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Medical ultrasound devices and metrology

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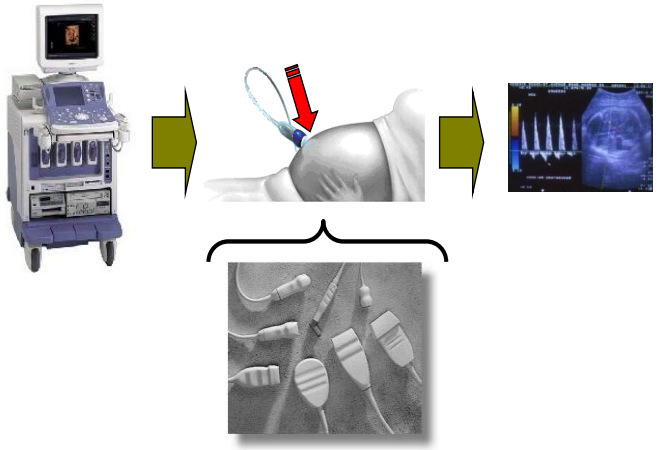
Motivation

Lack of measurement evidence regarding actual performance of medical ultrasound devices as time goes by.

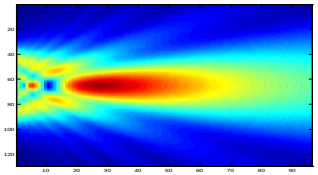
Can we trust in their time-invariant performance without doing periodic measurements?



Robust-enough devices?

Calibration services traceable to SI standards?

Accredited laboratories fulfilling ISO/IEC 17025 standard?



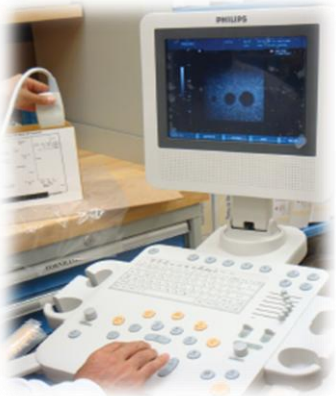
Purpose

To show results from two on-site measurement studies about performance of medical **ultrasound devices** used in **imaging diagnostics** and **physiotherapy treatments**.

Materials and Methods

Sample of study: medical ultrasound devices belonging to health care centres located in Queretaro-Mexico.

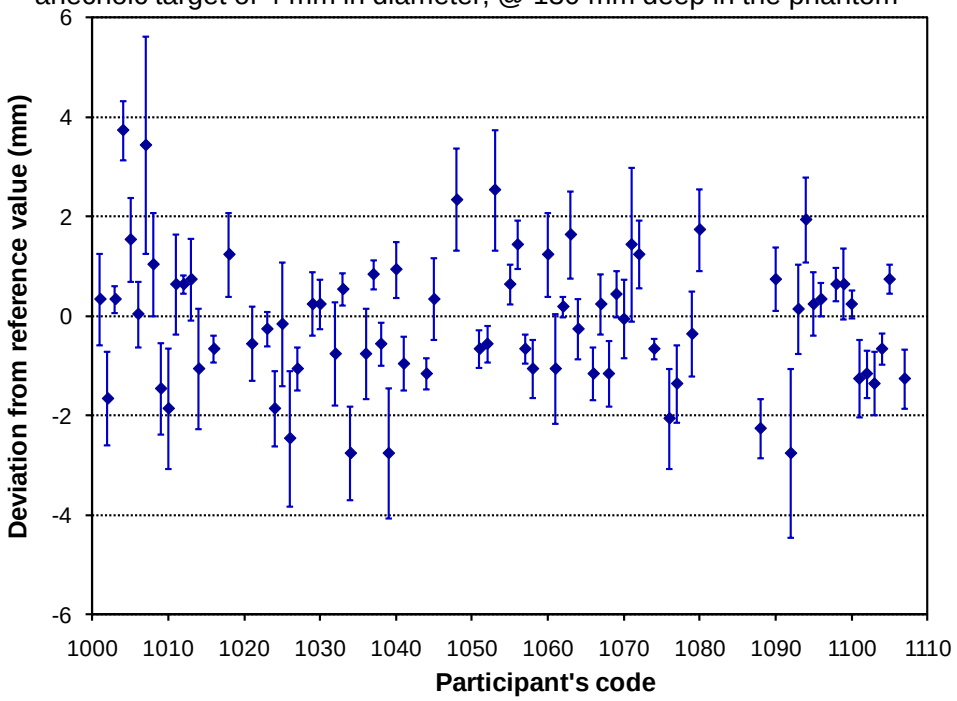
1) Measurements on ultrasound imaging devices. Size and depth of a set of reflecting and absorbing targets of an ultrasound rubber phantom were measured.



2) Measurements on ultrasonic physiotherapy devices. Total acoustic power was measured using a portable radiation force balance as reference standard.

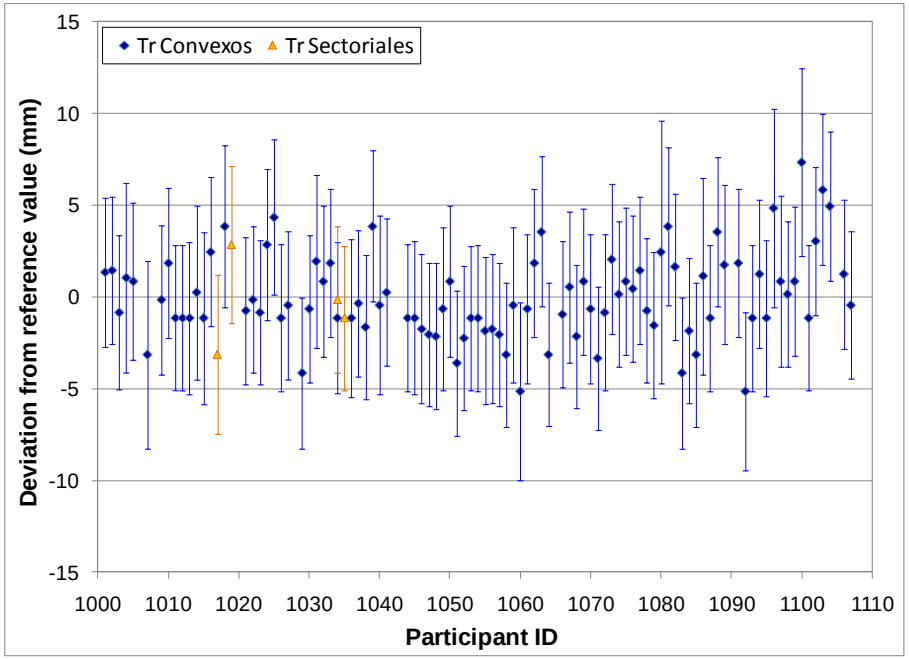
Measurement results: a sample here

Results from **imaging devices** using a convex transducer to measure an anechoic target of 4 mm in diameter, @ 130 mm deep in the phantom



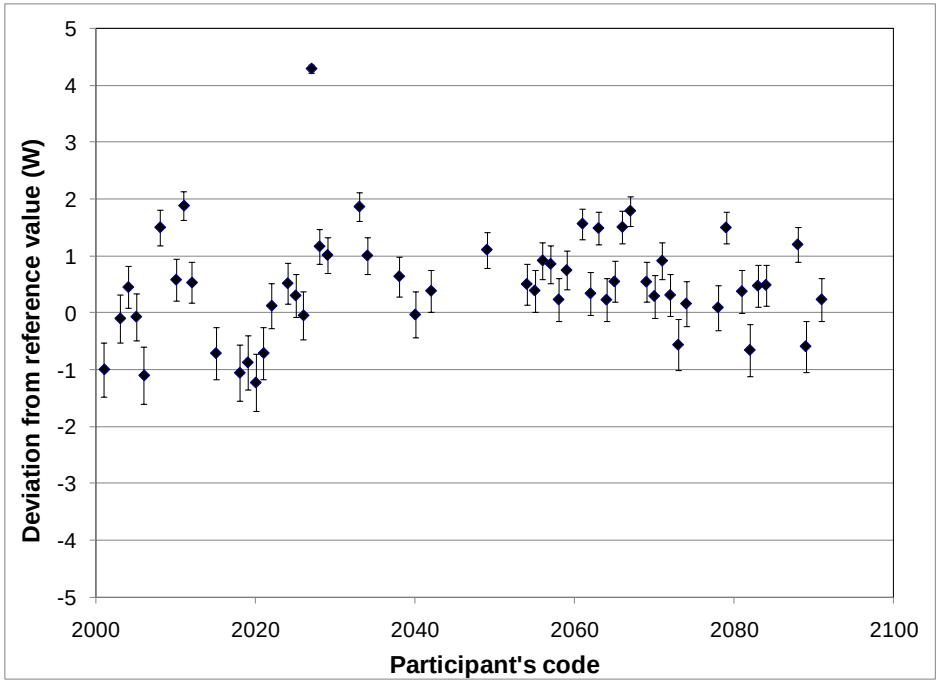
Ultrasound medical imaging units

Vertical accuracy, dispersion data



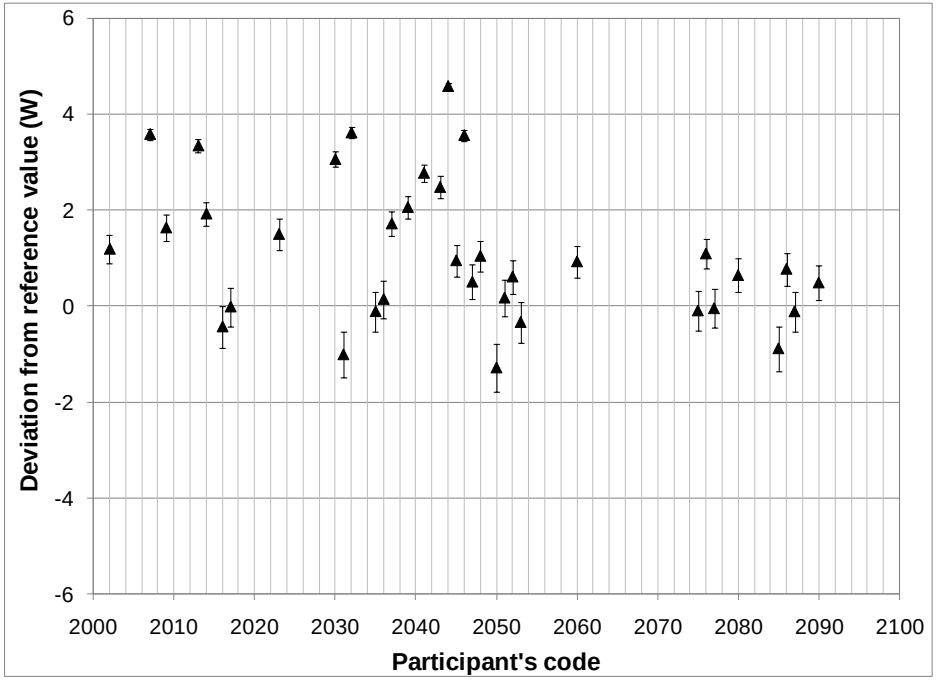
Measurement results: a sample here (cont.)

Measurement results for ultrasound devices operating at 5 W and 3 MHz



Physiotherapy devices

Measurement results for ultrasound devices operating at 5 W and 1 MHz



Summary of results

On-site study	Study 1 : 107 units measured	Study 2 : 91 units measured
Medical devices	Imaging ultrasound machines with linear and convex transducers	Physiotherapy units with single plane transducers
Tested parameters	Measurement system accuracy, dead zone, axial resolution, penetration depth, and anechoic target detection.	Actual ultrasound power emitted at 1 W, 5 W, 1.5 W/cm^2 and max. power settings, @ 1 MHz, 3 MHz.
Reference standard	Rubber-based ultrasound phantom	Radiation force balance
Main findings	Quantitative and qualitative results showed that 1 in 5 of ultrasonic imaging systems, using a convex transducer, may not visualize deep cyst-like targets of 4 mm in diameter.	About 1 in 4 of measured devices resulted with ultrasound power deviations larger than 20 %; which exceeds tolerance value stated in IEC 61689 standard.

Remarks

Data from recalls issued by the USA FDA suggest that thousands of ultrasound units sold in different countries may show a non-conformance operation respect to their performance specifications.

U.S. Food and Drug Administration

Medical & Radiation Emitting Device Recalls

From 2003 to January 2011: **111** records meeting your search criteria returned- **Product**: *ultrasound.*

Source:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=41&event_id=&productdescriptiontxt=ultrasound&centerclassificationtypetext=&recallnumber=&postdatefrom=&postdateto=&productshortreasontxt=&firmlegalnam=&pagenum=10&sortcolumn=cdd

Conclusions

- Quantitative and qualitative results showed that ultrasonic imaging systems may lead to false negative diagnostics when trying to visualize deep cyst-like targets; a serious limitation if only a convex transducer is available.

- Acoustic output power measurements on ultrasound physiotherapy devices presented deviations higher than the IEC 61689 tolerance (+/- 20 %). Higher deviations may compromise effectiveness of ultrasound treatments.

- Calibration of ultrasonic devices, either for physiotherapy or diagnostic purposes, shall be performed with traceable measurement standards, otherwise health care professionals will be lacking objective evidence about actual device performance. Leaps of faith on the robustness of an ultrasound device?

- Ultrasound metrology and basic requirements given in ISO/IEC 17025 standard regarding metrological traceability shall be part of quality assurance (QAs) programs available in a given hospital or health care unit.

Thanks for your attention!

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