Quality Control Program in Medical Ultrasound at Hamad Medical Corporation: Current Status

Nabil Iqeilan, Antar Aly, Salha Al Mohannadi, and Huda Al Naemi

ABSTRACT

The main purpose of QC program in diagnostic imaging modalities such as medical ultrasound equipment is to evaluate and define the performance and safety of ultrasound equipment. Ultrasound systems contain many sensitive transducers and soft parts which may be destroyed due to poor handling or use. Over time, any machines, regardless of their quality and usage, depreciates and incurs damage in many ways.

The results from the Quality Control (QC) reports for B-mode of the Ultrasound machines in the Clinical Imaging Department of Hamad Medical Corporation (HMC) has been reviewed. The average annual failures of equipment during the 4-year period includes 2.7% involved transducers and 51.3% involved mechanical integrity failures while the average annual failures rate from mechanical integrity and transducers were measured to be 12.8% and 0.7%, respectively. The main failure of the transducers could be from some artifacts or bad connection of individual elements or groups of elements. Evaluation of maximum depth of penetration showed that the measurement of distance accuracy is not effective in detecting equipment failures [1].

Keywords: Image, mechanical integrity, ultrasound, quality control.

I. INTRODUCTION

Diagnostic medical Ultrasound (US) is widely in use in different types of clinical set up by people with a variety of backgrounds and there by contributing to the hospital field.

Diagnostic quality of US not only adds to the technical quality assurance and image quality, but also diagnostic quality of US examinations depicts data accuracy, good patient management, informed decision, and appropriate care.

Technical quality assurance (QA) processes are therefore an important criterion in US practice accreditation programs [2]-[6] in order to provide base for the whole quality procedure and safety.

Because of the delicate parts of the US systems which are easily prone to physical damage by improper handling and use, careful and strict protection of the equipment while its operation has become an important requisite for the operator. Knocking or dropping the probe as well as passage of the wheels of the machine over the cable of the probe while moving must be avoided. (the US machines can be as heavy as 150 kg). Any frayed cords and cracked transducer casing may cause an electrical hazard to the operator or patient and the machine or the transducer must be used only after troubleshooting the problem by a specialist [7].

Sonographers and Ultrasound Physicians expect that all the details acquired from a clinical ultrasound procedure are accurate and seek assurance that the safety of the equipment is intact. Any kind of degradation in the image quality could be identified before seen on patient scans is the primary reason for setting a set of definitive measurements done periodically for each transducer and US unit. Another reason is that if an equipment failure is encountered, QC tests can easily be used to understand the reason of the malfunction. Periodic checking should be done for the equipment that is under service contract or warranty because it can verify that equipment is operating perfectly, and repairs were done on time with accuracy [5].

The most recommended and sensitive tests ideal for evaluating the US unit which should be used as a routine QC program for ultrasound machines include:

- Assessment of mechanical integrity and transducer integrity.
- Assessment of uniformity of images of all transducers so the device must be immediately switched off.

In mechanical inspection, the assurance of all mechanical component should be evaluated before performing the image quality tests.

Measurement of visualization depth, visual assessment of the homogeneity and the uniformity of the image, the lateral symmetry of the electronic noise and the visibility of contrast targets are included in the essential B-mode image-quality measurements.
II. MATERIAL AND METHODS

This study covers 4 years period between 2016-2019 and a total of 113 ultrasound units with 622 total number of transducers, distributed over 9 hospitals and each machine is equipped with 3 to 6 transducers as shown in Table I and II. Periodic QC measurements are recommended in order to ensure the performance, accuracy, and safety of ultrasound equipment. 113 ultrasound scanners and its transducers [622 in number], from various manufacturers [5 of them], were tested using Real-time B-mode ultrasound quality control test procedures Report of AAPM Ultrasound Task Group No.1. GAMMEX Ultrasound 403GS Grey Scale Precision Phantom, a tissue-mimicking phantom is shown in Fig. I which is used to elaborate assessments of image display as well as performance.

The results of tests done periodically can be compared with the help of results from baseline study of machine or performance of transducer. The baseline results are obtained either during the acceptance of a machine or at the beginning of the QC program. And all these shows the integrity and performance of transducer used. Fig. 2 is the form used for QC assessment which includes all QC tests performed annually for US in HMC clinical imaging department.

**TABLE I: NUMBER OF FAULTY ISSUES AND FAULTY TRANSDUCERS DURING THE PERIOD 2016-2019**

| Year | No. of Faulty issues | No. of Faulty transducers |
|------|-----------------------|---------------------------|
| 2016 | 24                    | 3                         |
| 2017 | 22                    | 3                         |
| 2018 | 19                    | 7                         |
| 2019 | 10                    | 4                         |
| Total| 75                    | 17                        |

**TABLE II: NUMBER OF MACHINES AND TRANSDUCERS FOR THE SELECTED US DURING 2017-2019**

| Manufacturer | No. of Machines | No. of transducers |
|--------------|----------------|--------------------|
| GE           | 61             | 466                |
| Philips      | 31             | 92                 |
| Canon        | 17             | 56                 |
| Siemens      | 3              | 6                  |
| Toshiba      | 1              | 2                  |
| Total        | 113            | 622                |

**Fig. 1. Ultrasound test phantoms by Gammex.**

**Fig. 2. Simple form for quality control report of medical ultrasound. Common QC Tests.**

*Common QC Tests*

**A. Mechanical Integrity**

This is mainly an inspection of the transducers, scanner keyboard and control switches to make sure that all mechanical systems are functional, and all the components are fully intact. The Physical and Mechanical Inspection Failures:

- Transducers: Check cables, housing, and transmitting surfaces for cracks, discolorations and separations. Mechanical real-time transducers must have a smooth vibration-free motion and free from air bubbles. Condition of connectors also should be checked.
- Power cord: Check for cracks, discoloration, and damage on cable and plug.
- Controls: Check operation of switches and knobs, note any burnt-out bulbs.
- Video Monitor: Check for cleanliness, scratches and operation of controls.
- Wheels and locks: Verify proper operation of wheels and locks.
- Dust Filters: Check for cleanliness. Person responsible should clean or replace filters at regular intervals.
- Scanner housing: Check for dents and other damage.
- Image Uniformity.
- Depth of Visualization.
- Vertical and Horizontal Accuracy.
- Anechoic Object Perception.
- Axial Resolution.
- Lateral Resolution.
- Dead Zone.

**B. Image Uniformity**

The image uniformity was assisted by using the images of commercial ultrasound phantom, (e.g., model GAMMEX Ultrasound 403GS Grey Scale Precision Phantom which is a
tissue-mimicking phantom). They are inspected visually for the presence of any artifacts and assessed for any potential clinical significance of any detected artifacts. To detect the different intensities of brightness it is good to keep the Grey scale targets as it also helps to check about the temporal resolution and contrast addition to border delineation capabilities of the ultrasound system.

III. RESULTS

From the data collected, it is noticeable that the number of failed transducers are very low, and this is may be due to a proper preventive maintenance PPM in quarterly basis which could lead to discover the faulty issues (mechanical and transducers faults) in between. In some situations, the users or operators could notice any malfunction within the unit and call for maintenance to fix or replace the transducers.

The average annual equipment failures detected in 4 years is 2.7% involving transducers and 51.3% involving mechanical integrity failures. The average annual mechanical integrity failures were measured to be 12.8% and transducer failure rates were 0.7 shown in Table III. The main failure of the transducers could be from some artifacts or dropout of groups of elements or individual elements. Testing the highest depth of penetration and measurement of distance accuracy did not help at finding out any failures of the equipment.

The reduction in the transducer percentage failure was almost 50% from 2019 to 2018 and almost 70 % for the years 2016 and 2017 compared to 2019, mostly due to the replacements of old machines with new ones.

As shown in Table I, it is notable that there are about 17 transducers which have failed the image quality test, and this could be from some artifacts or breakdown of individual piezoelectric elements. Sometimes this problem cannot be detected on images of patients and can only be detected when scanning uniform phantoms. As most of the modern array transducers contain many transducer elements and all of those must operate perfectly to obtain the best clinical output from the ultrasound machine. An individual element or a group of elements in an array can be damaged if the sensitivity of the element(s) has become low, any connection problem in the electric circuit occur, a loose matching layer or because of the lens materials, or any kind of malfunctioning of an electrical circuit in the machine.

Fig. 3 shows that transducer failure artifacts are shadowing due to element failure and image non-uniformity faults.

As shown in Table IV, it was found out also that for Transducers testing there are 55 failed from the tests which includes housing, cables, separations and discolorations, and cracks in the surfaces of transmission, transducer fail in mechanical function to provide smooth motion without vibration and occurrence of air bubbles and failures in the condition of connectors.

There are also 38 US machines which failed the test of Controls: burnt out bulbs, operation of knobs and switches.

Two machines have failed Video monitor: operation of controls and for scratches and cleanliness and while 3 machines have failed the locks and wheels: perfect function of locks and wheels and Dust Filters. The image acquired is one of a series of reverberations of horizontal bands because of the mismatch of transducer–air impedance.

IV. DISCUSSION

This is the first study explaining the status of QC for ultrasound in HMC and in Qatar.

The results were based on data retrieved from quality control reports during the last four years.

Based on our data, the transducers faults are leading to image uniformity problems. About 17 transducers have failed the image quality test and this could be from breakdown of individual piezoelectric elements or groups of elements in the transducer source of ultrasound equipment malfunction or from some artifacts, and usually this problem cannot be seen on clinical study but only if we scan uniformity phantoms.

An identical type of effectiveness study was earlier reported by [1], [8]. Reference [8] explained the output of the performance test of their 17 ultrasound machines and 30 transducers. Their conclusion was that they were not successful for finding damages that compromised the image quality (2 cases recorded and many unrecorded) according to their original testing scheme and testing with tissue equivalent phantoms had been discontinued. They also reported that to set an acceptance or tolerance limit for a particular measure is difficult. At the same time, it is hard to achieve with the subjectively made readings with a large variance. Reference [9] also reported the same problem with the set-up of tolerance limit in subjective measurements.

### TABLE III: PERCENTAGE OF FAILURE FOR MECHANICAL INTEGRITY AND TRANSDUCERS DURING THE PERIOD 2016-2019

| Years | Mechanical integrity failures | Transducers failures |
|-------|-------------------------------|-----------------------|
| 2016  | 18.6                          | 0.5                   |
| 2017  | 16.8                          | 0.5                   |
| 2018  | 10.6                          | 1.1                   |
| 2019  | 5.3                           | 0.6                   |
| Average Annual (%) | 12.8 | 0.7 |

### TABLE IV: PHYSICAL AND MECHANICAL INSPECTION FAILURES FOR DIFFERENT US MACHINES

| Inspection | Power Cord | Controls | Monitor | Wheels & Locks |
|------------|------------|----------|---------|---------------|
| Failure Type | Rupture, Stain and Impairment to Cable and Plug | Performance of Buttons, Knobs and not any out Bulbs | Focus, Cleanliness, Marks and Score and Operation of Controls | Wheels Rotate Freely and Are Secure, Make Sure Locks Work |
| Number of Failures | 12 | 38 | 2 | 3 |

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Fig. 3. a) transducer failure artifacts, b) shadowing due to element failure. c) image non-uniformity faults.

V. CONCLUSION

The most effective tests in finding out equipment failures were uniformity and mechanical integrity. Study of accuracy of distance measurement and highest depth of penetration were not successful at understanding failures in the equipment.

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