Guidelines for *Journal of Ultrasound in Medicine* Authors and Reviewers on Measurement and Reporting of Acoustic Output and Exposure

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Abbreviations
AIUM, American Institute of Ultrasound in Medicine; *JUM*, *Journal of Ultrasound in Medicine*; MI, mechanical index; MR, mandatory reporting; NEMA, National Electrical Manufacturers Association; ODS, Output Display Standard; TI, thermal index

Received December 17, 2004, from the Molecular Physics Laboratory, SRI International, Menlo Park, California USA (P.D.E.); Department of Obstetrics and Gynecology, University of Chicago Hospital, Chicago, Illinois USA (J.S.A.) (now with Department of Obstetrics and Gynecology, Rush University Medical Center, Chicago, Illinois USA); Department of Radiology, University of Michigan, Ann Arbor, Michigan USA (P.L.C.); Rochester Center for Biomedical Ultrasound and Department of Electrical and Computer Engineering, University of Rochester, Rochester, New York USA (E.L.C.); and Siemens Medical Solutions USA, Inc, Mountain View, California USA (K.L.S.). Revision requested December 20, 2004. Revised manuscript accepted for publication April 5, 2005.

This invited report was solicited by Deputy Editor Thomas Nelson, PhD, of the Journal of Ultrasound in Medicine (JUM) and has been reviewed by the American Institute of Ultrasound in Medicine's Technical Standards and Bioeffects Committees. The opinions expressed herein are those of the authors and not necessarily those of the members of these committees, the editors of the JUM, or the American Institute of Ultrasound in Medicine. Mr Sandstrom is an employee of Siemens Medical Solutions USA, Inc, but has no commercial, proprietary, or financial interest in the subjects and materials discussed herein.

We are grateful for the advice of the AIUM Technical Standards and Bioeffects Committees, both of which reviewed this article in draft, and for the contributions of the JUM editors when we sought clarification of their objectives. Deputy Editor Thomas Nelson, PhD, also contributed an outline of the accompanying tables. Morton Miller, PhD, contributed to the discussions that defined the scope of this article. We thank them both.

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Objective. This report responds to a request from a deputy editor of the *Journal of Ultrasound in Medicine* (*JUM*) for guidelines for measurement and reporting of acoustic output and exposure. The request was addressed to the American Institute of Ultrasound in Medicine's Technical Standards and Bioeffects Committees, which appointed a task group to draft a response. A basic premise of scientific reporting is the expectation that another investigator will wish to replicate a reported study. Therefore, it is essential that all pertinent information available or accessible to an investigator be reported. ***Methods and Guidelines.*** Rationales and checklists are presented to draw authors' attention to aspects of experimental design and exposimetry that require consideration in project planning, execution, and reporting. Checklists are presented for use in 2 distinct categories of activity: (1) clinical settings in which a biophysical end point (bioeffect) is observed incidentally during another procedure; and (2) research projects specifically planned to investigate biophysical end points (bioeffects). Reportable parameters for the former are limited to essentials, whereas those for the latter are presented in detail. Certain basic information is recommended as mandatory for reports in both categories; certain additional parameters are designated as expected (at 3 levels of importance) when results of research are reported. Clinical investigators should comply with the short, first table (Table 1) and the last (Table 5) if applicable, but are encouraged to include additional data specified in other tables, as appropriate. Bioeffects experimenters should comply with Table 2 and such supplementary tables as are applicable to their study design. Table 3 is applicable if the study involved animal or human subjects. Table 4 is applicable if the study was on cells or in vitro. Table 5 is applicable if contrast agents were used in the study. ***Conclusions.*** We recommend that principal authors be required to certify to the *JUM* editors that they have reviewed the appropriate checklists and complied with indicated expectations. We recommend to reviewers that they consider individually adopting a mandatory requirement for reporting a basic set of parameters and/or descriptors of the equipment that are readily ascertainable by, or should be known to, a clinical user. ***Key words:*** acoustic output; authors; bioeffects; exposure guidelines; measurement; reviewers; reporting.

The editors of the *Journal of Ultrasound in Medicine* (*JUM*) are concerned about the frequent need heretofore to revise submitted manuscripts reporting bioeffects to amplify the description of exposure methods and dosimetry. Therefore, this report presents rationales and checklists to draw authors' attention to aspects of experimental design and exposimetry that require consideration in project planning, execution, and reporting.

Checklists are presented for use in 2 distinct categories of activity:

1. Clinical settings in which a biophysical end point (bioeffect) is observed incidentally during another procedure; and
2. Research projects specifically planned to investigate biophysical end points (bioeffects).

Reportable parameters for the former are limited to essentials, whereas those for the latter are presented in as exhaustive detail as the writers could conceive. Certain elementary parameters, such as the identity of the ultrasonic equipment used, are recommended as mandatory for reports in both categories; certain additional parameters are designated as expected (at 3 levels of importance) when results of research are reported.

For an introduction to the subject, we recommend perusal of Ziskin and Lewin's *Ultrasonic Exposimetry*,[1] particularly Chapters 1, 2 (Parts II and III), 3 (Part II), 4, 11 (Parts II and III), 12, and 13. Chapter 5 delves into methods of measuring acoustic power and acoustic pressure. Although this book is out of print, it is available from some libraries (a useful website for checking holdings worldwide is www.librarytechnology.org/libwebcats).

In 1998 and 2003, the American Institute of Ultrasound in Medicine (AIUM) and the National Electrical Manufacturers Association (NEMA) jointly published editions of *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*.[2] This is a complex document, which rigorously addresses most aspects of acoustic output measurement and traceability to international reference standards. It is suitable for those required or willing to make a considerable investment in equipment and staff for frequent measurements, for example, some research laboratories, test houses, manufacturers, and regulators.

Clinical users face somewhat different situations than bioeffects investigators. On the one hand, manufacturers must provide information about the acoustic outputs of their equipment in a form that is useful in the day-to-day clinical practice of the entire diagnostic ultrasound community. The thermal index (TI) and mechanical index (MI)[3] were devised and are commonly displayed on screen to give the user a simple and rapid, but crude, estimate of relative acoustic output of their equipment. On the other hand, bioeffects investigators use the slow process of publication to communicate to the much smaller research community the actual exposures experienced by the subjects of their experiments. In research, greater accuracy is not only achievable but also is more important than in day-to-day clinical activity. Furthermore, the investigator's report to peers in the research community may use different language and should supply greater detail than a manufacturer provides to its customers.

In principle, every experiment presents unique problems of ultrasonic dosimetry. Most bioeffects studies, however, fall into 1 of 3 broad categories:

1. Animal studies, which have yielded most bioeffects information that is directly useful;
2. Observations of effects of ultrasound on cell preparations, which have yielded some basic knowledge; and
3. Pertinent clinical studies, including all our epidemiologic data on the use of diagnostic ultrasound.

As categories of research, each has its own dosimetry characteristics.

Animal Studies

The parameters of primary interest in a bioeffects study are usually a temperature rise and pressure amplitude at the specimen. These parameters have been related, respectively, to thermal and mechanical mechanisms, the two major, established effects of ultrasound in biological tissues. In principle, it should be possible to compute the temperature elevation from a complete knowledge of the acoustic and thermal parameters of the source and target. However,

this process is so challenging that a direct measurement of temperature is preferable even if it is difficult. Thermocouples may be threaded through tissue to record temperature rise directly. Thermocouple measurements during ultrasound exposure are subject to artifacts from viscous heating at the tissue-wire interface. Errors in determination of true mammalian tissue temperature that are introduced in this way are usually minimal if the thermocouple is small (<50 μm diameter) and the exposure times are long (>1 minute).

Even when the mechanism of action is assumed to be thermal, the acoustic pressures at the site of interest in the animal as well as the physical parameters needed to compute temperature rise should be reported. The former is normally accomplished by a hydrophone measurement of the free-field, peak-positive and -negative pressures (in megapascals) at the position to be occupied by the animal and then by estimating the actual pressures in the animal, using corrections for attenuation of the ultrasound field by the overlying tissue. Parameters reported for the latter should include distance between transducer and specimen or point of interest, pulsing conditions (mode, pulse repetition frequency, duty cycle, and frame rate), beam profile (–6 and –12 dB beam diameter in azimuthal and elevational directions at the depth of interest, if known, or elevational, focal depth), measured center frequency, bandwidth, and spatial-peak, temporal-average intensity. The same acoustic parameters should be reported for experiments in which the mechanism of action of ultrasound is assumed to be nonthermal.

In general, but particularly when the temporal-peak pressures are large and the waveforms are distorted by nonlinear propagation, it is useful to provide a pressure-time plot of the pulse profile at the site to be occupied by the experimental animal.

Justification for ignoring heating in these experiments can frequently be given analytically by reference to the measured, acoustic intensity and exposure time.[4] In borderline cases, however, direct, thermocouple measurements may be necessary to demonstrate that heating is negligible.

Cell Suspensions

The bioeffects literature is replete with reports of the effects resulting from ultrasonic exposures of suspensions of cells. From the standpoint of dosimetry, there is a fundamental difference between these exposures and those experienced by the tissues of experimental animals. In animal experiments, the beam pattern of the ultrasound field conveys the information about the distribution of exposure to different parts of the tissue. Cell suspensions, in contrast, are continuously stirred during exposure by acoustic streaming. Also, standing waves may be produced in the exposure vessel, and the distribution of cells in the exposure vessel may be affected by the standing waves. Standing waves introduce large gradients in the field to which the suspended cells are actually exposed. These may change the distribution of cells and bubbles in the medium, which in turn may influence the biological effect. Therefore, in addition to the acoustic parameters recommended for animal experiments, reports of experiments with cell suspensions should contain information about the exposure vessel and estimates of the temporal characteristics of the sound field that the cells experienced. A comprehensive review of exposure systems as well as in vitro bioeffects of inertial cavitation is provided by Miller et al.[5]

A Note on the Ultrasound Indices

Thermal and mechanical indices are descriptors of the output of diagnostic ultrasound systems and are defined in the AIUM/NEMA Output Display Standard (ODS).[3] In general, they are not appropriate indicators for reporting the acoustic exposure in a bioeffects experiment. In contrast to the simple numbers that describe exposure, the definitions of the indices are complicated and involve mathematical models and assumptions about the propagating media. They differ qualitatively from the acoustic exposure parameters needed to describe exposures in bioeffects experiments.

The importance of the TI and MI is to allow the operator to compare relative values of these indices under different operating conditions selected in the course of an imaging session.

The TI, for example, is a rough estimate of the maximum temperature increment in the field of an ultrasound source, assuming that the transducer is in contact with a medium whose properties are those that are built into the definition of the TI through the assumed model. The location of the temperature maximum in the ultrasound field is not known from the value of the TI, nor is the actual temperature rise anywhere in a specific tissue medium. For example, if the actual temperature rise at the site of interest in an animal experiment is 1°C and the actual maximum temperature rise elsewhere in the field is 3°C but the TI formula yields an estimate of 5, the thermal exposure is 1°C but the displayed TI would be 5. If the transducer is then removed from the tissue and without other change radiates into a water medium, temperature rises in the water would be minimal everywhere but the TI would still be 5, because the TI is a descriptor of the ultrasound system coupled to the specified tissue-equivalent medium, not an estimate of the maximum temperature rise in a different medium (ie, water). Thus, the TI is irrelevant to experiments conducted in aqueous media.

A similar rationale applies to the MI. It describes certain acoustic properties of the source, but it is not a basic exposure parameter. The use of the MI as an exposure parameter in several published reports has led to confusion and errors in the description of subject exposure.

These facts in no way denigrate the output indices. Their incorporation in standards and their display on the screens of diagnostic ultrasound systems are as important to ultrasound safety as basic bioeffects research. The output information they supply is limited in quantity and quality, but it comes in a form that is suitable and the best available for the concerned clinical user to make use of existing bioeffects knowledge.

Clinical Studies

At a minimum, the acoustic output of clinical equipment to be used for a bioeffects study should be measured before and spot-checked after the study, preferably by or with the assistance of its manufacturer using AIUM/NEMA or International Electrotechnical Commission (IEC) standard methods. Researchers are encouraged to seek assistance of the manufacturer or a qualified testing program. If test conditions were changed during the study, then recalibration would be necessary after the study.

Results will depend on the particular transducer assembly and equipment settings used. (Note: Acoustic output data provided in manuals supplied with ultrasound diagnostic equipment may not be relevant because of the many possible combinations of equipment settings and because transducer-to-transducer variations and, to a lesser degree, system-to-system variations can be substantial.) Results of these calibrations, specifying the test methods and equipment settings used in the study, should be reported in a manuscript. Notable disadvantages of this recommended calibration procedure are loss of the use of clinical equipment while it is being calibrated and associated transportation and test costs. To minimize these disadvantages, it may be considered adequate if only the investigator's transducer assembly is calibrated and assurance is given that the equipment console has been maintained to the manufacturer's performance specifications. *In all cases, essential calibration entails prediction of the ranges of equipment settings that will be used in the study.*

Clinical investigators fortunate enough to have biophysicists or biomedical engineers in-house may be able to expedite calibrations by making use of existing facilities. At a minimum, a standard, calibrated hydrophone and an instrumented testing tank are needed for such calibrations. An acoustic (radiation) force balance is desirable but not essential.

Reporting calibrated, acoustic output power is only the first step. Exposure refers to acoustic conditions at the specimen remote from the transducer assembly. Ultrasound propagated from the transducer assembly may be diffracted, focused, absorbed, scattered, reflected, refracted, or converted to a different frequency or propagation mode before it reaches the specimen. Ideally, the acoustic properties of all media intervening between the transducer assembly and the specimen will be reported to permit calculations, if desired. Practically, it is recognized that in some cases sufficient data may not be available. Nevertheless, due diligence should be exercised to report as comprehensively as possi-

ble. In the accompanying tables, parameters that are expected to be reported are ranked in importance.

With human subjects, direct measurement of temperature rises and acoustic pressures in situ are normally precluded. In these experiments, the on-screen values of TI and MI may be reported, but doing so does not relieve the investigators of the responsibility of computing the actual exposure data at the sites presumed to be affected by ultrasound exposure and reporting those values and the methods used in determining them.

Discussion and Recommendations

In all studies, the overarching purpose of reporting exposure parameters is to enable other investigators to replicate studies and thereby validate, supplement, or call in question published results. Reviewers bearing this purpose in mind may hold different opinions on what is necessary and sufficient to ensure replicability.

Authors may have complied with standards that specify precise methods for making ultrasound field measurements, or they may have relied on documentation or cited reports; in all cases, they are expected to report their sources and results. It is important for authors to review a checklist of factors that identify the equipment and determine the exposure to ensure that all expected or available data are included in a manuscript. However, as noted above, parameters important for one type of study may be unimportant for another type. The following checklists (Tables 1–5) are provided in tabular form to encourage reporting of information that reviewers will need to evaluate manuscripts and other investigators will need to replicate experiments or perform supplementary calculations.

Clinical investigators should comply with the short, first table (Table 1) and the last (Table 5), if applicable, but are encouraged to include additional data specified in other tables, as appropriate.

Bioeffects experimenters should comply with Table 2 and such supplementary tables as are applicable to their study design. Table 3 is applicable if the study involved animal or human subjects. Table 4 is applicable if the study was on cells or in vitro. Table 5 is applicable if contrast agents were used in the study.

We recommend that principal authors be required to certify to the JUM *editors that they have reviewed the appropriate checklists and complied with indicated expectations.*

Definitions of terms are provided in the AIUM's *Recommended Ultrasound Terminology*.[6]

Table 1. Checklist for Reporting OBSERVATIONS Involving Ultrasound Exposures of HUMAN SUBJECTS

Machine Parameters	Recommendation	Unit	Notes
Manufacturer	MR		
Console model	MR		Part number, serial number
Transducer model	MR		Style, part number, serial number
Software version number	MR		
Scanning mode and submode	MR		eg, B-mode, compounded, harmonic
Focusing	MR		Geometrical or electronic, static or dynamic
Focal range	MR	mm	
Machine settings	MR		Application type (eg, general, Ob, cardiac) and eg, selected center frequency, velocity scale, frame rate, sector size, displayed acoustic output %, sampling gate size (in spectral Doppler)
Displayed MI	MR		Per ODS, MI is defined only at the position of maximum pulse intensity integral (derated)
Displayed TI	MR		
Time of exposure	MR	min	

MI indicates mechanical index; MR, mandatory reporting recommended; Ob, obstetric; and TI, thermal index.

Table 2. Checklist for Reporting EXPERIMENTS Involving Ultrasound Exposures (ALL STUDIES)

Parameters	Recommendation	Unit	Notes
Machine parameters			
Manufacturer	MR		
Console model	MR		Part number, serial number
Transducer model	MR		Style, part number, serial number
Software version number	MR		
Scanning mode and submode	MR		eg, B-mode, compounded, harmonic
Machine settings	MR		Application type (eg, general, Ob, cardiac) and eg, selected center frequency, velocity scale, frame rate, sector size, displayed acoustic output %, sampling gate size (in spectral Doppler)
Displayed MI	+++		Per ODS, MI is defined only at the position of the maximum pulse intensity integral (derated)
Displayed TI	+++		
Calibration methods			
Standards invoked or traceability	(MR)		eg, following AIUM 1998 measurement standard or other
Transducer parameters			
Transducer type	+++		eg, single disk, circular array, liner array, multiunit rotating, immersed
Transducer aperture shape			eg, circular, rectangular
Transducer aperture dimensions	+++	mm	eg, physical diameter, height and width of the active elements
Number of elements			
Size of elements		mm	Length, width, and pitch
Beam pattern			Show figure
Beam cross-sectional profile or azimuthal and elevational beam widths	(+++)	mm	All at depth of interest or elevational, focal depth eg, Gaussian, Bessel If widths, –3, –6, and –12 dB
Focusing	+++		Geometric or electronic, static or dynamic
F-number(s) (or active dimensions)			
Focal length	+++	mm	Depth of ($PII._0$ max), if measurements are made; nominal values, if measurements are not made
Depth of focus (focal zone depth range)	++	mm	eg, 50–130 mm
Side lobes (dB down)	(++)	dB	Report as a negative number, eg, –30 dB
Grating lobes	(++)	dB	Report as a negative number, eg, –30 dB
Exposure parameters			
Acoustic power output at transducer (W_o)	(+++)	mW	Report estimated accuracy of acoustic power measurement
Mode of operation	+++		Pulse or continuous wave
Pulse center frequency	+++	MHz	Nominal values, if measurements are not made
Pulse echo-response profile			eg, damped single cycle, continuous wave burst (show figure)
Pulse duration	+++	μsec	Per standards if measured; nominal values, if measurements are not made
Duty factor		%	
Pulse repetition frequency	+++	Hz	If pulsed Doppler or color mode; nominal values, if measurements are not made
Frame rate	+++	Hz	If B-mode or color mode; nominal values, if measurements are not made

(continued)

Table 2. (continued) Checklist for Reporting EXPERIMENTS Involving Ultrasound Exposures (ALL STUDIES)

Parameters	Recommendation	Unit	Notes
Exposure parameters (continued)			
Nonderated intensity at specimen (I_{SPTP}, I_{SPTA}, I_{SATA})	(+++)	W/cm^2, mW/cm^2	Measured in water
Estimated attenuated intensity and power at specimen ($I_{SPTP,\alpha}$, $I_{SPTA,\alpha}$, $I_{SATA,\alpha}$, $W_{.3}[z]$)	(+++)	W/cm^2, mW/cm^2, W	Report attenuation coefficient α used in estimation
Peak rarefactional pressure at specimen (nonderated)	(+++)	MPa	Measured in water
Estimated attenuated peak rarefactional pressure at specimen	(+++)	MPa	Report attenuation coefficient used in estimation
Peak compressional pressure at specimen (nonderated)	(+++)	MPa	Measured in water
Estimated attenuated peak compressional pressure at specimen	(+++)	MPa	Report attenuation coefficient used in estimation
Measurement equipment used			
Acoustic power equipment and method	++		eg, radiation force balance, hydrophone raster scan, . . .
Hydrophone and amplifier	++		Which hydrophone and amplifier model and S/N used? When calibrated?
Digitizer	+		Manufacturer, model, number of bits resolution
Positioning system	+		eg, stepper motors, hand crank
Water temperature	+++	°C	
Exposure tank dimensions		cm or m	
Exposure tank volume		L	Filled volume
Exposure tank wall absorbers			Manufacturer, description
Exposure tank reflection coefficient		dB	Report as a negative number (dB down), eg, –20 dB
Medium degassing method (if water)			Report if water deionized, distilled, or from tap
Regassing precautions			eg, floating polystyrene balls
Experimental parameters and conditions			
Range from transducer to target or specimen (z)	MR	cm	
Acoustic coupling medium			eg, gel, gel pad, degassed water
Intervening media types	++		eg, fat, muscle, bone, amniotic fluid
Intervening media thicknesses	++	mm	
Intervening media boundary geometry			
Intervening media speeds of sound	+	m/s	
Intervening media acoustic impedances	+	Mrayl	rayl = kg · m^{-2} · s^{-1}
Intervening media acoustic attenuation coefficients	+	dB · cm^{-1} · MHz^{-1}	
Error analysis			
Probable random errors	+++		Or type A
Probable systematic errors	+++		Or type B
Supporting material			
Line drawing of experimental apparatus with dimensions			
Photograph of exposure in progress			

I_{SATA} indicates spatial-average, temporal-average intensity; I_{SPTA}, spatial-peak, temporal-average intensity; I_{SPTP}, spatial-peak, temporal peak intensity; α, attenuation coefficient assumed in calculations for the acoustic path between the transducer and the specimen; MR, mandatory reporting recommended; Ob, obstetric; $PII._0$, pulse intensity integral (nonderated); S/N, signal/noise ratio; and $W._3[z]$, estimated attenuated power at specimen. Data reports: +++ indicates definitely expected; ++, highly expected; +, expected; and (. . .), report data if measurements are made per ODS or other cited standard; otherwise, report is optional.

A feature of the tables is the ranking of parameters as "expected" (+), "highly expected" (++), and "definitely expected" (+++) to be reported. Rankings are based on an assessment of the value of the data to other researchers and the ease or difficulty of their determination. Data for all other, unranked parameters are nonetheless desirable.

Another feature is the term *mandatory reporting* (MR).

We recommend to reviewers that they consider individually adopting a mandatory requirement for reporting a basic set of parameters and/or descriptors of the equipment that are readily ascertainable by, or should be known to, a clinical user. The final decision rests with the editors, of course.

Table 3. SUPPLEMENTAL Checklist for Reporting EXPERIMENTS Involving Ultrasound Exposures (ANIMAL and HUMAN STUDIES)

Parameters	Recommendation	Unit	Notes
Skin shaved and depilated	+++		Proximally/distally
Distal acoustic impedance mismatch	++	Mrayl	eg, air, foam, fluid, fur? rayl = $kg \cdot m^{-2} \cdot s^{-1}$
Tissue temperature as function of time	(++)	°C(s)	Measured or estimated
Measurement protocol	+++		Describe in text
Skin temperature under transducer assembly		°C	
Actual or average tissue types	++		
Tissue thicknesses		mm	Between transducer and focal region
Tissue boundary geometry in beam path			
Tissue speed of sound		m/s	
Tissue attenuation coefficient		$dB \cdot cm^{-1} \cdot MHz^{-1}$	

Data reports: +++ indicates definitely expected; ++, highly expected; and (. . .), report data if measurements are made per ODS or other cited standard; otherwise, report is optional.

Table 4. SUPPLEMENTAL Checklist for Reporting EXPERIMENTS Involving Ultrasound Exposures (CELL or IN VITRO STUDIES)

Parameters	Recommendation	Unit	Notes
Chamber			
Chamber shape	+++		
Chamber dimensions	+++	mm	
Chamber commercial origin			Manufacturer's part number
Construction materials			Describe in text
Construction materials (density)	g/cm^3		
Construction materials (speed of sound)	m/s		
Chamber rotation speed	+++	rpm	If applicable
Chamber standing wave assessment			Describe in text
Suspending medium			
Suspending medium speed of sound	+++	m/s	
Suspending medium temperature	+++	°C	
Suspending medium viscosity	+	$g \cdot cm^{-1} \cdot s^{-1}$	
Suspending medium air/gas interface	+++		Describe and quantify in text
Suspending medium depth or volume	+++	mm or mL	
Suspending medium density	+++	g/cm^3	

Data reports: +++ indicates definitely expected; and +, expected.

Table 5. SUPPLEMENTAL Checklist for Reporting EXPERIMENTS Involving Ultrasound Exposures (CONTRAST AGENT STUDIES)

Parameters	Recommendation	Unit	Notes
Manufacturer	+++		
Type	+++		Trade name
Composition	+++		Capsule material and encapsulated gas or liquid
Total quantity of injected agent	+++	mm^3	
Concentration of injected agent	+++	$\#/mm^3$,	
Use protocol	+++	mm^3/kg	Describe in text, eg, injection as bolus, speed of injection
Liquid handling protocol	+++		From reservoir to heart; describe in text, eg, degassing method, residual gas (O_2) content

Data reports: +++ indicates definitely expected.

In justification of such extensive detail, we reiterate that a basic aspect of scientific reporting is the expectation that another investigator will wish to replicate a reported study. Therefore, it is essential for all pertinent information that is available or accessible to an investigator be reported. Our minimum goal is to avoid inadvertent omission of available or accessible information. Beyond that, we hope to stimulate investigators to give adequate consideration to the acoustic aspects of their experimental design and reviewers of their manuscripts to apply consistent criteria to the reports that they are evaluating for publication.

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