US quality control in Italy: present and future

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Abstract. US diagnostic equipments are widely diffused in Italy but, in spite of recommendations (e.g. ISPESL-Ministry of Health (1999) and SIRM (Società Italiana di Radiologia Medica, 2004), US quality controls are restricted to only a few public sanitary structure and a national (or even regional) quality assurance program for testing the performances of the US equipments is still missing.
A joint Research Centre among the three Piedmontese Universities and INRIM , partially funded by Regione Piemonte, has been established in 2009 as Reference Centre for Medical Ultrasounds (CRUM). In addition to research, development and training tasks, the Centre aims at the local diffusion of the quality assurance in clinical US equipments . According to data from the Ministry of Health (2006), around 7 % of the Italian US diagnostic equipments (946 over 13526) are located in Piedmont: mostly (75.6%) in public hospitals, 9.3 % in conventionated hospitals, 4.3% in public and 10.8% in private territorial structures. The goal is the provision of a regional database, which progressively includes data related to acceptance test, status and QC tests and maintenance, in order to drive equipment turnover and carefully monitoring the overall equipment efficiency. Moreover, facilities are available at CRUM for monitoring both beam geometry and acoustic power and performing quantitative assessment of the delivered energy intensity.

1. Introduction
Due to the wide diffusion of the US diagnostic equipments and the advances in computational techniques applied to ultrasound technology, systematic monitoring of the US scanners performances could be very important to assure efficiency during clinical examinations.

The elaboration of a common quality control (QC) program is therefore mandatory to protect (or better serve) patients and, on the other hand, to provide an objective assessment to optimize the equipment turnover.

In particular, in our region, Piemonte, according to the data published by the Italian Ministry of Health (2006) [6], is present about the 7% of the whole national US instrumentation: 75.6% in public hospitals, 9.3 % in conventionated hospitals, 4.3% in public and 10.8% in private territorial structures.

QC in Italy have been recommended (see ISPESL-Ministry of Health, 1999, and SIRM, Società Italiana di Radiologia Medica, 2004) [11] but are not compulsory, and as a consequence only few public structures practice them.

A joint Research Centre among the three Piedmontese Universities and INRIM , partially funded by Regione Piemonte, has been established in 2009 as Reference Center for Medical Ultrasounds (CRUM) and, in addition to perform research and education in the field, it has the aim to diffuse quality assurance in medical US equipments and promoting a regional database.

1.1 The starting point: the international experiences

The importance of testing the performances of US imaging has been detailed by many authors over the last three decades, and specific procedures, from tests based on the simple use of plexiglass block to more sophisticated tissue equivalent test objects, have been so far proposed.

In the USA, since the 70s of the twentieth century, many papers on this topic have been published: see for instance P L Carson et al, 'Calibration and quality control in diagnostic ultrasound', *Phys. Med. Biol.* (1974), 19, 229-230 [3], who first defined which parameters are to be checked and which procedures have to be followed, according to the indications of the AIUM (American Institute of Ultrasound in Medicine).

Successively, a number of guidelines have been published by professional bodies, that are periodically updated as technology develops. In 1995, Price recommended tests to be performed in routine quality assurance of ultrasound imaging systems [10]. Three years after, in 1998, Goodsit et al published the report of AAPM (American Association of Physicists in Medicine) "Ultrasound Task Group N° 1 about the Real-time B-mode Ultrasound quality control test procedures", which is one of the most important document on this topic: in this paper a set of limit values to follow are suggested and the use of computerized image analysis is recommended, to provide more accurate and reproducible results [4].

In the same years the scientific community faced the problem also in France, and VaIlbe and Donadey, starting from the most recent developments of the technology, described the main QC international experiences , the parameters to analyze and the procedures to follow, with a particular attention to the image resolution and contrast of the US equipments [16].

In most recent years, due to the rapid evolution of the equipments features and performances, several International Committees updated their guidelines. For example, AIUM published the documents: 'Routine Quality Assurance for Diagnostic Ultrasound Equipment' (2008) [2] and 'Standard Methods for Calibration of 2-Dimensional and 3-Dimensional Spatial Measurement Capabilities of Pulse Echo Ultrasound Imaging Systems' (2004) [1]. In the first paper, a basic QA program for clinical ultrasound facilities is outlined and a particular attention is devoted to the frequency of tests and the role of the personnel, with a number of examples of procedures fully described in the references paragraph. In the second document, the problem of the spatial accuracy in 2-dimensional (2D) and 3-dimensional (3D) imaging is investigated and calibration of measurements systems techniques are described. In particular, the following types of measurements are analyzed in details: 1) linear dimensions, 2) perimeters of areas, 3) areas, 4) curved dimensions, 5) volumes and surface areas, 6) position registration, 7) linear dimensions, areas, curved dimensions and volumes and surface areas in complex orientations and defined only by their difference in backscatter from the background, 8) representation of time, velocity and acceleration in M-scans and a whole chapter is dedicated to the test objects and their features.

In Italy, the most important document ,'Controlli di qualità in ecografia', has been published in 2004 by Società Italiana di Radiologia Medica, and collects the proposed procedures for US equipments QA, comparing them to the ones currently performed for NMR and x-rays equipments [11].

Such guidelines are actually based on the previous experience of Novario and his collaborators on QC in both Doppler [7] [8] and B-Mode [9], focusing on test objects, while, in most recent years, the same research group at the Ospedale di Circolo of Varese devoted his attention to the definition of ranges of acceptability for the parameters currently measured in QC routines[10].

Also in the Valle d'Aosta region, QA procedures are a solid experience, as described in [13]. In this paper the results in the 2007-2008 years are described and their positive aspects are shown: the authors conclude that the quality of US equipments has improved over the years and the overall costs have decreased, because QC made it possible to identify malfunctioning probes and to provide specific repairs instead of expensive interventions on the equipments. Finally, these positive results were

clearly perceived by the users, as confirmed by a survey among the sonographers, which shows the congruence between the phantom results and the clinical perception.

2. The protocol

Starting from the international and Italian experiences previously described, CRUM is elaborating a QA protocol, to establish the main parameters and the corresponding limit values and tolerances. In particular, we have considered as a starting point the AMUM, AAPM and SIRM guidelines, in addition to some significant national experiences of clinical routine. The protocol is currently under examination of a group of expert for overall assessment, and will shortly be submitted for the national accreditation procedures by INRIM.

In this protocol B-Mode imaging and Doppler are taken into account, which are the most common diagnostic US modalities performed in   medical practice, the protocol is composed by different sections: Italian and international regulations, measurement procedures, dedicated phantoms, test objects and software for imaging analysis, with an overview on the commercial products available.

Such QC program is particularly focused on the evaluation of progressive deterioration the US equipments over time, which is responsible of a slow but gradual deterioration of the image quality, which is hardly perceived by operators working daily with the same apparatus, and need therefore effective technical tools, based on objective parameters and reproducible measurements.

Data collection starts from the first check of the equipment (the so called acceptance tests), and continues with a series of annual 'status' or 'constancy' tests, where parameter values are checked and compared with the initial values recorded at the acceptance test (see Fig. 1)
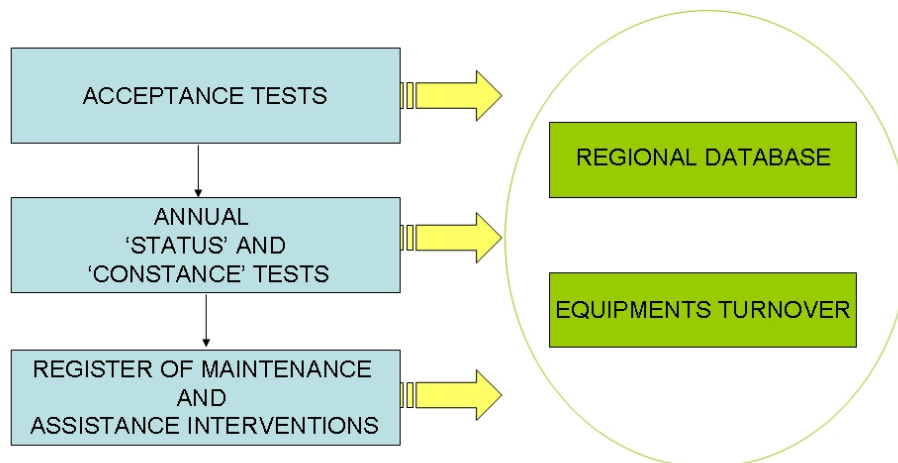

Figure 1. Sketch of the protocol proposed by CRUM for the US diagnostic equipment.

The US parameters both in gray scale and echo-colour Doppler which are evaluated are those refer red by the American Association of Physics in Medicine (Goodsitt et al. 1998) and recognized by the AIUM as reference standard.

In the following tables, the main QC parameters are shown:

Table 1. QC parameters in B-Mode modality

B-Mode modality
Image uniformity
Distance accuracy
Axial resolution
Lateral resolution
Anechoic –iperechoic object imaging
Dead zone
Depth of visualization
Focalization
Contrast resolution
Physical and mechanical inspection
Hardcopy and display monitor fidelity

Table 2. QC parameters in Doppler and Color-Doppler modality

Doppler modality	Color-Doppler modality
Doppler signal sensitivity	Color flow sensitivity
Flow sensitivity at depth	Color flow sensitivity at depth
Accuracy of flow velocity readout	Accuracy of the Color Doppler velocity
Accuracy of sample gate positioning	Color flow B-Mode image congruency
Wall filter	Colored noise
	Directional discrimination
	Motion discrimination

The above parameters have to be checked by the responsible of the equipment and/or by the medical physicists with a constant periodicity, but at least annually in the case of multidisciplinary US instruments heavily used daily in Radiological Departments, or even more frequently if required by the Radiologist.

In particular, the monitor fidelity, the image uniformity, the hard copy and display monitor fidelity, the distance accuracy and the depth of visualization are very easy to be tested, and their check should be performed more often: the time estimated for it is about 15 minutes and the time necessary to perform the whole QA protocol is about one hour / probe.

Moreover, a section of the protocol is devoted to the more recent diagnostic US modalities, e.g. 3D and 4D equipments and endocavitary probes, that need special phantoms and finally, to the available software to perform the automatic analysis of B-Mode images.

Another important problem still open is that of assessing the acoustic power emitted by the probes. As a matter of facts, although the use of ultrasound is commonly considered devoid of collateral effects, the widespread use of ultrasound examinations and the increase in output intensity level required by new devices (e.g. contrast agents modalities) settle the issue of defining the levels of US exposure which ensure both patients safety and best devices performance. Furthermore, an increasing interest in using ultrasound as a surgical and therapeutic tool, e.g. due to the use of High Intensity Focused Ultrasound (HIFU) for tissue ablation in the treatment of cancers and benign prostate hyperplasia, require a direct and quantitative assessment of the acoustic power delivered by the US beam in biological tissues.

For these reasons, at INRIM., many efforts have been done to develop effective techniques for ultrasonic sources and fields characterization, measurements set-ups and techniques for beam characterizations as required by national and international standards. Preliminary investigations of new technologies directed to the extension of the measurements capabilities to the field of HIFU devices are in progress.

In particular, the measurement of the total power emitted by an ultrasonic transducer based on the principle of the radiation force balance and following the guideline of the standard IEC 61161 can be performed using the apparatus described in Fig. 2.
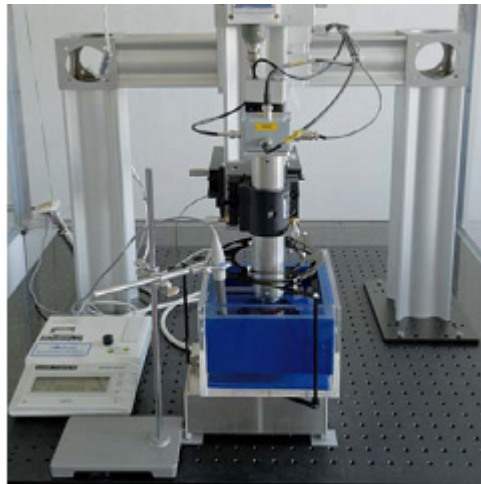

Figure 2. Radiation force balance

The ultrasonic power is determined by measuring the force exerted by the sound field generated by an ultrasonic source on a target, which is connected to a balance that estimates the apparent mass variation of the target itself due to ultrasonic field when the source is alternately switched on and off.

Two different radiation force balance set-ups are available at the INRIM ultrasound laboratory, which are used for different ultrasonic power ranges: the first set-up uses an absorbing target and is suitable for power less than 2 W, while the second set-up, used for higher power levels P>2W, adopts a reflecting target.

Such instrumentation is very bulky and at the moment measurements cannot be performed in hospitals, but a portable version is currently under study, making it feasible to include acoustic power control in QA protocol in the next future.

3. Conclusions

CRUM, Reference Center for Ultrasound in Medicine in Regione Piemonte, has the aim to promote and standardize US QC procedures in the regional territory, to create a regional database including all the diagnostic medical US equipments in Piemonte and monitoring their operational conditions.

Moreover, the training activity of CRUM aims at providing specific and updated skills in the field of medical US , in cooperation with the local Universities, not only to medical professionals and radiologists but also to graduates in Obstetrics, Radiology Technicians and Nurses following specific university training courses.

Finally, CRUM is interested in create interest and sensitizing all the professional figures involved with Medical US, with the aim of extending QC practice also to the US therapy equipments, developing appropriate protocols and procedures.

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