantage 256 research scanner (SN VV22032) and GE 9L-D probe (SN 417454P1) for clinical research.

The standard [1] defines indexes and procedures to characterize the thermal and acoustic output of ultrasonic diagnostic equipment. Tests according to [1] have been carried out at the Ultrasound Laboratory of the Department of Circulation and Medical Imaging of the Norwegian University of Science and Technology (Prinsesse Kristinas gt. 3, Akutten og Hjerte-lunge-senteret, 3.etg, 7030 Trondheim).

It is found that the studied sequences **comply** with the requirements of [1] since

1. the surface temperature does not exceed the stated limits, and
2. the correct acoustic indexes are displayed on the system.

The scope of the validity of this report is described in Chapter 1. The safety requirements of the standard [1] are described in Chapter 2. The experimental procedures and used intrumentation are described in Chapters 3 and 4. The test results are included in Chapters 5 and 6. Supporting information and all relevant certificates are included as Appendixes.

I hereby declare that the furnished details are true to the best of my knowledge.

Trondheim, November 2017

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1 SCOPE

1.1 SEQUENCES COVERED BY THIS REPORT

This report shows evidence on the compliance of the safety requirements stated in the international standard IEC606014-2-37 [1] for the use of Plane-Wave modalities in the Verasonics Vantage 256 research scanner (SN VV22032) and GE 9L-D probe (SN 417454P1).

The acoustic output of the following sequences has been characterized:

Sequence type	Mode	Elements	f_{awf}[MHz]	Cycles	V[V]	PRF[Hz]
Plane-Wave continuous	NS	192	4.808	2.5	10	12000
Plane-Wave continuous	NS	192	4.808	2.5	15	12000
Plane-Wave continuous	NS	192	6.250	1.5	10	12000
Plane-Wave continuous	NS	192	6.250	1.5	15	12000
Plane-Wave continuous	NS	192	6.250	2.5	10	12000
Plane-Wave continuous	NS	192	6.250	2.5	15	12000

Table 1: List of the sequences for which the acoustic output has been characterized. Legend: (S) scanning, (NS) non-scanning.

The surface temperature of the following sequences has been characterized:

Sequence type	Mode	Elements	f_{awf}[MHz]	Cycles	V_{max}[V]	PRF_{max}[Hz]
Plane-Wave continuous	NS	192	4.808	2.5	15	9000
Plane-Wave continuous	NS	192	6.250	2.5	15	9000
Plane-Wave (1.5 s / 1 s)	NS	192	4.808	2.5	15	12000
Plane-Wave (1.5 s / 1 s)	NS	192	4.808	2.5	15	12000

Table 2: List of the sequences for which the surface temperature has been characterized. Legend: (S) scanning, (NS) non-scanning.

1.1.1 *Scanned and non-scanned modes*

Ultrasound sequences are considered non-scanning if the same beam is transmitted several times consecutively. If the beam direction or focal distance is changed between consecutive transmissions the sequence is considered a scanning modality.

Plane-wave and diverging-wave sequences insonify the whole field of view. Even though the beam angle can change between consecutive transmission there will be tissue regions that will be subjected to approximately the same ultrasound energy in every transmission. Due to this, and to remain on the safe side, plane-wave and diverging-wave sequences must be considered as a non-scanning modality.

1.1.2 *Extension to other pulse repetition frequency*

The acoustic indexes can be extrapolated to other sequences using a different PRF from that in Table 1by using the method described in Chapter 7.

The surface temperature cannot be extrapolated to other sequences different from that in Table 2. It is safe to assume, however, that any sequence using a lower PRF, a lower voltage V, or a longer pause between acquisitions should produce lower temperatures than those reported here. Therefore, the requirements on the surface temperature in [1] are also fulfilled for other sequences as long as the PRF and V are not greater than those in Table 2, and as long as the pause, or cool-down period, is not shorter than those in Table 2.

1.1.3 *Extension to combined modes*

The acoustic indexes of a combination the modes in Table 1 can be estimated by using the method described in Chapter 7. These modes can have a PRF different from that in Table 1 or include a cool-down period, or pause between acquisitions.

The surface temperature cannot be estimated for other combined modes. Therefore combined modes using a larger voltage V or equivalent PRF larger than those in Table 2 are not covered by this report.

1.2 COMPLIANCE CONDITIONS

The scope is limited to the use of the equipment for clinical research only. **The data obtained will not be used, under any circumstance, for medical diagnosis**. Consequently, the diagnostic related sources of harm identified in Section 1.1 of the Standard [1] are not considered in this report.

The transducer GE 9L-D is **for external use only and will not be submitted to motion by any mechanical means**. Therefore, the motion related source of harm identified in Section 1.1 of the [1] is not considered by this report. In addition, as the transducer is for external use only, the ST does not need to be displayed, as stated Section 51.2 of the Standard.

The excessive acoustic output and surface temperature are within the scope of this report.

In order to comply with the requirements established by the Standard, **empirical models** have been derived for the acoustic output of the GE 9L-D probe for a number of covered sequences. Those models are based on measurements carried out in the Ultrasound Laboratory of the Department of Circulation and Medical Imaging with the equipment detailed in Chapter 4. The measurements have been done following the guidelines in [1] and [2]. The derived models predict the relevant acoustic indexes based on the sequence input parameters, i.e. peak voltage V and pulse repetition frequency PRF.

However, **these models cannot be used outside of the range specified in Table Table 1**. In other words: the maximum peak voltage and maximum PRF should not exceed the values set in Table 1; the pulse duration should not exceed the values set in Table 1, for each frequency; no other frequencies than the ones in Table 1 should be used.

To comply with the Standard, the corresponding acoustic indexes will be **displayed on the screen of the scanner** to be assessed by the operator.

If the operator selects a mode of operation outside of the range specified in Table Table 2 **the operator will be notified of the risk of excessive temperature and the sequence will be automatically halted**.

No limit is set in the Standard for the maximum TI and MI indexes, and it is left to the operator to decide which levels are safe for each specific situation. However, for further security **the operator will be notified in case** $\mathrm{MI} > 1.9$**, or** $\mathrm{TI} > 3$.

1.3 IMPORTANT INFORMATION FOR OPERATORS

The Standard [1] imposes specific limits to excessive output temperatures. However, no limits are imposed to an excessive acoustic output. Annex HH of the Standard states that *"It is the responsibility of the OPERATOR to understand the risk of the output of the equipment, and to act appropriately in order to obtain the needed diagnostics information with the minimum risk to the patient"*. Guidance is provided in Annex HH of the Standard on the relevance of TI and MI indexes:

1. Embryonic and fetal in situ temperature above 41° for 5 min or more should be considered potentially hazardous.
2. A risk-benefit analysis should be performed if the pressure amplitude at the surface of postnatal lung tissue may exceed 1 MPa.
3. TI values greater than 1 might best be avoided in obstetric applications.
4. For applications where poorly perfused tissues are expected, the TI should be maintained at a lower value.

Additional guidelines can be found in the FDA regulation [3]:

1. The derated time-averaged intensity integral $I_{spta,3}$ should not exceed 720 mW/cm^2 when used on peripheral vessels, 430 mW/cm^2 when used in cardiac imaging, and 94 mW/cm^2 for the rest of applications (fetal, abdominal, intra-operative, pediatric, small organ, cephalic).
2. The MI should not exceed 1.9 for non-ophthalmic use, and 0.23 for ophthalmic use.

For further guidance the operator is referred to [1, 3] and supporting literature.

2 SAFETY REQUIREMENTS

2.1 THE SAFETY REQUIREMENTS IN IEC 60601-2-37

The international Standard IEC 60601-2-37 [1] establishes the safety requirements that ultrasonic medical diagnostic equipment should meet.

Section 3 of the Standard identifies the following potential sources of harm:

1. Noise on a waveform, artifacts, distortion in an image or error;
2. displaying inaccurate numerical values associated with the diagnosis to be performed;
3. displaying inaccurate safety-related indications;
4. the production of excessive ultrasound output;
5. the production of excessive transducer surface temperature; and
6. the production of excessive motion of the transducer.

In addition, in Section 6.3, the Standard establishes that, under certain circumstances, the following quantities should be displayed on the control panel or screen of the equipment:

1. Thermal index (TI),
2. Mechanical index (MI),
3. Surface temperature (ST), and
4. the ultrasound output levels.

The circumstances at which the quantities above should be displayed are established in Section 51.2 of the Standard, and are also detailed in Section 2.1.1 and Section 2.1.2.

2.1.1 *Excessive temperatures*

Section 42.3 of the Standard [1] establishes the following requirements regarding excessive temperatures of an ultrasonic transducer:

1. For external use the ST rise shall not exceed 10°C under simulated conditions,
2. for internal use the ST rise shall not exceed 6°C under simulated conditions, and
3. regardless of use the ST rise shall not exceed 27°C in still air.

The methods to perform the temperature test, for both simulated and still air conditions, are established in section 42.3 a) of the Standard, and are also detailed in Chapter 3.

Section 51.2 of the Standard establishes that the ST should be displayed if a transducer is intended for trans-oesophageal use and capable of exceeding a ST of 41°C.

2.1.2 *Excessive acoustic output*

Section 51.2 of the Standard establishes the acoustic quantities that should be displayed and in which circumstances:

1. If the equipment is not capable of exceeding either a soft tissue index TIS or a bone thermal index TIB of 1,0, in any mode of operation, then no display of the TI is required. Otherwise, both TIS and TIB should be displayable when they exceed the value 0.4.

2. If the equipment is intended solely for adult cephalic applications, then the cranial thermal index TIC should be displayable when equal to, or exceeding, the value 0.4.

3. If the equipment is capable of exceeding a MI of 1.0 in real-time B-mode imaging the the MI shall be displayed when it equals or exceeds a value of 0.4.

4. If the equipment is not capable of real-time B-mode imaging both the MI and TI shall be displayable.

The Standard establishes the following on the displayed resolution of TI and MI:

1. The TI shall be displayed with a minimum resolution of 0.2 (for $\mathrm{TI} \leqslant 2.0$) and of 0.5 (for $\mathrm{TI} > 2$).

2. The MI shall use a minimum resolution of 0.2.

In addition, it states that the equipment should be automatically switched to an appropriate default setting after power up or patient change.

3 PROCEDURES

This chapter describes the experimental procedures used to characterize the thermal and acoustical properties according to the safety requirements established by [1].

3.1 TEMPERATURE MEASUREMENT

Section 42 of [1] describes the procedure to check the compliance of ultrasonic diagnostic equipment regarding temperature limitations. Two tests are required: under simulated conditions and in still-air. In the following sections we describe the procedures we followed to carry out both tests.

3.1.1 *Simulated conditions*

We followed the procedure based upon temperature rise measurements, as described in Section 42.3.a.1.B) of [1]:

1. The ultrasonic transducer was coupled acoustically to a thermal phantom with the same thermal and acoustical properties of tissue (see Chapter 4 for details).
2. A thermocouple was set in between the transducer and the thermal phantom. The thermocouple was placed at the center of the active area where the highest surface temperature is expected.
3. Before starting the test it was checked that both the transducer and the test subject were at ambient temperature T_{amb} (23°C ±3°C).
4. The ultrasonic diagnostic equipment was continually operated for 30 minutes and the surface temperature was continuously monitored.
5. The initial temperature T_0[°C] and the temperature after 30 minutes T_{30}[°C] was recorded.
6. The temperature rise in 30 minutes was calculated as,

$$\Delta T_{30} = T_{30} - T_0. \tag{1}$$

For this test, the Standard [1] establishes that the temperature rise shall not exceed 10°C.

3.1.2 *Still air*

We followed the procedure described in Section 42.3.a.2) og [1]:

1. The ultrasonic transducer was set inside a environmental chamber with minimal air flow.

2. A thermocouple was thermally coupled to the transducer surface using a thin layer of thermal paste (see Chapter 4 for details). The thermocouple was placed at the center of the active area where the highest surface temperature is expected.

3. Before starting the test it was checked that the transducer surface temperature was at ambient temperature T_{amb} (23 ° C ±3°).

4. The ultrasonic diagnostic equipment was continually operated for 30 minutes and the surface temperature was continuously monitored.

5. The initial temperature T_0[°C] and the temperature after 30 minutes T_{30}[°C] was recorded.

6. The temperature rise in 30 minutes was calculated as,

$$\Delta T_{30} = T_{30} - T_0. \tag{2}$$

For this test, the Standard [1] establishes that the temperature rise shall not exceed 27°C.

3.2 ACOUSTIC MEASUREMENTS

The procedures to measure the MI and TI indexes are established in Section 7 of IEC 61102 standard [2]. In the following Sections we describe the entire procedure we followed to obtain the relevant acoustic indexes. The standard makes use of non-SI units (MHz, MPa, mW and cm). While this makes expressions simpler it may create confussion on the units that must be used on each equation. In this report we chose to use SI units instead (Hz, Pa, W and m).

3.2.1 *Preparation*

The measurement was prepared as it follows:

1. A capsule hydrophone (see Chapter 4 for details) was set into a water tank 20 minutes before the measurement.

2. The hydrophone was moved 20 cm down from the water surface.

3. The GE 9L-D probe was set on a scanning micropositioning system (see Chapter 4 for details) and positioned at the water surface.

4. Any bubbles on the hydrophone and the GE 9L-D surfaces were removed with a jet of water.

5. The hydrophone was placed 1 mm away from the GE 9L-D probe face, approximately at the center of the aperture.

6. The scanner was operated.

7. The scanner out-trigger was connected to the oscilloscope (see Chapter 4 for details).

8. The alignment of hydrophone and the GE 9L-D probe was initially checked and corrected using the scanner display.

9. A series of raster scans[1] were performed to improve the alignment between hydrophone and the GE 9L-D probe.

10. The water temperature was measured.

3.2.2 *Definition of the beam axis*

The location of the beam axis was estimated as follows:

1. Three raster scans were performed at depths 1 mm, 60 mm, and 100 mm.

2. Any scan that didn't cover the whole -12 dB output beam area was readjusted and repeated.

3. Any scan with less than 7 samples inside the -12 dB output beam area was readjusted and repeated.

4. The beam axis was estimated by least squares fitting of the center of each raster scan.

3.2.3 *Output beam area*

The -12 output beam area and breakpoint distance were estimated as follow:

1. The hydrophone was set as close as possible to the GE 9L-D probe but without touching it.

2. Two linear scans [2] were performed in the elevation and azimuthal directions with resolution 0.1 mm abd 0.5 mm, respectively.

3. For each point (x, y, z) the pulse pressure squared integral PPI was calculated:

$$PPI(x, y, z) = \int_0^T p^2(x, y, z, t)dt \; [Pa^2 \cdot s]. \tag{3}$$

   where $p(x, y, z, t)$ is the instantaneous acoustic pressure measured at (x, y, z), T is a time larger than the sum of the time-of-flight and the pulse duration.

4. The PPI was expressed in dB as:

$$PPI_{dB}(x, y, z) = 10 \log \left(\frac{PPI(x, y, z)}{\max(PPI(x, y, z))} \right) \; [dB]. \tag{4}$$

5. The points where PPI_{dB} dropped below -12 dB were marked in both linear scans.

1 Raster scan: acquisition of acoustic pressure on a grid of equi-spaced points that lie on a plane parallel to the transducer's face.

2 Linear scan: acquisition of acoustic pressure on a line of equi-spaced points on a plane parallel to the transducer's face.

6. The beam with $L_x[m]$ and beam height $L_y[m]$ were noted.
7. The -12 dB output area was calculated as

$$A_{aprt} = L_x L_y \ [m^2]. \tag{5}$$

8. The equivalent aperture diameter was calculated as

$$D_{eq} = \max\left(\sqrt{4A_{aprt}/\pi}, 10^{-3}\right) \ [m]. \tag{6}$$

9. The breakpoint depth was calculated as

$$z_{bp} = 1.5\, D_{eq} \ [m]. \tag{7}$$

3.2.4 *The derated time-averaged intensity integral $I_{spta,3}$ and the depth of maximum derated intensity z_3*

The depth of maximum derated intensity z_3 was estimated as follows:

1. An axis scan[3] was performed with 0.5 mm resolution.
2. For each point along the beam axis the pulse pressure squared integral PPI was calculated as:

$$PPI(z) = \int_0^T p^2(z,t)dt \ [Pa^2 \cdot s], \tag{8}$$

where (x, y) are omitted for convenience.

3. The derated pulse intensity integral was computed as:

$$PII_3(z) = \frac{PPI(z)}{\rho c} \cdot 10^{-\alpha z f_{awf}/10} \ [J/m^2], \tag{9}$$

where ρ and c are the density and speed of sound of water, $\alpha = 3 \cdot 10^{-5}$ dB/(m Hz) is the acoustic attenuation coefficient, z is the depth in m, and f_{awf} is the acoustic working frequency in Hz.

4. The derated time-averaged intensity integral was computed as:

$$I_{spta,3}(z) = PRF \cdot PII_3 \ [W/m^2], \tag{10}$$

where PRF is the pulse repetition frequency in Hz.

5. The depth of the maximum derated intensity $z_3[m]$ is given by the depth where the maximum of $I_{spta,3}$ lies, i.e.:

$$z_3 = \arg\max\left(I_{spta,3}(z)\right) \ [m]. \tag{11}$$

3 Axis scan: acquisition of acoustic pressure on a line of equi-spaced points coincident with the beam axis.

3.2.5 *Mechanical index* MI

The mechanical index MI was estimated as follows:

1. The instantaneous acoustic pressure was measured on the scan axis at the depth of maximum derated intensity z_3.

2. The derated peak-rarefactional pressure was computed as

$$p_{r3} = \min\left(p(z_3, t)\right) \cdot 10^{-\alpha z_3 f_{awf}/20} \, [Pa]. \tag{12}$$

   Note the 20 factor in the denominator of the derating factor.

3. The mechanical index was calculated as stated in Section GG.2.2 of [1],

$$MI = \begin{cases} \frac{p_{r3}/[MPa]}{\sqrt{f_{awf}/[MHz]}} & f_{awf} < 4\text{MHz}, \\ \frac{p_{r3}/[MPa]}{2} & f_{awf} \geqslant 4\text{MHz}. \end{cases} \tag{13}$$

3.2.6 *Measurement of the Acoustic Power* P

The Acoustic Power was measured as follows:

1. A raster scan was performed at the breakpoint depth z_{bp} with a minimum resolution of 0.5 mm in each direction.

2. Any scan that didn't cover the whole -12 dB output beam area was readjusted and repeated.

3. Any scan with less than 7 samples inside the -12 dB output beam area was readjusted and repeated.

4. For each point the time-averaged acoustic intensity (I) was calculated as:

$$I(x, y, z_{bp}) = \frac{PRF}{\rho c} \int_0^T p^2(x, y, z_{bp}, t) \, dt \, [W/m^2]. \tag{14}$$

5. The acoustic power (P) was then computed as

$$P = \int \int I(x, y, z_{bp}) \, dx \, dy \, [W]. \tag{15}$$

6. The derated acoustic Power P_3 at depth z was then obtained by:

$$P_3(z) = P \cdot 10^{-\alpha z f_{awf}/10} \, [W]. \tag{16}$$

3.2.7 *Measurement of the bounded acoustic power* P_1

Electronic apodization was used to limit the transducer aperture to 1 cm lenght in the azimuthal direction. Then the bounded acoustic power was computed as follows:

1. A raster scan was performed at the breakpoint depth z_{bp}.

2. For each point the bounded time-averaged acoustic intensity (I) was calculated as:

$$I_1(x, y, z_{bp}) = \frac{PRF}{\rho c} \int_0^T p^2(x, y, z_{bp}, t)\, dt \ [W/m^2]. \tag{17}$$

3. The bounded acoustic power P_1 was then computed as

$$P_1 = \int\int I_1(x, y, z_{bp})\, dx\, dy \ [W]. \tag{18}$$

3.2.8 *Calculation of the soft-tissue thermal index* TIS

1. We defined the equivalent derated acoustic power $P_{eq,3}$ at depth z as the derated time-averaged intensity integral multiplied by 1 cm^2, i.e.

$$P_{eq,3}(z) = \left(I_{spta,3}(z) \cdot 10^{-4}[m^2]\right) \ [W]. \tag{19}$$

2. The depth $z_s[m]$ was obtained as the depth of the maximum of the minimun of the derated acoustic power and the equivalent derated acoustic power, or as z_{bp} if lower, i.e.

$$z_s = \max\left(z_{bp}, \arg\max\left(\min\left(P_3(z), P_{eq,3}(z)\right)\right)\right) \ [m]. \tag{20}$$

3. For non-scaning applications if the ouput beam area is greater than 1 cm^2 ($A_{aprt} > 10^{-4}m^2$) then the thermal index was computed

$$TIS_{non-scan} = \min\left(\frac{P_3(z_s)\, f_{awf}}{2.1 \cdot 10^5 [W\,Hz]}, \frac{P_{eq,3}(z_s)\, f_{awf}}{2.1 \cdot 10^5 [W\,Hz]}\right) \tag{21}$$

If the ouput beam area is smaller or equal to 1 cm^2 ($A_{aprt} \leqslant 10^{-4}m^2$) then the thermal index was obtained as

$$TIS_{non-scan} = \frac{P\, f_{awf}}{2.1 \cdot 10^5 \ [W\,Hz]}. \tag{22}$$

4. For scanning applications the thermal index was given by:

$$TIS_{scan} = \frac{P_1\, f_{awf}}{2.1 \cdot 10^5 \ [W\,Hz]}. \tag{23}$$

3.2.9 *Calculation of the bone thermal index* TIB

1. The depth $z_b[m]$ was obtained as the depth of the maximum of the product of the derated acoustic power and the derated time averaged intensity integral, i.e.

$$z_b = \arg\max\left(P_3(z) \cdot I_{spta,3}(z)\right) \ [m]. \tag{24}$$

2. For non-scaning applications the thermal index was given by

$$TIB_{non-scan} = \min\left(\frac{\sqrt{P_3(z_b) \cdot I_{spta,3}(z_b)}}{5\,[W/m]}, \frac{P_3(z_b)}{4.4 \cdot 10^{-3}\,[W]}\right). \tag{25}$$

3. For scanning applications the thermal index was given by:

$$TIB_{scan} = \frac{P_1\, f_{awf}}{2.1 \cdot 10^5 \ [W\,Hz]}. \tag{26}$$

3.2.10 *Calculation of the cranial thermal index* TIC

1. The cranial thermal index (bone at surface) was computed as

$$\mathrm{TIC} = \frac{P}{D_{eq}\, 4\ [W/m]}. \tag{27}$$

4 INSTRUMENTATION

In the following section we describe the instruments and equiment used to carry out the measurements.

4.1 THERMAL MEASUREMENTS

1. Thermocouples CO1–K from Omega Engineering, Internal serial number TC02 (surface) and TC03 (ambient). Datasheet included in Appendix A.
2. PicoTech USB TC-08 thermocouple data logger, Serial number AO016/739. Related documents are included in Appendix A.
3. Nathional Physical Laboratory surface temperature test phantom, Serial number NPL-2-37 TTP1 2015-30. Related documents are included in Appendix B.
4. In-house developed Matlab-based software, "Thermolab", to control the acquisition and data storage.
5. In-house developed climatic enclosure.

4.2 ACOUSTICS MEASUREMENTS

1. Water tank with degassed water.
2. Intellistages stepper motor and controller (positioning robot) from Physik Instrumente (PI) GmbH Co. (Karlsruhe/Palmbach, Germany).
3. 85 um Capsule hydrophone from Onda HGL-0085, Serial number SN1253. Calibration certificate included in Appendix E.
4. Hydrophone preamplifier AH-2020, Serial number SN1057. Calibration certificate included in Appendix E.
5. Le Croy WaveSurfer 42Xs digital oscilloscope, Serial number SNLCRY0308M17202.
6. In-house developed Matlab-based software, ProbeLab, was used to control the positioning robot and oscilloscope, collecting data and calculating safety indices.

5 TEMPERATURE MEASUREMENTS

5.1 STILL-AIR CONDITIONS

The following measurements were carried out in still-air conditions:

Sequence	Elements	f_{awf}[MHz]	Cycles	Voltage [V]	PRF[Hz]	T_{amb}[°C]	ΔT_{30}[°C]
Plane-Wave continuous	192	4.808	2.5	15	9000	24.54	11.79
Plane-Wave continuous	192	6.250	2.5	15	9000	24.64	10.68
Plane-Wave (1.5 s / 1 s)	192	4.808	2.5	15	12000	25.00	3.57

Table 3: Temperature measurements in still-air conditions.

5.2 SIMULATED CONDITIONS

The following measurements were carried out on simulated conditions:

Sequence	Elements	f_{awf}[MHz]	Cycles	Voltage [V]	PRF[Hz]	T_{amb}[°C]	ΔT_{30}[°C]
Plane-Wave continuous	192	4.808	2.5	15	9000	23.50	5.74
Plane-Wave (1.5 s / 1 s)	192	6.250	2.5	15	12000	24.30	0.23

Table 4: Temperature measurements in simulated conditions.

5.3 MEASUREMENT UNCERTAINTY

CO1–K thermocouples from Omega Engineering declare an standard uncertainty of

$$\sigma_{TC} = \max\left(\frac{0.75}{100}T, 2.2\right) \ [^\circ C], \tag{28}$$

where T is the measured temperature in ° C. For any temperature $T < 300°C$, $\sigma_{TC} = 2.2°C$. The PicoTech USB TC-08 data-logger declares an standard uncertainty of

$$\sigma_{DL} = \frac{0.2}{100}T + 0.5 \ [^\circ C], \tag{29}$$

for the maximum measured temperature of 50°C, $\sigma_{DL} = 0.6°C$.

The standard deviation of our temperature measurements is therefore:

$$\sigma_T = \sqrt{\sigma_{TC}^2 + \sigma_{DL}^2} = \sqrt{2.2^2 + 0.6^2} = 2.3[^\circ \ C]. \tag{30}$$

Finally, the standard deviation of the temperature increase ΔT_{30} is

$$\sigma_{\Delta T} = \sqrt{2}\sigma_T = 3.2[^\circ \ C]. \tag{31}$$

6

ACOUSTIC MEASUREMENTS

The following acoustic measurements were carried out:

f[MHz]	Cycl	V_{pk}[V]	PRF[Hz]	MI	TIS	TIB	TIC	P[mW]	I_{SPTA}[mW/cm^2]
4.808	2.5	10	12000	0.2408	1.224	2.445	2.445	89.7	159.5
4.808	2.5	15	12000	0.357	2.961	5.91	5.91	216.8	382
6.250	1.5	10	12000	0.2018	0.561	1.071	1.071	39.3	84.6
6.250	1.5	15	12000	0.2993	1.356	2.592	2.592	95	208.9
6.250	2.5	10	12000	0.2014	0.887	1.681	1.681	61.6	145.5
6.250	2.5	15	12000	0.2944	2.194	4.2	4.2	153.9	354

Table 5: Acoustics measurements carried out to characterize the sequence.

6.1 MEASUREMENT UNCERTAINTY

It is assumed that the measurement uncertainty is the same as declared in previous reports [4], since the same instruments were used. In [4] a relative standard uncertainty of 7.3% is estimated for MI, and of 15% for TI.

7

ACOUSTIC MODEL

In this chapter an empirical model is specified to estimate the acoustic indexes for other modes of operations. The model is fed with the values in Chapter 6 . The scope of the validity of the acoustic model is specified in Chapter 1.

7.1 MECHANICAL INDEX

All the rest kept equal and disregarding non-linear effects, the mechanical index MI increases proportionally to the peak voltage ($MI \propto V_{pk}$). It is therefore safe to use piece-wise linear interpolation to estimate the MI between the intervals specified in Chapter 6.

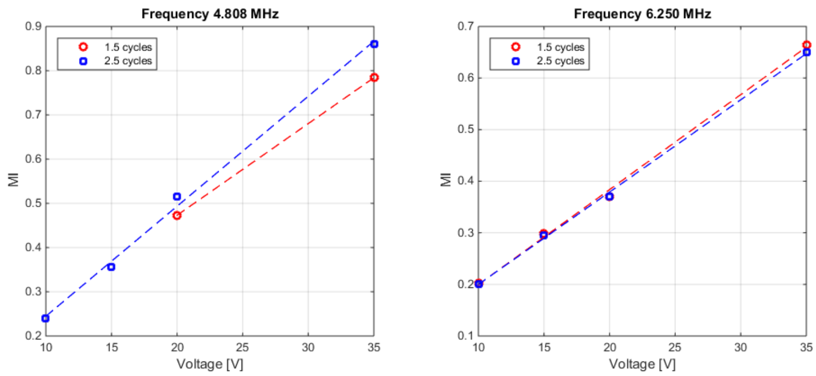

Figure 1: Measurement of the MI and first order polynomial model

The MI cannot be extrapolated to voltage values greater than the maximum value in Chapter 6. It is safe to use the minimum MI value for voltage levels lower than the minimum in Chapter 6.

The MI cannot be interpolated or extrapolated to other frequency values.

The MI cannot be interpolated or extrapolated to other pulse durations.

The MI is independent of the pulse repetition frequency, hence the same value can be used for sequences using a different PRF.

7.2 THERMAL INDEXES

By definition all the thermal indexes (TIS, TIB, and TIC) are proportional to the pulse repetition frequency PRF. It is therefore possible to calculate the appropriate indexes for other sequences using a different PRF just by,

$$TI_{PRF} = TI_{measured} \frac{PRF}{PRF_{measured}}. \tag{32}$$

In addition, thermal indexes are approximately proportional to the peak voltage squared ($MI \propto V_{pk}^2$). It is therefore safe to use piece-wise linear interpolation to estimate the thermal indexes between the intervals specified in Chapter 6.

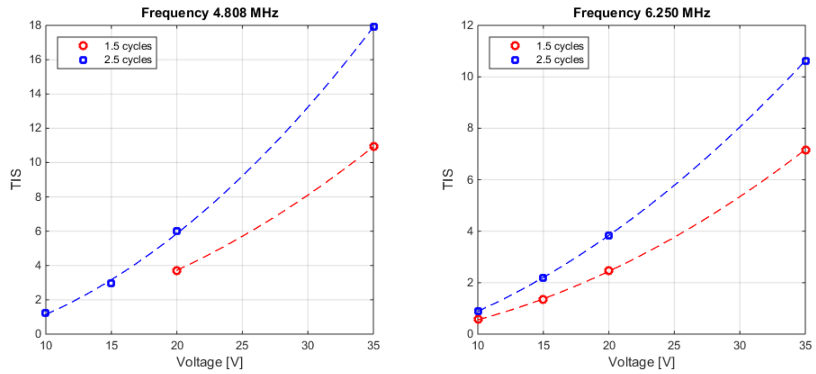

Figure 2: Measurement of the TIS and second order polynomial model.

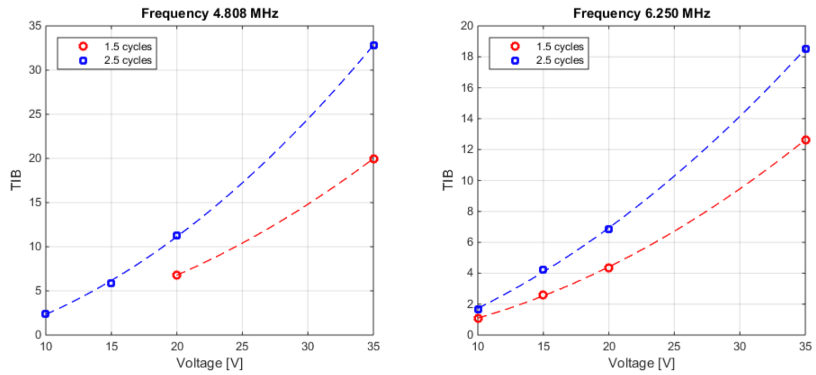

Figure 3: Measurement of the TIB and second order polynomial model.

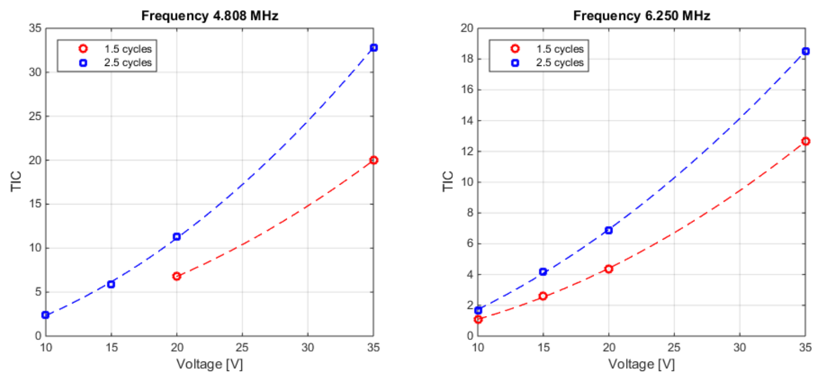

Figure 4: Measurement of the TIC and second order polynomial model.

Thermal indexes cannot be extrapolated to voltage levels larger than those in Chapter 6. It is safe to use the minimum corresponding thermal index for voltage levels lower than those in Chapter 6.

Thermal indexes cannot be interpolated or extrapolated to other frequency values.

To stay on the safe side, thermal indexes cannot be interpolated or extrapolated to other pulse durations.

7.3 COMBINED-OPERATING MODE

Section DD.6 of the Standard [1] establishes how to calculate the relevant indexes in case of combined operation.

1. The mechanical index MI of the combined-mode shall be the largest MI of all individual modes.
2. If the -12 dB output beam area is smaller or equal than 1 cm^2, the thermal index TI of the combined-mode shall be sum of the TI of all modes.
3. If the -12 dB output beam area is larger than 1 cm^2, the thermal index TI of the combined-mode shall be the maximum of the sum of the TI of all scanned modes and of the sum of the TI of all non-scanned modes.

In that regard it is convenient to define the effective pulse repetition frequency PRF_{eff} of the combined-operating mode,

$$PRF_{eff} = \frac{\sum_{m=1}^{M} t_m PRF_m}{\sum_{m=1}^{M} t_m} \text{ [Hz]}, \tag{33}$$

where m denotes each single operating mode and M is the number of operating modes, PRF_m is the pulse repetition frequency of mode m, and t_m is the time interval the mode m is active. If different operating modes are combined (33) can be used to calculate the relevant indexes (ΔT_{30} and TI) for each individual mode. The total index is obtained by adding the individual indexes together. Note that MI do not depend on PRF and hence the maximum is taken.

Expression (33) can be further simplified in case an active mode is combined with a inactive period in order to limit the temperature increase:

$$PRF_{eff} = \frac{t_{active}}{t_{active} + t_{inactive}} PRF \text{ [Hz]}, \tag{34}$$

where t_{active} is the duration of the active period, and $t_{inactive}$ is the duration of the cool-down period. However, to avoid perverting (34) we set the following constrain to t_{active},

$$t_{active} < \frac{TI_{active}}{3} \text{ [s]}. \tag{35}$$

A

DOCUMENTATION FOR THERMOCOUPLES AND DATA LOGGER

pico Technology

TC-08

THERMOCOUPLE DATA LOGGER

LOW COST, HIGH RESOLUTION

- Measures and records up to 8 thermocouples
- Works with all popular thermocouple types
- Wide temperature range (–270 °C to +1820 °C)
- Built in cold junction compensation
- High resolution (20 bits) and high accuracy
- Up to 10 measurements per second
- No power supply required
- Supplied with PicoLog data logging software
- USB interface ensures problem-free installation
- Multiple units can be run on a single PC

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TC-08 THERMOCOUPLE DATA LOGGER

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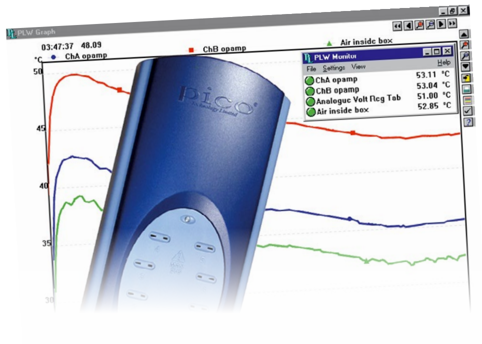
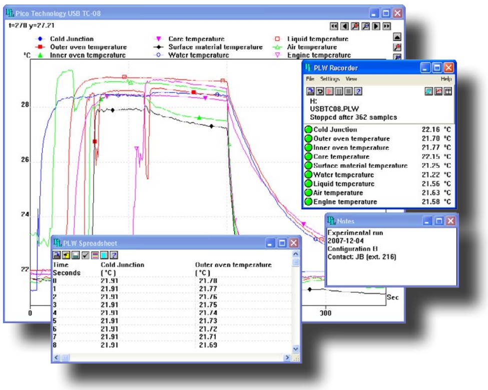


PicoLog



In addition to the monitor view, PicoLog can also display a graph, a spreadsheet and user notes. It can display them all at once, as shown here, or individually in any combination.

PicoLog is a powerful but flexible data acquisition program designed for collecting, analyzing and displaying data over long or short periods of time. Data can be viewed both during and after data collection in spreadsheet or graphical format. If required, the data can also be easily exported to other applications.

SOFTWARE DRIVERS

For users who wish to write their own software or use our products with third party software, we provide, free of charge a range of software drivers and examples. Drivers are included for Windows XP (SP3), Windows Vista, Windows 7, Windows 8 (not Windows RT) and Windows 10 (32 and 64 bit). The SDK supports all C-compatible languages, and programming examples are supplied for C, Visual Basic for Applications (Microsoft Excel) and National Instruments LabVIEW.

THERMOCOUPLES

Pico Technology offers both off the shelf and built to order thermocouples for use with our data logging products. The TC-08 is compatible with all popular thermocouples offering high accuracy without compromising acquisition speed. Thermocouple types and temperature ranges are shown in the table below.

Type	Overall Range °C	0.1 °C Resolution	0.025 °C Resolution
B	20 to 1820	150 to1820	600 to 1820
E	-270 to 910	-270 to 910	-260 to 910
J	-210 to 1200	-210 to 1200	-210 to 1200
K	-270 to 1370	-270 to 1370	-250 to 1370
N	-270 to 1300	-260 to 1300	-230 to 1300
R	-50 to 1760	-50 to 1760	20 to 1760
S	-50 to 1760	-50 to 1760	20 to 1760
T	-270 to 400	-270 to 400	-250 to 400

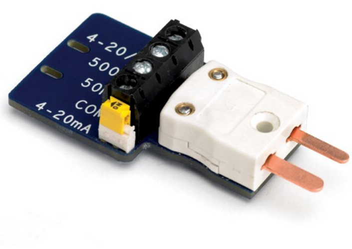
TC-08 SPECIFICATIONS

Number of channels	8
Temperature accuracy	The sum of ±0.2% and ±0.5 °C
Voltage accuracy	The sum of ±0.2% and ±10 μV
Overload protection	±30 V
Voltage input	±70 mV
Reading rate	Up to 10 per second
Input connectors	Miniature thermocouple
PC connection	USB
Dimensions	201 x 104 x 34 mm

ORDER CODES and PRICES

ORDER CODE	DESCRIPTION	GBP*	USD*	EUR*
PP222	TC-08	249	409	349
PP624	Terminal Board	18	30	26

* Prices are correct at the time of publication. VAT not included. Please contact Pico Technology for the latest prices before ordering.



The PP624 is an optional terminal board for the TC-08. The screw terminals allow wires to be attached to the data logger without soldering and enable the TC-08 to measure voltages from 0 to +5 V, or 4-20 mA loop current.

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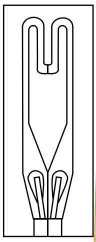
“Cement-On” Thermocouples

- Response Time in Milliseconds
- Made from 0.013 mm (0.0005") Foil and 0.25 mm (0.010") Diameter Thermocouple Wire
- Very Low Thermal Inertia
- Four Calibrations J, K, E, and T
- Three Styles Ideal for Surface Measurement

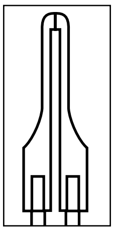
OMEGA introduces its Cement-On, fast response thermocouples for fast surface temperature measurement applications in three convenient styles. Styles 1 and 2 are made from 0.013 mm (0.0005") thermocouple alloy foil by a special process where the butt welded thermocouple junction is 0.013 mm (0.0005") in thickness. Styles 1 and 2 are flat, extremely low inertia construction and are an ideal means of measuring the temperature of both flat and curved metals, plastic and ceramic surfaces where very fast response is desired.

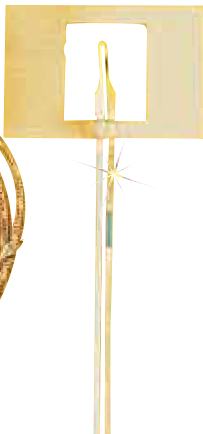
OMEGA’s Cement-On Style 1 and 2 thermocouples are fabricated from ANSI “Special Limits of Error” grade thermocouple materials in K, E and T calibrations and yield accurate temperature indication when used with standard thermocouple instrumentation. Styles 1 and 2 have the fastest response. Style 3 is an economy version constructed from 0.25 mm (0.010") diameter bead welded standard limit of error thermocouple wire. It should be used where extremely fast response is not essential.

CO Series

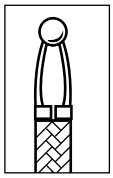


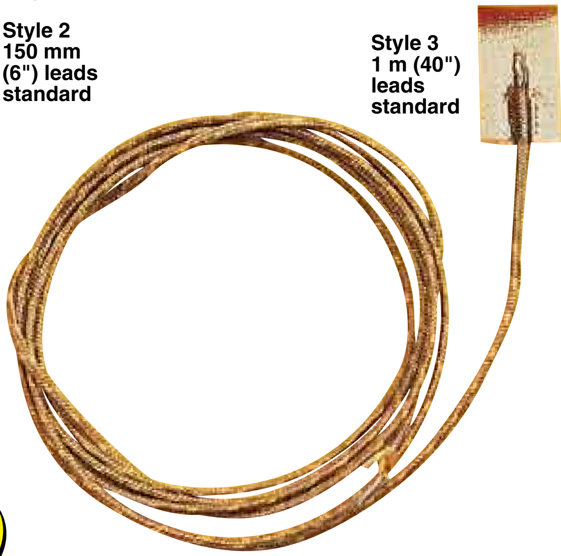
Style 1
1 m (40")
leads
standard





Style 2
150 mm
(6") leads
standard





Style 3
1 m (40")
leads
standard

MEETS OR EXCEEDS SPECIAL LIMITS OF ERROR (SLE) AND EN 60584-2: Tolerance Class 1

Dimensions and Additional Information Available at omega.com/co-k

To Order *Visit omega.com/co-k for Pricing and Details*

Model No.	Style	Thermocouple Type	Length	Maximum Temperature °C (°F)* Continuous	600 hr	10 hr
CO1-K	1	K CHROMEGA®-ALOMEGA®	1 m (40")	260 (500)	315 (600)	370 (700)
CO1-E		E CHROMEGA®-Constantan	1 m (40")	260 (500)	315 (600)	370 (700)
CO1-T		T Copper - Constantan	1 m (40")	150 (300)	205 (400)	260 (500)
CO2-K	2	K CHROMEGA®-ALOMEGA®	150 mm (6")	540 (1000)	540 (1000)	650 (120)
CO2-E		E CHROMEGA®-Constantan	150 mm (6")	425 (800)	425 (800)	540 (1000)
CO2-T		T Copper-Constantan	150 mm (6")	150 (300)	150 (300)	260 (500)
CO3-J	3	J Iron - Constantan	1 m (40")	260 (500)	370 (700)	370 (700)
CO3-K		K CHROMEGA®-ALOMEGA®	1 m (40")	260 (500)	370 (700)	370 (700)
CO3-E		E CHROMEGA®-Constantan	1 m (40")	260 (500)	370 (700)	370 (700)
CO3-T		T Copper-Constantan	1 m (40")	205 (400)	260 (500)	370 (700)

** The temperature range high limits given are greatly influenced by environmental conditions, installation method, accuracy and lifetime requirements and may vary from the general guidelines listed in the table.*

Style 1 and 3 cannot be used with CC High Temperature Cement; CC Cement will break down insulation.

*Response time when “grounded” or “cemented” to surface: **Style 1** (10 to 20 milliseconds), **Style 2** (2 to 5 milliseconds), **Style 3** (300 milliseconds). The response time or “time constant” is the time required to reach 63.2% of an instantaneous temperature change.*

Additional length wire can be ordered for Styles 1 and 3, add cost per 300 mm (12"), for Style 2 add cost per 300 mm (12").

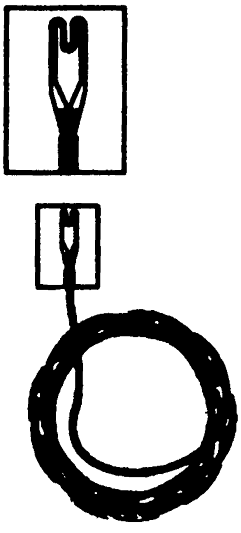
***Ordering Example: CO1-K** is a style 1, Type K thermocouple, 1 m (40") long.*

1 YEAR WARRANTY

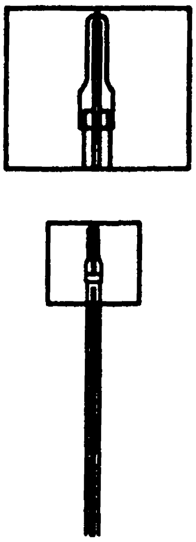
MADE IN USA

CE

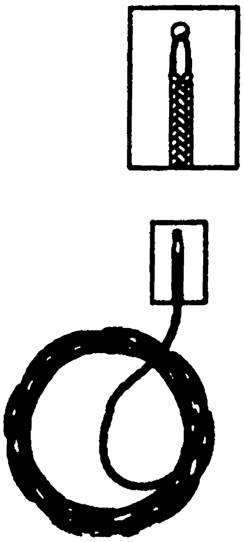
User's Guide



Style I



Style II



Style III

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ISO 9001 CERTIFIED CORPORATE QUALITY	ISO 9001 CERTIFIED CORPORATE QUALITY
STAMFORD, CT	MANCHESTER, UK

CO1, CO2, CO3

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FAX: +44 (0)161 777-6622
e-mail: sales@omega.co.uk

Section 1 General Description

Style I "Cement-On" Thermocouples are made from 0.0005" thick thermocouple foil embedded between two layers of high temperature polymer/glass laminate. This laminate generally limits the maximum temperature for construction to 260°C (500° F) continuous, 370° C (698°F) for short duration.The insulated lead wire is silicone impregnated glass braid. The silicone impregnation provides abrasion resistance, but is destroyed at approximately 205°C (400° F). The glass braid provides electrical insulation to 480°C (896° F).

Style II "Cement-On" sensors are made from .0005" foil with .002" leads. The foil leads are fastened to a polyimide film frame which is a tough, flexible, dimensionally stable material rated for 260°C (500° F) continuous service.

NOTE: SENSORS ARE FRAGILE, HANDLE THEM CAREFULLY.

Style III "Cement-On's" are made from 30 gauge (0.010") diameter thermocouple wire. The thermocouple is bead welded and embedded between two layers of paper thin polyimide film. This film is rated up to 370° C (698°F). The insulated lead wire is silicone impregnated glass braid with the same qualities listed above for Style I. The table on the following page lists the maximum temperature for the three styles of thermocouples.

Style	Thermocouple Type	Maximum Temperature °C Continuous	600 hr	10 hr	Catalog Number
I	K Chromega®-Alomega™	260	315	370	CO1-K
	E Chromega®-Constantan	260	315	370	CO1-E
	T Copper-Constantan	150	205	260	CO1-T
II	K Chromega®-Alomega™	540	540	650	CO2-K
	E Chromega®-Constantan	425	425	540	CO2-E
	T Copper-Constantan	150	150	260	CO2-T
III	J Iron-Constantan	260	315	370	CO3-J
	K Chromega®-Alomega™	260	315	370	CO3-K
	E Chromega®-Constantan	260	315	370	CO3-E
	T Copper-Constantan	205	260	370	CO3-T

Section 2 Installation

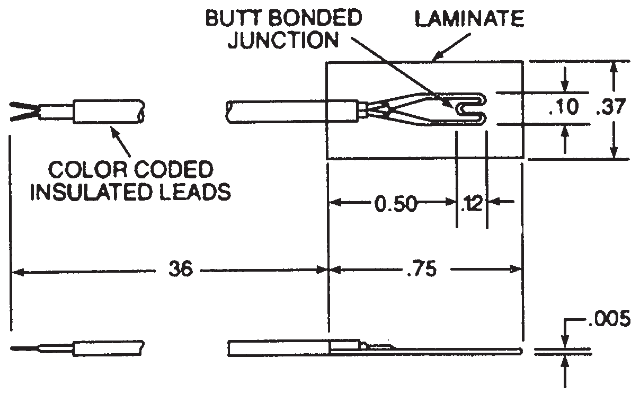
2.1 Using Adhesives

1. "Cement-On" Thermocouples can be bonded to most surfaces using OB Epoxy Adhesives 100, 101, and 200. Each epoxy has different temperature ratings, cure characteristics, and thermal conductivity factors. Refer to the Omega Temperature Measurement Handbook for more information on OB Epoxies.
2. When using epoxies, be sure that the surfaces to be bonded are clean. Use an appropriate solvent or detergent for cleaning.
3. For temperatures above 500°F, use Omega CC High Temperature Cement to bond Style II "Cement-On" Thermocouples to most metals and ceramics. CC Cement is not recommended for Style I and Style III "Cement-On's".
4. For applications under 260°C (500°F), use OB 200 Epoxy.
5. OB 200 is a specially formulated epoxy with high thermal conductivity. To retain the fast speed of response, use a thin layer of adhesive.

2.2 Installation Tips

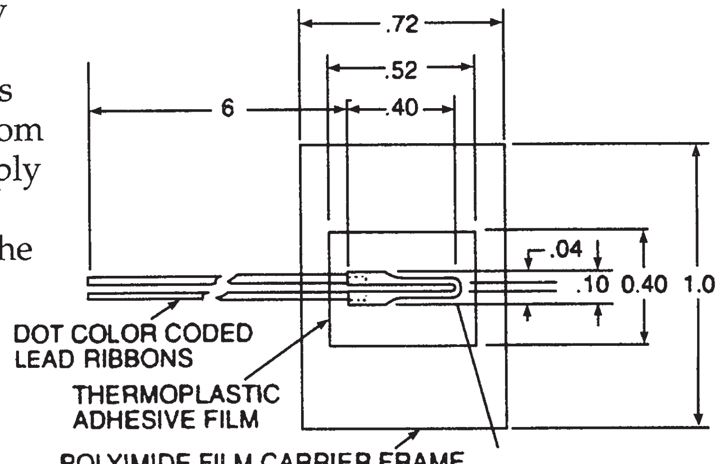
Style I: Use a clamp to strain relief the lead wire downstream from the sensor.

Style I



Style II:

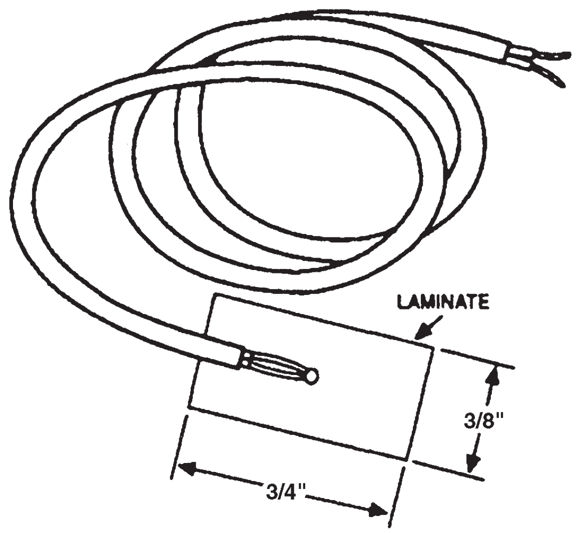
1. During application, the foil thermocouple can either be peeled from the frame or released by applying heat.
2. The .002" foil leads are uninsulated. Before working on electrically conductive surfaces, lay down a thin layer of insulating Omega CC Cement or OB Epoxy and let it dry. This ensures that the leads are fully insulated from the surface. Then apply a thin layer of the cement or epoxy to the surface, and brush the leads into it (use this step alone for non-conductive surfaces).



Style II

3. Bond insulated thermocouple lead wire to the foil leads by silver soldering or resistance welding. Use thirty gauge insulated thermocouple lead wire such as GG- (K or E or T) -30. Refer to the Omega Temperature Measurement Handbook for information on thermocouple wire.
4. Install Type T (Copper/Constantan) foil junction by carefully pressing into a flowed thin layer of soft solder.
5. Type K (Chromega®/Alomega™) and Type E (Chromega®/Constantan) will not bond properly with soft solder. However, with care and skill, a bond can be made using a low temperature silver solder of less than 1000°F.

Style III: These "Cement-On" Thermocouples may be bonded to most surfaces using the same technique as for Style I.



Style III

WARRANTY/DISCLAIMER

OMEGA ENGINEERING, INC. warrants this unit to be free of defects in materials and workmanship for a period of **13 months** from date of purchase. OMEGA's WARRANTY adds an additional one (1) month grace period to the normal **one (1) year product warranty** to cover handling and shipping time. This ensures that OMEGA's customers receive maximum coverage on each product.

If the unit malfunctions, it must be returned to the factory for evaluation. OMEGA's Customer Service Department will issue an Authorized Return (AR) number immediately upon phone or written request. Upon examination by OMEGA, if the unit is found to be defective, it will be repaired or replaced at no charge. OMEGA's WARRANTY does not apply to defects resulting from any action of the purchaser, including but not limited to mishandling, improper interfacing, operation outside of design limits, improper repair, or unauthorized modification. This WARRANTY is VOID if the unit shows evidence of having been tampered with or shows evidence of having been damaged as a result of excessive corrosion; or current, heat, moisture or vibration; improper specification; misapplication; misuse or other operating conditions outside of OMEGA's control. Components in which wear is not warranted, include but are not limited to contact points, fuses, and triacs.

OMEGA is pleased to offer suggestions on the use of its various products. However, OMEGA neither assumes responsibility for any omissions or errors nor assumes liability for any damages that result from the use of its products in accordance with information provided by OMEGA, either verbal or written. OMEGA warrants only that the parts manufactured by the company will be as specified and free of defects. OMEGA MAKES NO OTHER WARRANTIES OR REPRESENTATIONS OF ANY KIND WHATSOEVER, EXPRESSED OR IMPLIED, EXCEPT THAT OF TITLE, AND ALL IMPLIED WARRANTIES INCLUDING ANY WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED. LIMITATION OF LIABILITY: The remedies of purchaser set forth herein are exclusive, and the total liability of OMEGA with respect to this order, whether based on contract, warranty, negligence, indemnification, strict liability or otherwise, shall not exceed the purchase price of the component upon which liability is based. In no event shall OMEGA be liable for consequential, incidental or special damages.

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RETURN REQUESTS/INQUIRIES

Direct all warranty and repair requests/inquiries to the OMEGA Customer Service Department. BEFORE RETURNING ANY PRODUCT(S) TO OMEGA, PURCHASER MUST OBTAIN AN AUTHORIZED RETURN (AR) NUMBER FROM OMEGA'S CUSTOMER SERVICE DEPARTMENT (IN ORDER TO AVOID PROCESSING DELAYS). The assigned AR number should then be marked on the outside of the return package and on any correspondence.

The purchaser is responsible for shipping charges, freight, insurance and proper packaging to prevent breakage in transit.

FOR **WARRANTY** RETURNS, please have the following information available BEFORE contacting OMEGA:

1. Purchase Order number under which the product was PURCHASED,
2. Model and serial number of the product under warranty, and
3. Repair instructions and/or specific problems relative to the product.

FOR **NON-WARRANTY** REPAIRS, consult OMEGA for current repair charges. Have the following information available BEFORE contacting OMEGA:

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DOCUMENTATION FOR THE NPL SURFACE TEMPERATURE TEST PHANTOM

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Heimdal
NTNU
Norway

Telephone +44 20 8977 3222
Fax +44 20 8943 6161
Date 16 Dec 2015

Dear Alfonso,

Please find enclosed the following:

1. One bespoke TMM phantom (NPL-2-37 TTP1 2015-30).
2. One 250 mL jar of top-up fluid (11.9% aqueous glycerol solution) for the phantom.
3. 1 set of skin mimics (thicknesses 0.5 mm, 1.0 mm, and 1.5 mm).
4. Data sheet for the thermal and acoustic properties of the TMM.
5. Important notes on usage of the TMM.
6. Safety data sheet for handling and storage of the TMM. *Please read this before first use of the phantom.*

Due to the chemical content, it is advisable that the samples be handled with gloves at all times.

For disposal, local regulations should be followed or the materials returned to the Acoustics group at NPL (by prior arrangement) for disposal. The phantom has been topped up with a fluid solution designed to prevent the TMM drying out. The solution is 88.1% deionised (and degassed) water and 11.9% glycerol. Due to evaporation, the phantom should be topped up with additional solution so that the surface remains covered while in storage.

I hope this is useful. If you have any further questions regarding the phantom and its use then please do not hesitate to contact us.

Kind regards,

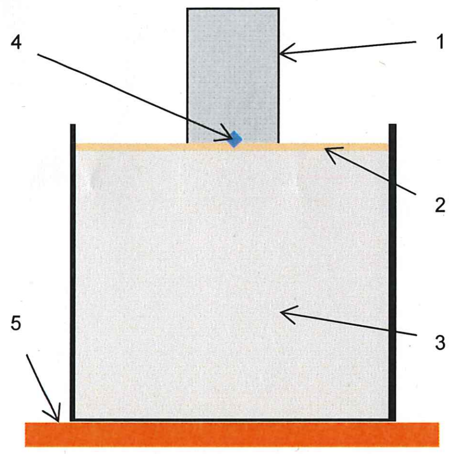
Neelaksh Sadhoo

Acoustics and Ionising Radiation Division
National Physical Laboratory
neelaksh.sadhoo@npl.co.uk

NPL

Tissue phantom for assessment of surface temperature of an ultrasonic transducer

Schematic diagram of a typical setup to measure surface temperature



1. Ultrasonic transducer under test
2. Silicone skin-mimic (0.5 to 1.5 mm)
3. Agar tissue-mimicking material (TMM)
4. Thermal sensor (thermocouple)
5. Acoustic absorber

Note: Thermal sensor and acoustic absorber are not included as part of this phantom

Specifications

The TMM complies with the specification given in clause 11 of IEC 60601-2-37 Ed 2, and is prepared following guidelines given in Annex DD of the same standard.

Maintenance

The TMM should be stored in the closed container under normal laboratory conditions (18–25 °C). While it is stored, keep the TMM in a water/glycerol solution to prevent it from drying out and to avoid air contact. This solution contains 88.1 % (by weight) deionised water and 11.9 % (by weight) glycerol (purity > 99 %). While the TMM is stored, its surface should be submerged by at least 5 mm of solution.

The shelf life of the TMM, if it is preserved without air contact, is at least 1 year. To extend the shelf life to at least 2 years, add to the storage solution an anti-fungal agent: 0.5 % (by weight) benzalkonium chloride.

Disposal

For disposal, local regulations should be followed. Alternatively, the samples may be returned (by prior arrangement) to the Acoustics group at NPL.

Acoustic and thermal properties of materials (from Annex DD of IEC 60601-2-37 Ed 2)

Sample	Velocity C ($m\ s^{-1}$)	Density ρ ($kg\ m^{-3}$)	Attenuation coefficient α ($dB\ cm^{-1}\ MHz^{-1}$)	Acoustic Impedance Z ($kg\ m^{-2}\ s^{-1}$)	Spec. heat capacity C ($J\ kg^{-1}\ K^{-1}$)	Thermal conductivity κ ($W\ m^{-1}\ K^{-1}$)	Thermal diffusivity D ($m^2\ s^{-1}$)	Source of data
TMM	1540	1050	0.5	1.6×10^6	3800	0.58	0.15×10^{-6}	TNO
Silicone rubber	1021	1243	1.8	1.3×10^6	-	0.25	-	TNO/Dow Corning

Proportion of pure components in TMM

Component	% (by weight)
Glycerol	11.21
Water	82.95
Benzalkonium chloride	0.47
Silicon carbide (SiC (-400 mesh))	0.53
Aluminium oxide (Al_2O_3 (0.3μm))	0.88
Aluminium oxide (Al_2O_3 (3μm))	0.94
Agar	3.02
Sum	100

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Switchboard 020 8977 3222 www.npl.co.uk/contact

Important notes for the storage and use of the NPL agar-based Thermal Test Phantoms (TTPs)

1. The TTP material is fragile and must be handled with care.

2. On delivery, remove the polystyrene spacers, which are needed only for protection during transport, and remove any small pieces of polystyrene which might have come off the spacers.

3. Store the TTP upright, in the closed container, under normal laboratory conditions (18-25°C). Do not expose the TTP to temperatures below 5°C or above 55°C.

4. If the TTP is stored at a significantly different temperature from the one it is used at, it may take up to 24 hours for the centre of the TTP to reach the new ambient temperature.

5. While stored, keep the material covered in the 12% glycerol/water mixture to prevent it from drying out and to avoid air contact.

6. During use the surface of the TTP should be protected from drying out by covering with one of the silicone rubber skin mimic pieces (other covering materials can also be used) or a thin layer of the 12% glycerol/water mixture (water can be used as an alternative for short periods of use but not for storage). If using the silicone rubber skin mimic pieces (or another solid covering material), a thin layer of the 12% glycerol/water mixture is required on top of the TTP material to keep it moist and to ensure acoustic and thermal coupling to the TTP.

7. When using a transducer with the TTP for investigations, the pressure applied should be the minimum necessary for good thermal contact. Excessive pressure can damage the TTP, leaving permanent indentations or occasionally even cracks. High pressures can arise particularly around the edge of transducers or other objects in contact with the TTP.

8. Some variation in the appearance, mechanical and physical properties is to be expected. We are also not able to guarantee any specific mechanical properties such as stiffness, fracture strength or elastic limit.

9. Due to the fragile nature of the TTP material, some cosmetic damage may occur, especially around the top edge during transport or due to rough handling. Provided this damage is away from the insonated area and any spaces are filled with the 12% glycerol/water mixture, it will not affect the performance of the product.

10. A small number of bubbles may be present on the top surface of the TTP. Provided they are away from the insonated area they will not affect the performance of the product.

For phantoms with an internal lumen or cavity only

11. Ensure that the TTP is stored with the filling piece (if supplied) inserted into the cavity to prevent the walls of the cavity distorting over time. If there is no filling piece, the cavity must be filled with the 12% glycerol/water mixture during storage.

12. Regarding using gel as a couplant, it may be difficult to remove old gel from the bottom of the cavity. It is preferable to use a less viscous liquid couplant if this can be done without affecting the temperature rise significantly.

13. Take care not to form an air-tight seal around the transducer in the cavity. There needs to be enough room for the coupling medium to flow into the space created when starting to withdraw the transducer. Otherwise (as we have discovered!) the resulting vacuum makes to

difficult to withdraw the transducer and can damage the internal surface of the cavity. If using a gel couplant, withdraw the transducer very slowly to begin with.

14. The top edge of the cavity is likely to be fragile and could be subject to quite high pressures if the edge of the transducer is in contact with it. (It may be possible to make a thin collar to go around and inside the top of the hole to spread the load.)

15. Don't push too hard on the transducer! Often the contact area will be smaller than for most transducers and it will not be possible to see the contact region. So it would be easy to produce contact pressures which are too high for the phantom material, which is not very elastic. Some break up of the material will not be thermally significant as long as there is fluid around to fill the cracks. But it is advisable to experiment on the top surface first to see how much force can be used safely.

Prepared by:
Neelaksh Sadhoo, Adam Shaw
8 December 2008

Agar Tissue Mimic Material

NPLUS0002

SECTION 1 Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name : Agar Tissue Mimic Material

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use : Tissue mimic material for use during ultrasound research.

1.3. Details of the supplier of the safety data sheet

Company identification : Acoustics, AIRD
National Physical Laboratory
Hampton Road
Teddington TW11 0LW UNITED KINGDOM
Tel: +44 (0) 20 8977 3222
Fax: +44 (0) 20 8943 6161
Email: acoustics_enquiries@npl.co.uk

Name and function of the responsible person : Group Leader, Acoustics, AIRD

1.4. Emergency telephone number

Emergency phone nr : +44 (0) 20 8977 3222

SECTION 2 Hazards identification

- **Inhalation** : May cause irritation to the respiratory tract and to other mucous membranes.
- **Skin contact** : May produce skin irritation.
- **Eye contact** : May cause eye irritation.
- **Ingestion** : May cause a light irritation of the linings of the mouth, throat, and gastrointestinal tract.

2.1. Classification of the substance or mixture

Classification EC 67/548 or EC 1999/45

Hazard Class and Category Code Regulation EC 1272/2008 (CLP)

2.2. Label elements

Labelling EC 67/548 or EC 1999/45

Symbol(s) :
None.

Labelling Regulation EC 1272/2008 (CLP)

- **Hazard pictograms code** : ---
- **Precautionary statements**

2.3. Other hazards

None under normal conditions.

SECTION 3 Composition/information on ingredients

Components : A gel stored in an aqueous glycerol solution.

SECTION 4 First aid measures

4.1. Description of first aid measures

First aid measures

- Inhalation	: Remove person to uncontaminated area. Seek medical advice.
- Skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical attention if ill effects develop.
- Eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
- Ingestion	: Rinse mouth. Do not induce vomiting. Seek medical advice.

SECTION 5 Fire-fighting measures

5.1. Extinguishing media

Extinguishing media

- Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards	: When exposed to heat, may decompose liberating hazardous gases.

5.3. Advice for fire-fighters

Protection against fire	: Do not enter fire area without proper protective equipment, including respiratory protection.
Prevention	: No naked lights. No smoking.
Special procedures	: Exercise caution when fighting any chemical fire.
Surrounding fires	: Use water spray or fog for cooling exposed containers.

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	: Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

6.2. Environmental precautions

Environmental precautions	: Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Clean up methods	: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible.

SECTION 7 Handling and storage

7.1. Precautions for safe handling

General	: Ventilate confined spaces before entering.
Handling	: Handle in accordance with good industrial hygiene and safety procedures. Ensure prompt removal from eyes, skin and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
Precautions in handling and storage	: Avoid all unnecessary exposure.

7.2. Conditions for safe storage, including any incompatibilities

Acoustics, AIRD
National Physical Laboratory Hampton Road Teddington TW11 0LW UNITED KINGDOM
Tel: +44 (0) 20 8977 3222
Fax: +44 (0) 20 8943 6161
Email: acoustics_enquiries@npl.co.uk

SECTION 7 Handling and storage (continued)

Storage : Store in tightly closed, properly ventilated containers away from heat, sparks, open flame. Keep container closed when not in use.

SECTION 8 Exposure controls/personal protection

8.1. Control parameters

Personal protection

- Respiratory protection : No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation.

- Skin protection : Wear suitable protective clothing.

- Eye protection : Safety glasses with side shields. Ensure eye bath is to hand.

- Hand protection : Wear gloves.

- Ingestion : When using, do not eat, drink or smoke.

Industrial hygiene : Provide good ventilation in process area to prevent formation of vapour.

SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state at 20 ℃ : A gel stored in an aqueous glycerol solution.

Colour : Grey.

Solubility in water : Insoluble.

SECTION 10 Stability and reactivity

10.2. Chemical stability

Stability : Stable under normal conditions.

10.4. Conditions to avoid

Conditions to avoid : Heat.

10.5. Incompatible materials

Materials to avoid : Strong acids. Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products : When heated to decomposition, emits toxic fumes.

SECTION 11 Toxicological information

11.1. Information on toxicological effects

Rat oral LD50 [mg/kg] : No data available.

Chronic toxicity : No evidence of carcinogenicity.

SECTION 12 Ecological information

12.1. Toxicity

SECTION 12 Ecological information (continued)

LC50-96 Hour - fish [mg/l] : No data available.

SECTION 13 Disposal considerations

13.1. Waste treatment methods

General : Avoid release to the environment. Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14 Transport information

General information : Not classified.

SECTION 15 Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Ensure all national/local regulations are observed.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006.

Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006.

Symbol(s) : None.
R Phrase(s) : None.
S Phrase(s) : None.
Other : None.

SECTION 16 Other information

Sources of key data used : Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended October 2007, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition.

Revision : All sections have been updated.

DISCLAIMER OF LIABILITY : The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. NPL makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.
This SDS was prepared in English.

The contents and format of this SDS are in accordance with REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

End of document

C

DOCUMENTATION FOR AIMS III WATER TANK

ONDA

Putting Confidence in Ultrasound

Acoustic Intensity Measurement System

AIMS III with Soniq Software

AIMS III is the latest generation hydrophone scanning system that enhances acoustic measurement productivity to map acoustic fields in liquids. User workflow is improved by productivity enhancements that save time in the measurement set-up, scanning, and reporting. These enhancements are based on decades of scanning technology development. Combined with *Soniq* software, the user benefits from real-time plotting, automated FDA reporting, and improved positioning performance. AIMS III continues to be the de facto standard scanning tank for hydrophone-based measurements.

Features:

- Productivity enhancements to measurement set-up, scanning, and reporting
- Compatible with Windows 7 (32 or 64 bit)
- Real-time plotting to confirm optimal measurement set-up early
- Automated diagnostic and physiotherapy reporting tables compliant with the latest IEC standards and FDA guidance documents
- Mechanical improvements to advance the positioning accuracy and reliability
- Automatic temperature readings with USB temperature probe
- .dll interface for external software control
- SmartSCAN to enable forward and reverse scanning to reduce scanning time
- Angular positioner to accommodate various orientations including “shoot down”
- Over 100 measurement parameters available

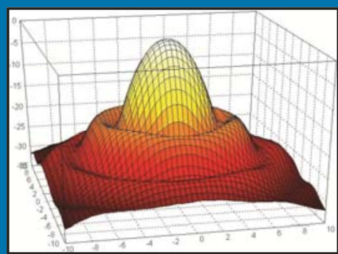
Applications:

The AIMS III offers the right balance between versatility and easy-to-use operations to meet the most advanced requirements in R&D characterization, regulatory testing, and production QC.

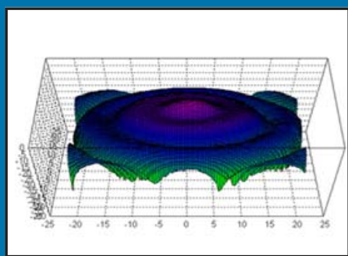
The system is commonly used to characterize and validate transducer designs. Features such as the 5 axis motion, various firing/measuring orientations, and real-time plotting make it the tool of choice to meet the most stringent environments.

The AIMS platform has also established itself as the premier instrument in the regulatory community. The system allows for automatic reporting compliant with standards for diagnostic equipment (AIUM-NEMA UD-2/UD-3 and IEC 60601-2-37, 61217-1, and 62359) as well as for physiotherapy (US 21 CFR1050.10 and IEC 60601-2-5 and 61689).

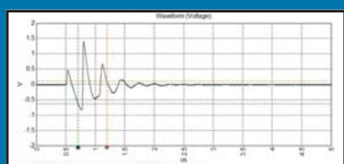
AIMS III System



2D Beam Intensity Plot



2D transaxial planar scan of a 1 MHz physiotherapy probe



Waveform

Technical Specifications

Tank:
- Acrylic tank with water circulation connections
- Large viewing area
- Compatible with AQUAS water conditioner
- Inside Dimensions:
  Small: 0.73 m X 0.36 m X 0.44 m
  Large: 0.89 m X 0.51 m X 0.58 m

Motion:
- Positioning repeatability: < 5 µm
- X, Y, Z step size: 5.5 µm
- Rotary step size: 0.025 °
- Max speed: 11 mm per second
- Travel range (with standard HW fixtures):
  Small: 380 mm x 265 mm x 330 mm vertical
  Large: 575 mm x 425 mm x 495 mm vertical
- 3-axis scanning (standard); 2-rotational axis (optional)

Temperature:
- Temperature Probe , 3 meter cable with USB connection

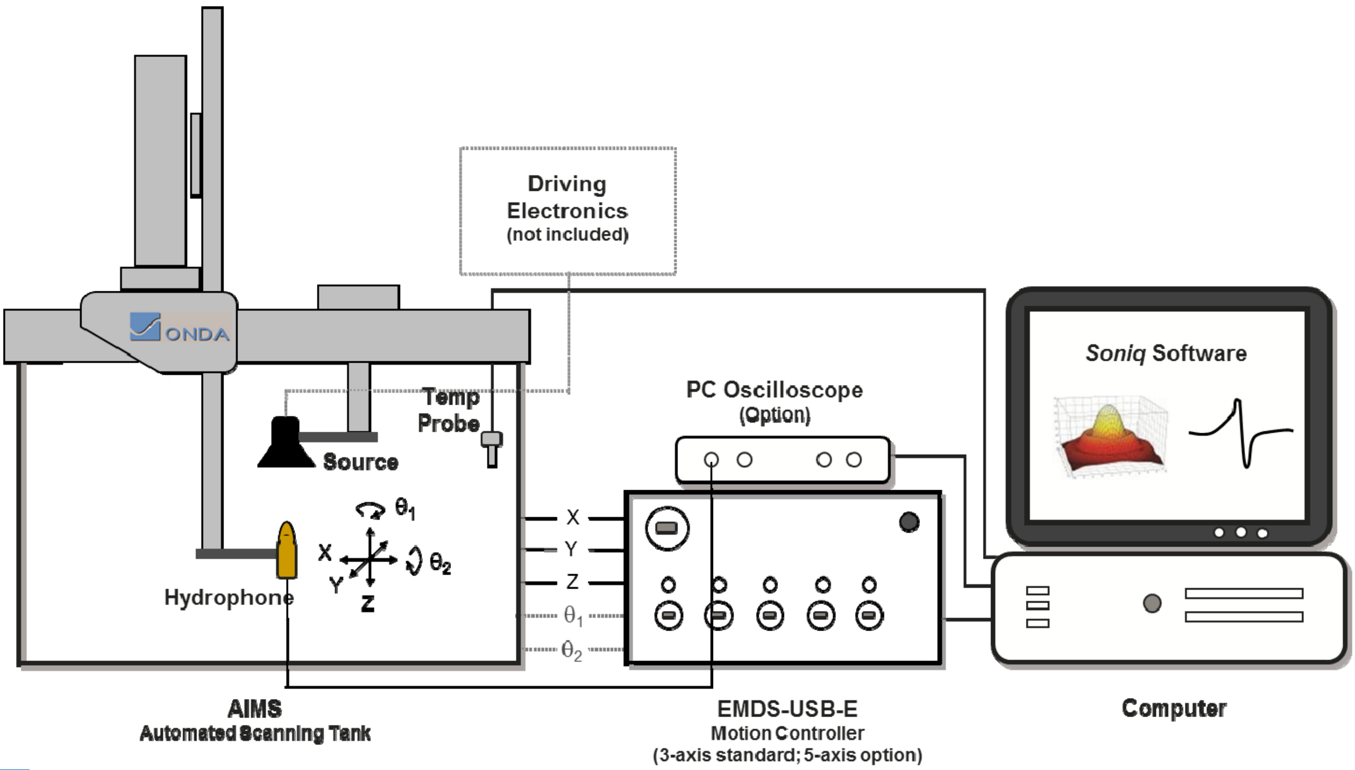
***Soniq* Software:**
- Mapping of acoustic fields in 1, 2, or 3D
- Acquisition of waveform data for analysis
- Real-time plotting of data acquisition
- Over 100 calculated parameters including Prms, Pii, Ispta, TI, and MI.
- Compliant with AIUM-NEMA and IEC standards.
- Waveform deconvolution
- Automatic temperature measurements

Recommended PC Requirements:
- PC: Windows 7 (32 and 64 bit), Intel Core i3, dual core 3.6 GHz, 4 GB RAM, 500 GB HD, DVD drive, 7 available USB ports
- Software:
  Required: Adobe Reader, PicoScope.
  Optional: Microsoft Excel and web browser.

Oscilloscope:
- Support for PicoScope 5244A

Simple Measurement Set-up

[Not to scale]



ONDA 1290 Hammerwood Avenue, Sunnyvale, CA 94089, USA | Tel: 408.745.0383 | Fax: 408.745.0956 | www.ondacorp.com

D

DOCUMENTATION FOR THE AQUAS WATER TREATMENT UNIT

Putting Confidence in Ultrasound

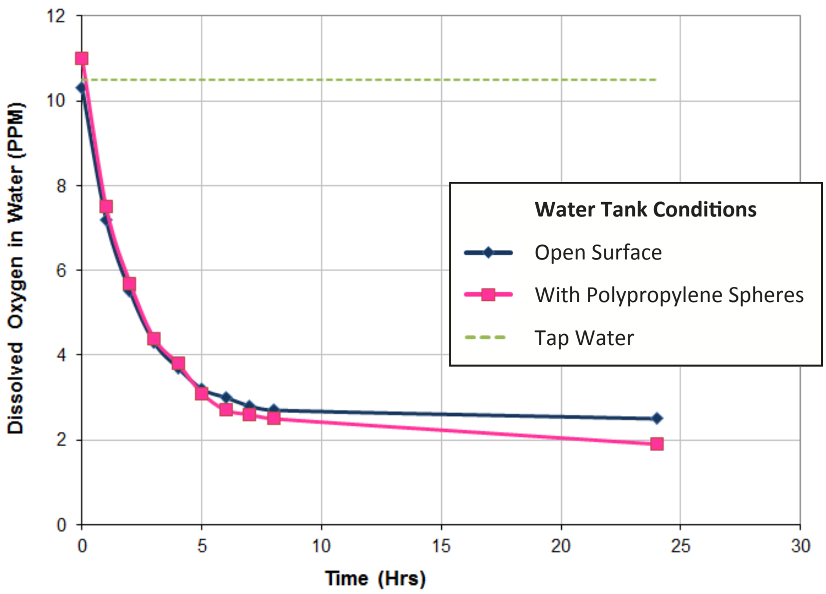
Water Conditioner (AQUAS-10)

The AQUAS-10 is a complete water conditioner designed for use with ultrasound measurements in compliance with Technical Report IEC 62781. Because the quality of acoustic measurement can be significantly affected by various impurities - such as dissolved gases, deionized compounds, suspended particulates, and biological contaminants - a water treatment system is critical. The AQUAS-10 controls each of these factors in a fully integrated simple-to-use system.

Features:

- Simple installation for use with ultrasound measurement system
- Degasses water to remove undesired bubbles that perturb the acoustic field
- Deionizes water to minimize electrical noise received by hydrophone
- Removes suspended particles that scatter ultrasound
- Removes biological contaminants that pose as a health risk
- Remote power switch easily turns the water pump ON and OFF
- Transparent removable front panel quickly determines maintenance needs
- Replace particle and DI filters in less than 15 minutes
- Water sensor safeguards against any leaks
- Compact portable design fits under standard laboratory bench

Degassing Performance:



* Results tested at room temperature with AIMS III (S) tank which has an water surface area of ~3900 cm^2

** Layer of hollow polypropylene spheres (1.4 inch diam) added to the AIMS III (S) tank, reducing the surface area and limiting oxygen re-absorption

AQUAS-10 Water Conditioner

Remote ON/OFF Pump Switch

Revised: November 30, 2016

Technical Specifications

- **Degassing:** dissolved oxygen reduced down to 4 ppm (or mg/L) in 5 hours for a 100 liter tank
- **Flow rate:** approx. 1.2 L per min
- **Filter cartridges:** 1 micron particle filter, deionizing filter
- **UV Sterilizer:** in-line ultraviolet lamp
- **Power:** 110-120VAC, 50/60Hz, approx. 2 amps running
  220-240VAC, 50/60Hz, approx. 1 amps running
- **Cabinet dimensions:** 55 cm (W) x 56 cm (H) x 52 cm (D)
  21.5” (W) x 22” (H) x 20.5” (D)
- **System Dry Weight (approximate):** 25 kilograms or 55 pounds

Contents

- Two (2) hoses for inlet and outlet, 0.5” ID and 36” length
- Two (2) sets of DI and particle filters (one set as spare)
- Filter canister removal tool
- Remote ON/OFF switch for water pump (10 feet long cable)
- AC power cord

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E
DOCUMENTATION FOR ONDA HMB-0500 HYDROPHONE

ONDA

Putting Confidence in Ultrasound

HM Hydrophones

The HM Series membrane hydrophones are designed for measuring pulsed ultrasound fields. Their extremely flat sensitivity results in the best reproduction of acoustic waveforms. Version A is the traditional hydrophone configuration, and a more rugged version B prevents membrane vibration during scanning motion. Version A is recommended for high power ultrasound work, where the absorption of energy by the backing could result in damage to the hydrophone. Both types are excellent choices as in-house primary or secondary standard, and for general purpose field mapping.

HM Hydrophone

Features

- Rugged
- High Sensitivity
- Broadband
- Sealed design
- Integral preamplifier
- Choice of aperture sizes

Models

- HMA — free membrane
- HMB — backed membrane

Technical Specifications

	HMA-0200	HMA-0500	HMB-0200	HMB-0500
Frequency range (±3dB)	0.5 to 45 MHz			
Nominal Sensitivity [dB re 1V/µPa] *	-260	-248	-256	-244
Nominal Sensitivity [nV/Pa]	100	398	158	631
Max Pressure (p-p) within Linearity Range of Integral Preamp (MPa) **	53	12	25	7
Output Impedance	50 Ω			
Max. Operating Temperature	40 °C			

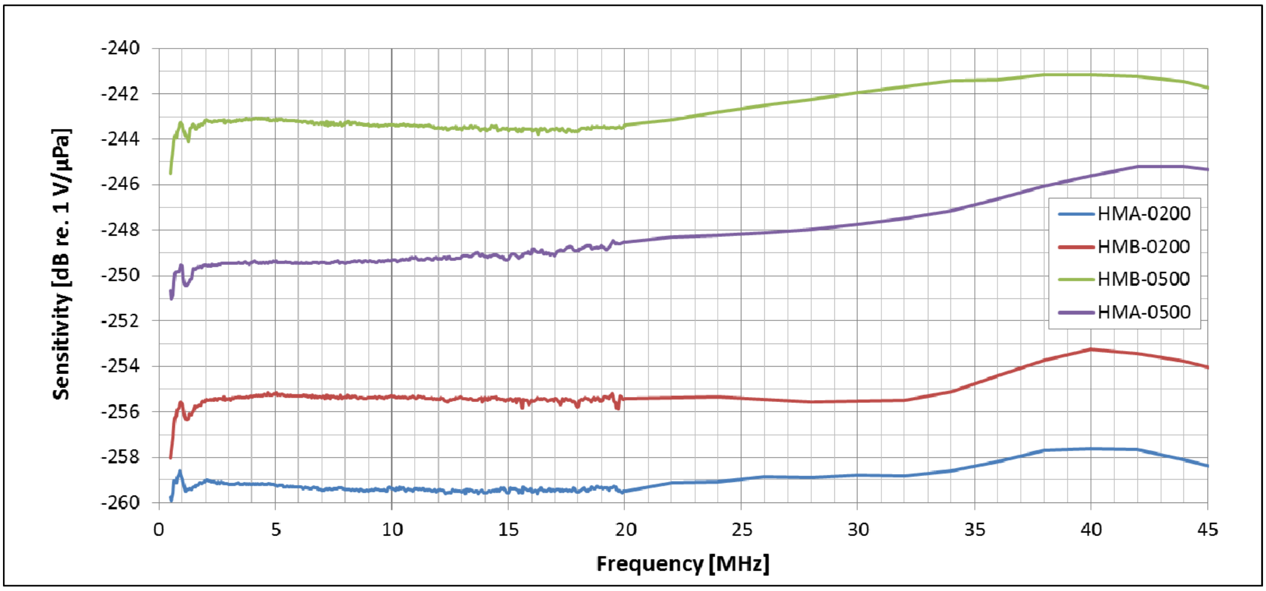
* Provided with traceable calibration 1-20 MHz at 50 KHz intervals. For other calibrations available visit our web site.

** Based on criterion defined by the International Electrotechnical Commission (IEC)

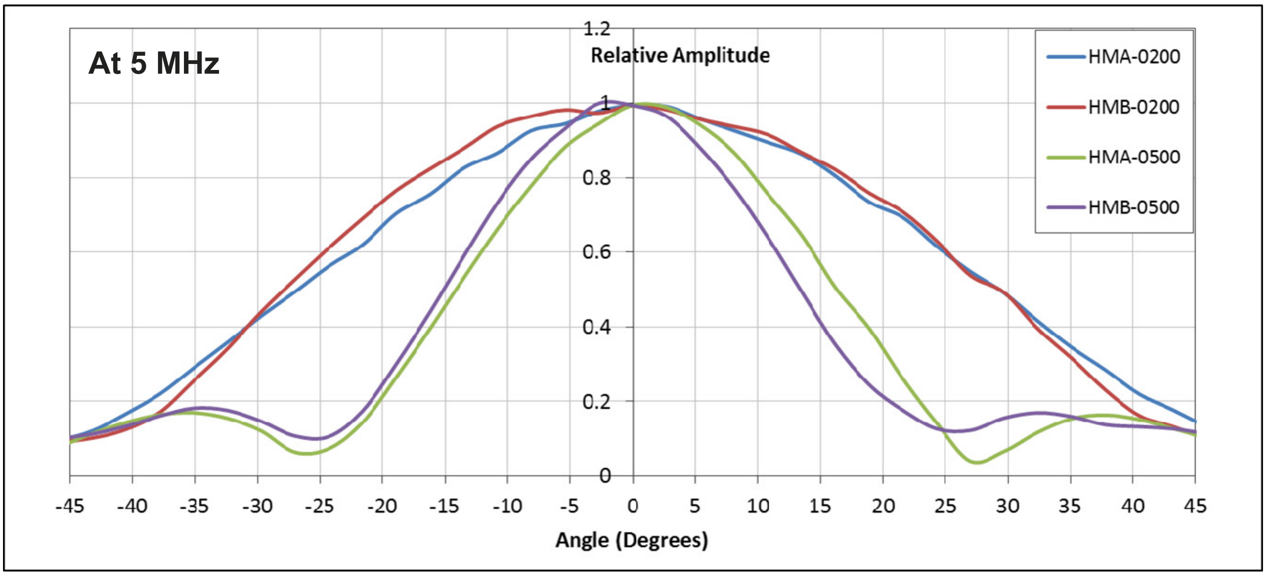
Specifications are subject to change without notice.

Revised: October 15, 2015

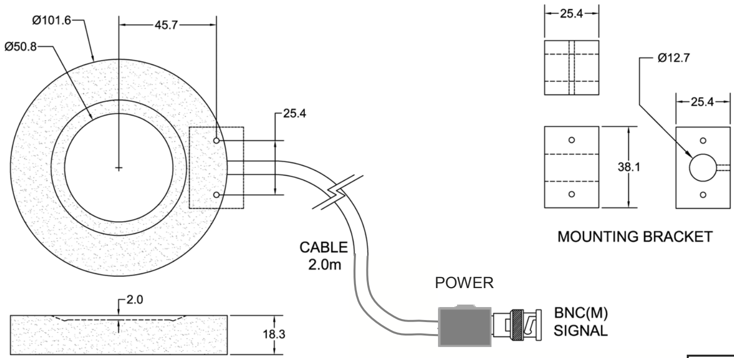
Typical Sensitivity Plot



Typical Directivity Plot



Mechanical



Universal Power Supply Included

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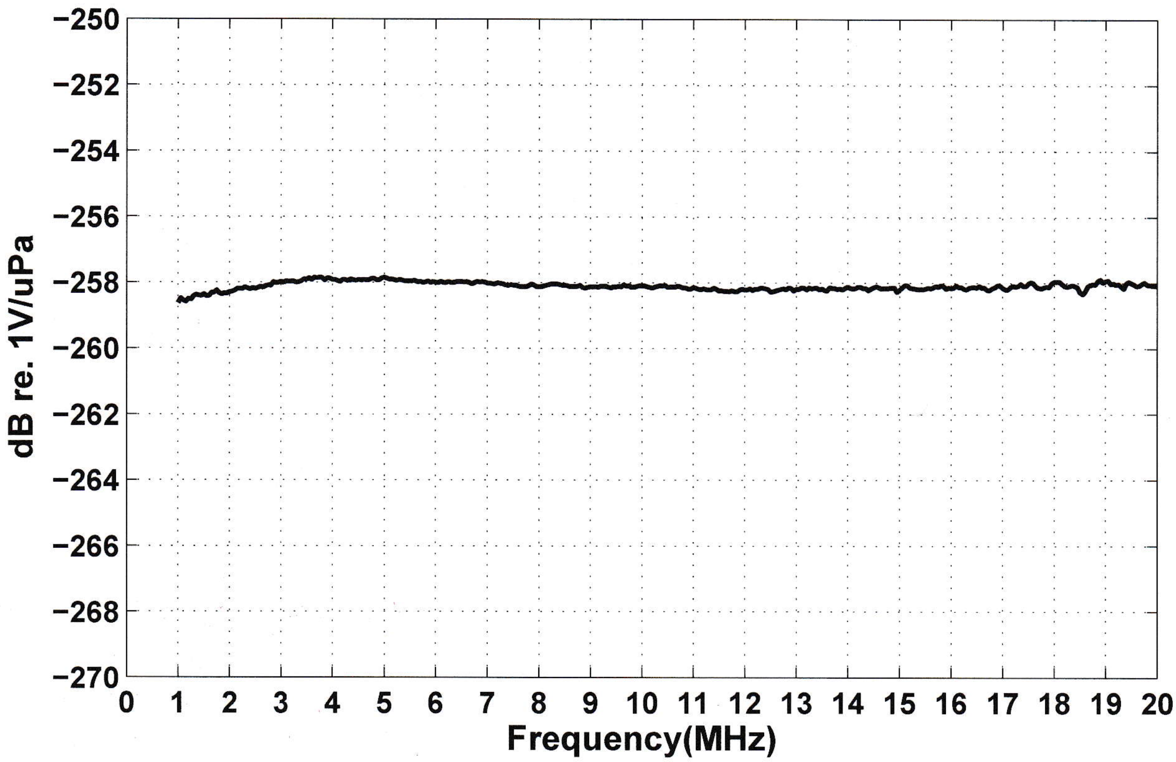
Certificate of Hydrophone Calibration

Hydrophone:	Onda HMB-0200 S/N: 1347
Cable/Adaptor:	NONE
External Amplifier:	NONE
Electrical Loading:	50Ohms
Temperature:	23.5 deg C
Calibration Completed:	02-Aug-2016
Data File Name:	HMB0200-1347_xxxxxx-xxxx-xx_xx_20160802.txt



Calibration Method: Stepped single frequency comparison to Reference Standard

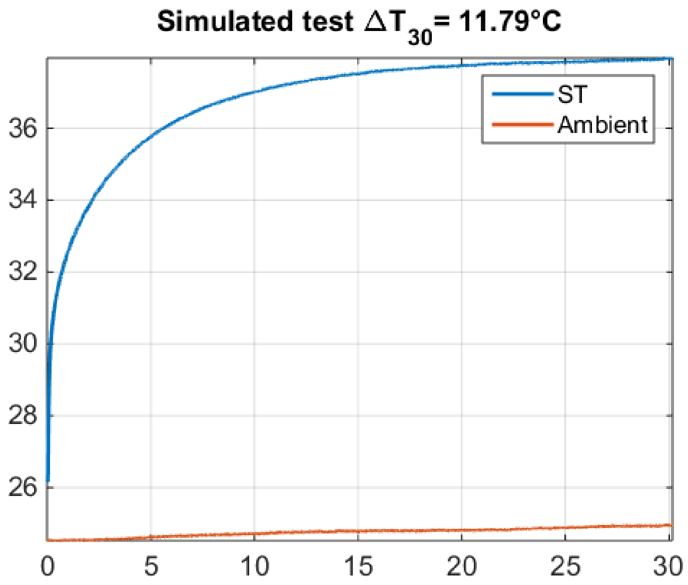
Measurement Uncertainty: 1-15 MHz: 1 dB; 15-20 MHz: 1.5 dB

Signature: ________________ Date: 8/2/2016

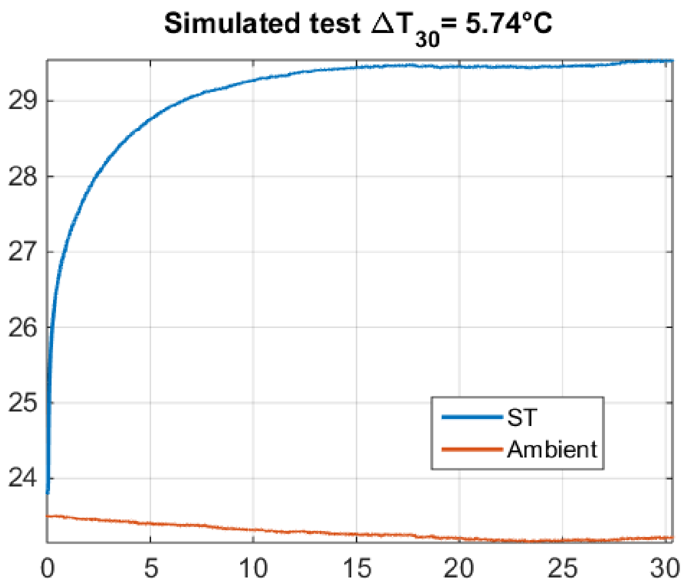
1290 Hammerwood Avenue, Sunnyvale, CA 94089 T: (408) 745-0383 F: (408) 745-0956
www.ondacorp.com

F TEMPERATURE MEASUREMENTS

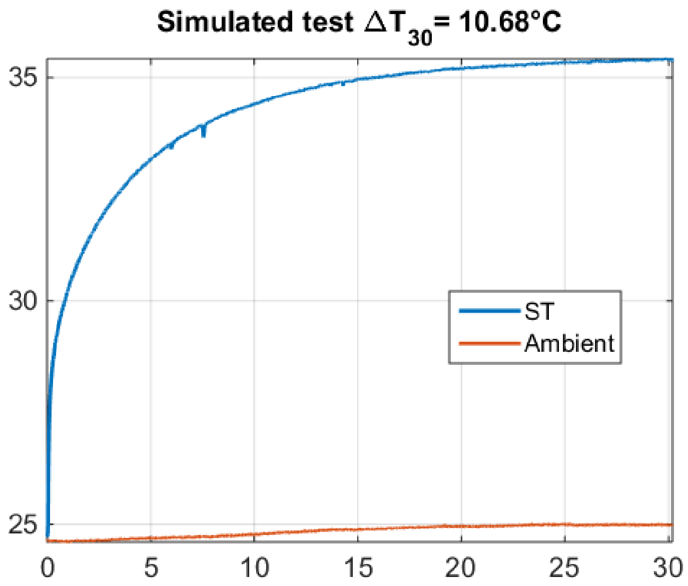
F.1 PW NAVIGATION, PRF = 9000 HZ, V_{peak}=15 V, f = 4.808 MHZ, 2.5 CYCLES, STILL-AIR



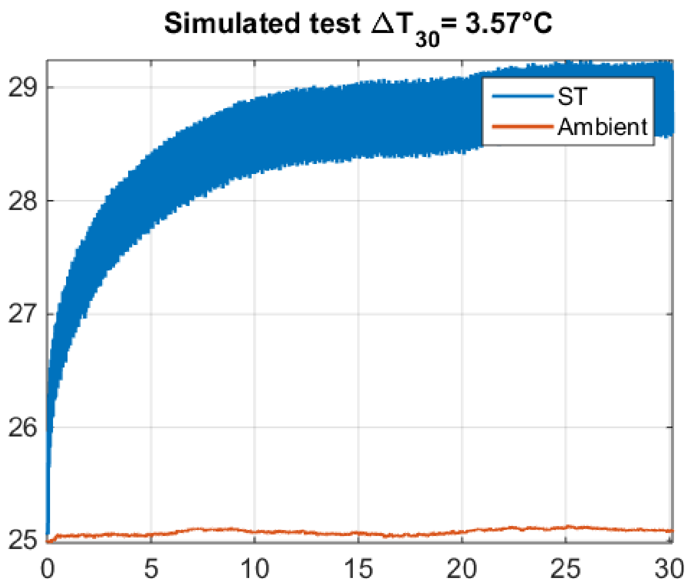
F.2 PW NAVIGATION, PRF = 9000 HZ, V_{peak}=15 V, f = 4.808 MHZ, 2.5 CYCLES, PHANTOM



F.3 PW NAVIGATION, PRF = 9000 HZ, V_{peak}=15 V, f = 6.250 MHZ, 2.5 CYCLES, STILL-AIR

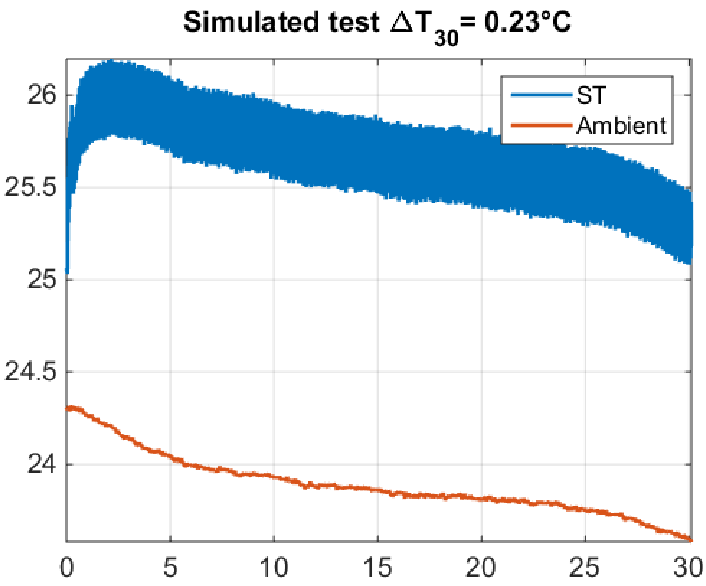


F.4 PW RECORDING (1.5 S + 1.0 S PAUSE), PRF = 12000 HZ, V_{peak}=15 V, f = 4.808 MHZ, 2.5 CYCLES, STILL-AIR



F.5 PW RECORDING (1.5 S + 1.0 S PAUSE), PRF = 12000 HZ, V_{peak}=15 V, f = 6.250 MHZ, 2.5 CYCLES, PHAN

F.5 PW RECORDING (1.5 S + 1.0 S PAUSE), PRF = 12000 HZ, V_{peak}=15 V, f = 6.250 MHZ, 2.5 CYCLES, PHANTOM



G IEC TABLES

MODE________________

Index Label			*MI*	*TIS*		*TIB*		*TIC*
				At Surface	**Below Surface**	**At Surface**	**Below Surface**	
Maximum index value			0.2408	1.224		2.445		n/a
Index component value			---	0.47	1.224	2.445	1.177	---
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.533	---	---	---	---	---
	P	(mW)	---	89.7		89.7		n/a
	P_{1x1}	(mW)	---	20.18		20.18		---
	z_s	(cm)	---	---	1.582	---	---	---
	z_b	(cm)	---	---	---	---	1.948	---
	z_{MI}	(cm)	2.06	---	---	---	---	---
	$z_{pii,\alpha}$	(cm)	2.06	---	---	---	---	---
	f_{awf}	(MHz)	4.89	4.89		4.89		n/a
Other Information	*prr*	(Hz)	12000	---	---	---	---	---
	srr	(Hz)	n/a	---	---	---	---	---
	n_{pps}		n/a	---	---	---	---	---
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	10.96	---	---	---	---	---
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	72.7	---	---	---	---	---
	I_{spta} at z_{pii} or z_{sii}	(mW/cm²)	159.5	---	---	---	---	---
	p_r at z_{pii}	(MPa)	0.787	---	---	---	---	---
---	---		---	---	---	---	---	---
Operating control conditions	See accompanying file for operating control conditions: C:\Users\Public\Documents\GE L9 & Verasonics\15112017\4d8MHz_2d5cycles_10V_12kHz_OutputIEC201103_Ctrls.txt							

MODE______________

Index Label			*MI*	*TIS*		*TIB*		*TIC*
				At Surface	**Below Surface**	**At Surface**	**Below Surface**	
Maximum index value			0.357	2.961		5.91		n/a
Index component value			---	1.141	2.961	5.91	2.815	---
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.791	---	---	---	---	---
	P	(mW)	---	216.8		216.8		n/a
	P_{1x1}	(mW)	---	48.9		48.9		---
	z_s	(cm)	---	---	1.582	---	---	---
	z_b	(cm)	---	---	---	---	1.906	---
	z_{MI}	(cm)	2.06	---	---	---	---	---
	$z_{pii,\alpha}$	(cm)	2.06	---	---	---	---	---
	f_{awf}	(MHz)	4.9	4.9		4.9		n/a
Other Information	*prr*	(Hz)	12000	---	---	---	---	---
	srr	(Hz)	n/a	---	---	---	---	---
	n_{pps}		n/a	---	---	---	---	---
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	26.24	---	---	---	---	---
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	173.6	---	---	---	---	---
	I_{spta} at z_{pii} or z_{sii}	(mW/cm²)	382	---	---	---	---	---
	p_r at z_{pii}	(MPa)	1.131	---	---	---	---	---
---	---		---	---	---	---	---	---
Operating control conditions	See accompanying file for operating control conditions: C:\Users\Public\Documents\GE L9 & Verasonics\15112017\4d8MHz_2d5cycles_15V_12kHz_OutputIEC201103_Ctrls.txt							

MODE________________

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			0.2018	0.561		1.071		n/a
Index component value			---	0.2587	0.561	1.071	0.448	---
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.492	---	---	---	---	---
	P	(mW)	---	39.3		39.3		n/a
	P_{1x1}	(mW)	---	9.14		9.14		---
	z_s	(cm)	---	---	1.667	---	---	---
	z_b	(cm)	---	---	---	---	2.06	---
	z_{MI}	(cm)	2.215	---	---	---	---	---
	$z_{pii,\alpha}$	(cm)	2.215	---	---	---	---	---
	f_{awf}	(MHz)	5.94	5.94		5.94		n/a
Other Information	prr	(Hz)	12000	---	---	---	---	---
	srr	(Hz)	n/a	---	---	---	---	---
	n_{pps}		n/a	---	---	---	---	---
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	8.28	---	---	---	---	---
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	31.4	---	---	---	---	---
	I_{spta} at z_{pii} or z_{sii}	(mW/cm²)	84.6	---	---	---	---	---
	p_r at z_{pii}	(MPa)	0.758	---	---	---	---	---
---	---		---	---	---	---	---	---
Operating control conditions	See accompanying file for operating control conditions: C:\Users\Public\Documents\GE L9 & Verasonics\15112017\6d25MHz_1d5cycles_10V_12kHz_OutputIEC201103_Ctrls.txt							

MODE________________

Index Label			MI	TIS At Surface	TIS Below Surface	TIB At Surface	TIB Below Surface	TIC
Maximum index value			0.2993	1.356		2.592		n/a
Index component value			---	0.627	1.356	2.592	1.092	---
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.728	---	---	---	---	---
	P	(mW)	---	95		95		n/a
	P_{1x1}	(mW)	---	22.22		22.22		---
	z_s	(cm)	---	---	1.667	---	---	---
	z_b	(cm)	---	---	---	---	2.06	---
	z_{MI}	(cm)	2.257	---	---	---	---	---
	$z_{pii,\alpha}$	(cm)	2.257	---	---	---	---	---
	f_{awf}	(MHz)	5.92	5.92		5.92		n/a
Other Information	prr	(Hz)	12000	---	---	---	---	---
	srr	(Hz)	n/a	---	---	---	---	---
	n_{pps}		n/a	---	---	---	---	---
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	20.71	---	---	---	---	---
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	76	---	---	---	---	---
	I_{spta} at z_{pii} or z_{sii}	(mW/cm²)	208.9	---	---	---	---	---
	p_r at z_{pii}	(MPa)	1.1	---	---	---	---	---
---	---		---	---	---	---	---	---
Operating control conditions	See accompanying file for operating control conditions: C:\Users\Public\Documents\GE L9 & Verasonics\15112017\6d25MHz_1d5cycles_15V_12kHz_OutputIEC201103_Ctrls.txt							

MODE________________

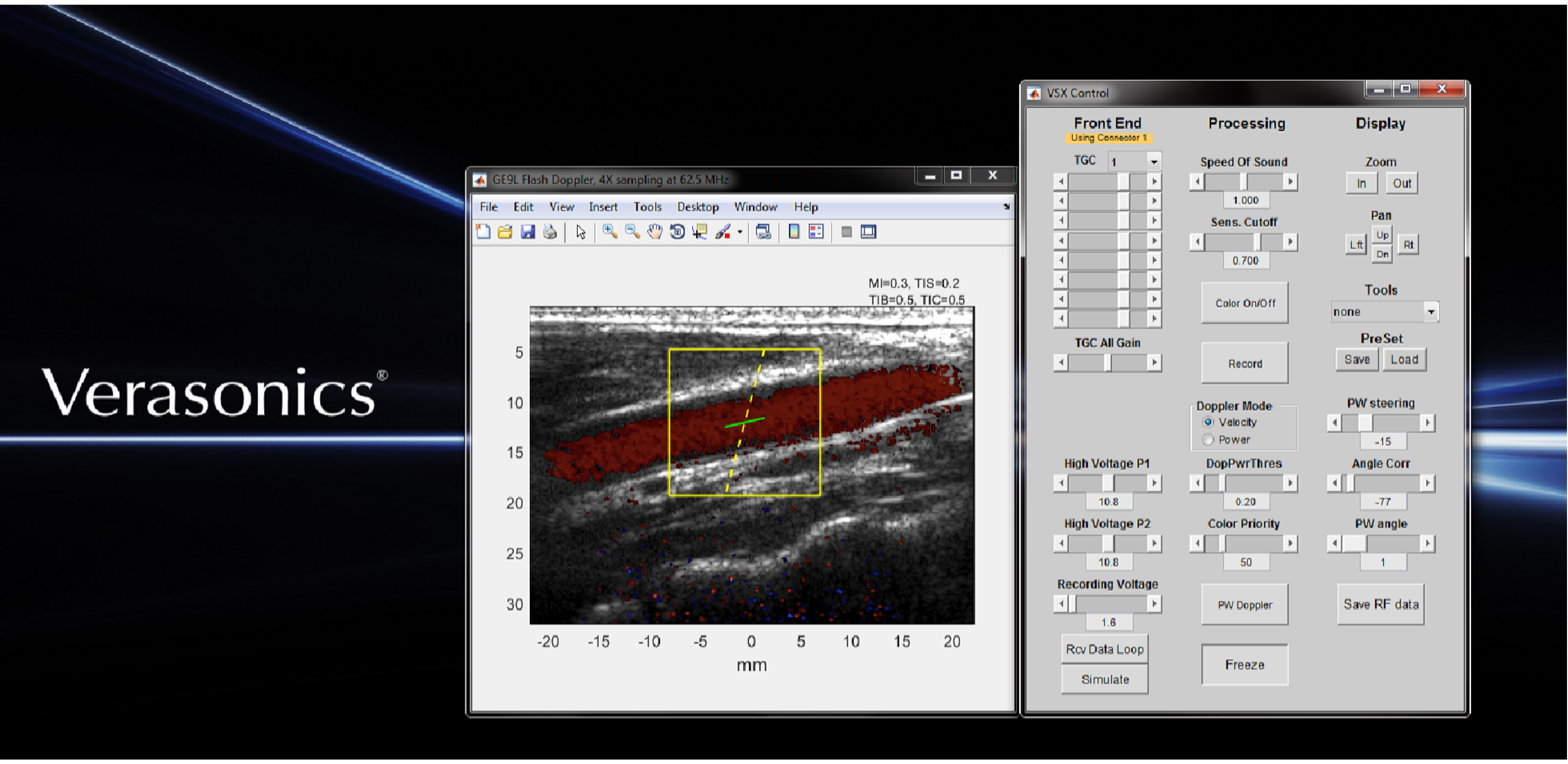
Index Label			***MI***	***TIS***		***TIB***		***TIC***
				At Surface	**Below Surface**	**At Surface**	**Below Surface**	
Maximum index value			0.2014	0.887		1.681		n/a
Index component value			---	0.418	0.887	1.681	0.717	---
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.495	---	---	---	---	---
	P	(mW)	---	61.6		61.6		n/a
	P_{1x1}	(mW)	---	14.52		14.52		---
	z_s	(cm)	---	---	1.653	---	---	---
	z_b	(cm)	---	---	---	---	2.046	---
	z_{MI}	(cm)	2.243	---	---	---	---	---
	$z_{pii,\alpha}$	(cm)	2.243	---	---	---	---	---
	f_{awf}	(MHz)	6.05	6.05		6.05		n/a
Other Information	prr	(Hz)	12000	---	---	---	---	---
	srr	(Hz)	n/a	---	---	---	---	---
	n_{pps}		n/a	---	---	---	---	---
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	9.41	---	---	---	---	---
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	49.1	---	---	---	---	---
	I_{spta} at z_{pii} or z_{sii}	(mW/cm²)	145.5	---	---	---	---	---
	p_r at z_{pii}	(MPa)	0.796	---	---	---	---	---
---	---		---	---	---	---	---	---
Operating control conditions	See accompanying file for operating control conditions: C:\Users\Public\Documents\GE L9 & Verasonics\15112017\6d25MHz_2d5cycles_10V_12kHz_OutputIEC201103_Ctrls.txt							

MODE ________________

Index Label			*MI*	*TIS*		*TIB*		*TIC*
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			0.2944	2.194		4.2		n/a
Index component value			---	1.044	2.194	4.2	1.744	---
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.723	---	---	---	---	---
	P	(mW)	---	153.9		153.9		n/a
	P_{1x1}	(mW)	---	36.4		36.4		---
	z_s	(cm)	---	---	1.681	---	---	---
	z_b	(cm)	---	---	---	---	2.088	---
	z_{MI}	(cm)	2.369	---	---	---	---	---
	$z_{pii,\alpha}$	(cm)	2.369	---	---	---	---	---
	f_{awf}	(MHz)	6.03	6.03		6.03		n/a
Other Information	*prr*	(Hz)	12000	---	---	---	---	---
	srr	(Hz)	n/a	---	---	---	---	---
	n_{pps}		n/a	---	---	---	---	---
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	23.38	---	---	---	---	---
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	121.3	---	---	---	---	---
	I_{spta} at z_{pii} or z_{sii}	(mW/cm²)	354	---	---	---	---	---
	p_r at z_{pii}	(MPa)	1.135	---	---	---	---	---
---	---		---	---	---	---	---	---
Operating control conditions	See accompanying file for operating control conditions: C:\Users\Public\Documents\GE L9 & Verasonics\15112017\6d25MHz_2d5cycles_15V_12kHz_OutputIEC201103_Ctrls.txt							

H

INDEX DISPLAY


Verasonics®
GE9L Flash Doppler, 4X sampling at 62.5 MHz
File Edit View Insert Tools Desktop Window Help
MI=0.3, TIS=0.2
TIB=0.5, TIC=0.5
5
10
15
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25
30
-20 -15 -10 -5 0 5 10 15 20
mm
VSX Control
Front End
Using Connector 1
Processing
Display
TGC
1
Speed Of Sound
1.000
Zoom
In Out
Sens. Cutoff
0.700
Pan
Lft Up Dn Rt
Color On/Off
Tools
none
TGC All Gain
Record
PreSet
Save Load
Doppler Mode
Velocity
Power
PW steering
-15
High Voltage P1
10.8
DopPwrThres
0.20
Angle Corr
-77
High Voltage P2
10.8
Color Priority
50
PW angle
1
Recording Voltage
1.6
PW Doppler
Save RF data
Rcv Data Loop
Simulate
Freeze

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