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ROUTINE ULTRASOUND QUALITY ASSURANCE IN A MULTI-UNIT RADIOLOGY DEPARTMENT : A RETROSPECTIVE EVALUATION OF TRANSDUCER FAILURES

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2 ***Routine Ultrasound Quality Assurance in a Multi-Unit Radiological***
3 ***Department: a Retrospective Evaluation of Transducer Failures***

4

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19

1

2 **Abstract**

3 The importance of quality assurance (QA) in medical ultrasound (US) has been widely
4 recognized, and recommendations concerning technical QA have been published over the
5 years. However, the demonstrated impact of a properly working QA protocol on clinical
6 routine has been scarce. We investigated the transducer write-off causes over a period of
7 5 years in a multi-unit radiological department with an average of 230 transducers in
8 demanding diagnostic use annually. The transducer faults and the initial observers of the
9 faults leading to transducer write-offs were traced and categorized. The most common
10 cause of transducer write-off was image uniformity problem or element failure. Mechanical
11 faults or excessive leakage current and defects in the lens constituted smaller yet
12 substantial shares. Our results suggests that a properly working routine QA program can
13 detect majority of the faults before they are reported by users.

14 **Keywords**

15 ultrasound, quality assurance, quality control, technical quality assurance, diagnostic
16 radiology, image quality

17

1

2 **Introduction**

3 Diagnostic medical ultrasound (US) makes a significant contribution to patient care and is
4 increasingly used in a variety of clinical settings by many different professionals with
5 varying technical backgrounds. Diagnostic quality of the US examinations includes more
6 than the technical quality assurance and the image quality, ranging from data accuracy to
7 good patient management, informed decision and appropriate care. In order to lay grounds
8 for the whole quality process and safety, technical quality assurance (QA) processes have
9 been required as an essential part in ultrasound practice accreditation programs such as
10 American College of Radiology (ACR) (ACR 2011) and American Institute of Ultrasound in
11 Medicine programs (AIUM) (AIUM 2010). Major international scientific bodies have
12 published recommendations solely concerning technical QA including AIUM (AIUM 2008),
13 The American Association of Physics in Medicine (AAPM) (Goodsitt et al. 1998), ACR
14 (ACR 2011; ACR 2015), Institute of Physics and Engineering in Medicine (IPEM)(Russell
15 et al. 2010), European Federation of Societies for Ultrasound in Medicine and Biology
16 (EFSUMB) (Kollmann et al. 2012) and International Electrotechnical Commission
17 (IEC)(IEC 1986; IEC 1996; IEC 2006; IEC 2010; IEC 2015) . In addition, there are several
18 recommended performance tests, measurement tools and methods described in the
19 literature over the past few decades, from single commercial tools to the computer-based
20 analysis of phantom and air images (Goodsitt et al. 1998; Goldstein et al. 1989; Gibson et
21 al. 2001; Kofler and Madsen 2001; Moore et al. 2005; Satrapa et al. 2006; Dolezal et al.
22 2007; Thijssen et al. 2007; Rowland et al. 2009; MacGillivray et al. 2010; Rosenfeld et al.

2014; Quinn and Verma 2014).

The common objective of grey scale imaging is to determine the position, shape, size, texture and dynamics of soft tissue structures, organs, and masses (Powis and Moore 2004). User's ability to meet these demands depends on the proper functioning of the ultrasound devices and transducers in use. Proper functioning can be ensured by knowing the current technical state of the equipment, most importantly the transducers (Thijssen et al. 2007; Weigang et al. 2003; Mårtensson et al. 2009). The highly-operator dependent nature of ultrasound examinations and the multitude of professionals performing them makes technical QA a vital part of the department's quality system for US. As the number of US devices increases, it is imperative to guide the limited resources to those routine QA tests that provide the most efficient detection of transducer faults. It is also useful if the results can be compared with the performance history of the device or with a cohort of similar devices.

We present our 5-step ultrasound QA program, discuss its value in detecting transducer faults, and review the write-off causes over a period of five years with the full operation of a routine QA program. Also, relative occurrence of different kinds of transducer faults are clarified and the importance of recommended QA tests assessed. This is a retrospective study, based on the information collected during 5-year period of working QA process.

1 **Materials and Methods**

2 The operational environment for our radiological department's US QA program
3 encompasses 19 radiological units distributed over a large geographical area. The
4 radiological department is the leading provider of medical imaging studies and
5 interventional radiology in Finland producing services for the nearly 1.6 million residents.
6 The imaging studies and services cover the requirements from primary to special health
7 care, for university hospital research and teaching, and nationwide responsibility in certain
8 areas of specialist medical care. At the beginning of the 2016, the equipment comprised of
9 60 US devices with 226 transducers in demanding radiological use, and 19 devices with
10 53 transducers in not demanding use (e.g. used in guiding biopsy needles etc.). The
11 number of the US devices has been on a slight increase over the recent years.

12
13 The personnel groups involved in our QA process are medical physicists, sonographers,
14 in-house medical engineers, and personnel at the departments. The technical QA program
15 is coordinated and overseen by a qualified medical physicist. Image quality is tested with
16 an image quality phantom. The image quality tests at device acceptance, annually during a
17 multi-year guarantee and just before the expiration of the guarantee are done by the
18 medical physicist. After the expiration of the guarantee, the image quality tests are done
19 annually by sonographers. The image quality tests done by sonographers are allocated to
20 the last quarter of the year. The physical condition of the US device and transducers is
21 assessed at the beginning of the image quality test. In-house medical engineers perform
22 the annual mandatory leakage current measurements together with transducer electrical

1 element sensitivity tests and inspect the physical condition of the US devices. Medical
2 engineers distribute the annual checks throughout the year. Manufacturers' medical
3 engineers don't have a direct role in our QA process although they perform on demand
4 repairs on US devices. The personnel at the departments are involved in the QA process
5 by checking and documenting air image and the physical condition of the US device and
6 transducer quarterly. The outline of our routine US QA program, the scheduling and the
7 personnel involved is given in Table 1.

8
9 All measurements are carried out at the clinical sites, so special attention has been paid to
10 technical solutions enabling centralized organization, coordination, and review of the QA
11 measures. The devices are listed and maintained in the hospital district's online medical
12 equipment asset and maintenance management system (Mequsoft, Sofor Oy, Kauhava,
13 Finland). The system ideally holds all the information starting from the purchasing and
14 acceptance of the device until the device is retired from active use. The QA image
15 communication is routed through radiological picture archiving and communication system
16 (Impax, Agfa HealthCare, Mortsel, Belgium) to the dedicated image QA server for storage
17 and centralized backup. Our routine QA program complies with the recommendations for
18 technical QA by AAPM (Goodsitt et al. 1998).

19
20 To obtain comparable air and phantom images and results, a standardized QA
21 measurement setup is required. To achieve this, a unified QA preset was created and
22 saved for each device and transducer. The settings in the preset were aimed to minimize

the user adjustments and the processing that the US device is applying to the image. Similar preset choices were made as in (Sipilä et al. 2011b) with a modification of the measured frequencies and time gain compensation (TGC) settings: The output power was set to maximum, as also recommended in the IPEM guidelines (Russell 2010). The TGC switches were all set in center position to achieve straightforward measurement setup with minimal inter-user variability. All image processing settings (such as harmonic imaging, spatial or time averaging, compounding etc.) were set to off or to minimum value. The focus width was set to middle value where possible, and the number of focuses was set to one, except for the image homogeneity test with three focuses. For linear transducers the highest frequency, and for convex transducers the lowest frequency was selected to reflect the clinical use of the transducers. Also, the use of only one frequency was chosen to keep the measurement protocol as straightforward as possible.

The air image, an image taken when the transducer is clean, dry and in free air was used to visually assess the condition of the element array of the transducers. In addition to the aforementioned QA preset, internal guidelines were followed on image and focus depth choices: The image depth is set to predefined transducer model dependent value to a depth closest to transducer surface where the reverberation bands can be seen completely. The transmit focus was set to a position as close to the transducer surface as possible to provide clear view of the bands. The irregularities in the bands in the air image were seen as an indication of possible element fault in the system (Quinn et al. 2014).

1 The B-mode image quality was assessed with a multi-purpose multi-tissue ultrasound
2 phantom (CIRS 040GS, Norfolk, Virginia, USA) designed for large frequency range. The
3 image QA with the phantom was divided into advanced and essential measurements.
4 Advanced B-mode phantom measurements are done at the acceptance of the device and
5 when the warranty is about to end. The advanced measurement protocol is published
6 earlier in the Sipilä et al. (2011b) and it is complying with the IPEM recommendations
7 (Russell et al. 2010). Essential B-mode phantom measurements are done annually during
8 a multi-year US device guarantee and after the guarantee has expired. The outline of
9 scheduling is presented in Table 1 and the breakdown of the measurement protocol is
10 given as supplementary material (table A).

11
12 Briefly, the essential B-mode image quality measurements include the measurement of
13 visualization depth, visual assessment of the homogeneity and the uniformity of the image,
14 the lateral symmetry of the electronic noise, and the visibility of contrast targets. The axial
15 and lateral resolution is determined with measurement of height and width of a filament at
16 specified depth, the axial and lateral measurement accuracy is determined, and the depth
17 of the dead zone is measured with the phantom filaments near the surface. In addition to
18 these, advanced image quality measurements include visual assessment of the image
19 uniformity with three focuses, the measurement of focus depth in the slice thickness plane,
20 the visibility of anechoic targets of variable depths and resolution determined with
21 resolution groups within the visualization depth. In addition to imaging preset, internal
22 guidelines were followed on device adjustments (such as gain, image depth and focus) to

1 obtain optimal standardized images for the analysis.

2
3 The transducer electrical element sensitivity was assessed with FirstCall aPerio™ system
4 (Sonora Medical Systems Inc., Longmont, Colorado, USA). In the transducer electrical
5 element sensitivity measurements the manufacturer's recommended criteria was used with
6 the same modification as Mårtensson et al. (2009) to decide if an individual element was
7 working properly (sensitivity >75% of the mean value), weakly (sensitivity >10% and <75%
8 of the mean value), or not at all (sensitivity <10% of the highest value; dead element). The
9 portion of our transducers compatible with our FirstCall system has been around 70-75 %
10 with slight yearly variance due to introduction of new transducer models and available
11 FirstCall adapters.

12
13 The quality of the phantoms is followed by weighing the phantoms annually and handling
14 them according to the guidelines by the manufacturer (CIRS 2013).

15
16 If a transducer fault was detected in any of the QA measures, the viability of the transducer
17 was assessed and the initial fault was categorized either as a minor or major fault,
18 according to Table 2. Following the detection of the fault a transducer viability evaluation
19 process was initiated. In this evaluation process the transducer might be subjected to
20 further analysis depending on the initial observer and the first evaluation of the severity of
21 the detected fault. Transducers with minor faults were subjected to monitoring. In case of
22 major fault the transducer was either repaired or written off and replaced. In any case, the

1 final assessment of the transducer was based on the clinical usage of the device and the
2 transducer, the nature and appearance of the fault, and the compensatory equipment at
3 hand.

4
5 The number of transducer faults was studied by listing all transducers that were written off
6 during the last five years according to the Hospital district's medical equipment asset and
7 maintenance management system. The list contained the write-off dates of transducers
8 and, in most cases, also notes about the reason of write-off. In the cases where the reason
9 was not present in the database, it was sought out using quality assurance documents,
10 procurement documents or personal e-mail transactions of the QA personnel. The
11 transducers that were retired with outdated US device are not included in results.

12
13 The data of all defects was categorized to obtain the relative occurrence of different types
14 of faults. The dominant reason for transducer write-off was divided into five categories: Air
15 image or image uniformity problem, transducer electrical element sensitivity issue, the
16 defect of the lens including wear with age and accidental puncture with a needle, leakage
17 current out of limits and mechanical fault. Additionally, the reason of write-off was labeled
18 as "not documented" if the final reason for the write-off could not be retrieved.

19
20 Also, we studied which personnel group made the initial observation of the fault that led to
21 the write-off of the transducer. For this purpose the personnel involved in the routine QA
22 were divided in four groups: Medical physicists and sonographers, medical engineers, the

personnel at the department, and other representing a purchased service for the electrical transducer element sensitivity measurements in 2012.

Results

In total, 85 transducers were written-off due to defects during the period, of which 23 were withdrawn in 2012, 24 in 2013, 13 in 2014, 25 in 2015, and 17 in 2016. The reason for the transducer write-offs on a yearly basis is presented in Figure 1 with the five fault categories. Extensive unechoic streaks in the air image or image uniformity problem in the phantom image was the leading cause of write-offs in 49% of the documented cases during the period of investigation. There were no transducers which were written off because of failure in any of the phantom tests alone other than air image or image uniformity failure. A transducer electrical element sensitivity problem without visible effect on the image quality comes second with 21% share of the write-offs. Together the air image or image uniformity problem and electrical transducer element sensitivity problem were the reason behind 69 % of the transducer write offs. Wearing or defect in the transducer lens came in the third place the share being 18% of all transducer write-offs. The majority of the lens defects were caused by the general wearing of lenses. Half of the transducers written of due general wearing of the lens had been used for less than five years and the other half more than five years. Mechanical breakdown of the transducer casing or failure in leakage current test have caused almost equal share of the write-offs, combined in total 13% of the documented write-offs during the investigation period.

Annual fluctuation of each fault category is presented in Figure 2. The category “Not documented” is added to represent those write-offs where the dominant fault could not be retrieved. The share of transducer faults detected by air image or phantom image uniformity test is increased over the study period. At same time the share of transducer faults detected by the transducer electrical element sensitivity test has decreased. The share of write-offs originating from a lens defect or leakage current have stabilized in recent years being equal for last three years. The occurrence of mechanical faults have had small and variable share annually being non existent in 2012 and 2016. The amount of undocumented cases have decreased over the study period.

The yearly distribution of the initial fault observer is presented in Figure 3. The portion of transducer faults detected by the personnel of the departments have stayed fairly constant at 1 / 3 through the years whereas the rest of the faults are detected by physicist, sonographers and medical engineers responsible for phantom and transducer electrical element sensitivity tests. In 2012, the transducer electrical element sensitivity tests were purchased from third party vendor, and from 2013 onwards the tests were incorporated to the QA program as in-house tests.

Discussion

Based on our results, the air image problem or image uniformity problem detected with phantom image is the leading cause for transducer write-offs. Relevant information on element condition can be obtained with the air image by evaluating visible irregularities in

1 the reverberation bands and the image uniformity in the phantom image. The air image
2 based tests can be easily applied by personnel at the departments with consultation from
3 experienced QA professional. The visual air image inspection, phantom measurements
4 and transducer electrical element sensitivity testing are partly overlapping methods in
5 detecting transducer faults. They all are able to detect problems in element array. The
6 element based problem in a transducer is thus rarely detectable only with transducer
7 electrical element sensitivity tester and equally good detection is achieved with more
8 available visual air image and phantom image testing. Based on our results only 21% of
9 the fault detections leading to write-offs were made with transducer electrical element
10 sensitivity tests. In addition, our timely interleaved QA process may emphasize the role of
11 transducer electrical element sensitivity testing, as the element sensitivity drops could be
12 detected with the air image test. However, electrical element sensitivity testing can provide
13 valuable information in grading the fault. This may be used in deciding if the transducer
14 can be repaired or need to be replaced.

15
16 The transducers written off due defects in the lens were, with a few exceptions, linear
17 transducers in heavy diagnostic use in busy radiological imaging units. The majority of the
18 lens defects were caused by the general wearing of lenses suggesting that the durability of
19 the lens may not last the whole lifespan of the transducer in demanding radiological use.

20
21 Substantial part of the transducer write-offs were caused by transducer leakage current
22 being out of limits or mechanical failure. This can be mostly considered as a sign on heavy

1 physical usage that is stressing the transducers in clinical environment. Some of the
2 failures can be traced to single occasion such transducer dropped on the floor or cabling
3 run over by US machine itself. However, most of the leakage current and mechanical
4 failures in our study could be traced to simple cabling or casing fatigue in heavy use.

5
6 The share of air image or image uniformity problem and faults detected by electrical
7 element sensitivity testing are on slight increase over the reviewed time period. The
8 emphases of the faults in general have changed from the coarse mechanical problems
9 towards more delicate image quality issues. This could be taken as a measure to roughly
10 estimate the maturity of the routine QA program in an organization.

11
12 Despite the hospital district's asset and device management system the final write-off
13 reason was left unspecified on a few transducers each year. The most of the
14 undocumented write-offs occurred during the early years when the documentation of the
15 transducer QA was still in a run-up phase. Although it is advised to make notes about the
16 write-off reason to the system, it is not mandatory by design.

17
18 The relative share of faults identified by each personnel group is varying slightly on yearly
19 basis. An annual fluctuation can be seen in the shares of identified faults between medical
20 physicist, sonographers and medical engineers. We have not identified clear reason
21 behind this inconstancy. It is likely because of normal variation in the occurrence of
22 different types of transducer faults, personnel changes and increasing experience in QA

1 tests and measurements. Based on the results, 2/3 of the detected defects are found by
2 scheduled dedicated QA tasks carried out by medical physicists, sonographers and
3 medical engineers. This indicates that the majority of the defects in transducers are found
4 before they are detected by personnel at departments in clinical work or the quarterly QA
5 tests. This share can be noted as a figure depicting the capability of the QA program.

6
7 The presented 5-step QA program is at the moment adjusted to the requirements of a
8 rather large and sparse radiological department, which has grown with multiple outlets
9 during the period of investigation. It has multiple personnel bodies doing partly overlapping
10 tasks requiring effective mutual communication. At the same time, the system is relatively
11 agile with distributed QA tasking. There are clearly defined responsibilities that are not
12 dependent on any single person. Also, personnel in each unit performing US examinations
13 are involved in routine technical QA with quarterly check-ups.

14
15 In a large department with the plenitude of different US devices, mutual information can be
16 used to evaluate the condition of a single device. For example, if one US device is
17 suspected of fading out in terms of the penetration depth or the overall visibility, the results
18 from one device-transducer pair could be compared with other pairs of the same
19 manufacturer and age. Thus, equipment replacements could be focused on the most worn
20 out devices.

21
22 Similar type of effectiveness analysis has been previously reported by Dudley et al. (2001)

1 and Hangiandreou et al. (2011). Dudley et al. reviewed the results of the performance test
2 of their 17 ultrasound devices, and 30 transducers. They concluded that their original
3 testing scheme was unsuccessful for detecting faults that affected the image quality (2
4 recorded cases and several unrecorded), and they discontinued routine tests with tissue
5 equivalent phantoms. They also noted that acceptance or tolerance criteria for any single
6 measure are hard to set and achieve with the subjectively made measurements with large
7 variance. The same difficulties regarding the setting of tolerance criteria in subjective
8 measurements has been also presented by Sipilä et al. (2011a). In the work by
9 Hangiandreou et al. presented data from a slightly smaller radiological department than
10 covered in our study. The image uniformity evaluation was the most effective test in
11 detecting equipment failure, accounting for 66.3% of the defects, a result very similar to
12 ours.

13
14 Transducer electrical element sensitivity testers have been available for some time, and
15 they have become a widely used method for transducer viability checks by hospitals,
16 ultrasound device manufacturers and third party transducer repairers globally. As large as
17 40% of 676 transducers used daily in clinical departments in 32 hospital in Sweden were
18 found to be defective (Mårtensson et al. 2009). Most often (26.5%) the problem was due to
19 the delamination of the lens, while cable related problems consisted approximately 1/4 of
20 the found faults. With our current routine 5-step QA program almost 70% of the written-off
21 transducers are due to transducer element breakdown, corresponding 2-4% of the whole
22 stock of transducers annually.

1

2 It is noteworthy that in our study not a single write-off was initiated because of image
3 quality defects without an element fault or an image uniformity problem. In this respect, it is
4 questionable if extensive image quality tests are justified on a yearly basis (or even more
5 frequent) after the acceptance tests. Based on our five-year data, annual technical QA with
6 an image quality phantom could be reduced to air image and image uniformity measures.
7 Reduction in the amount of annual routine QA tests would release time of the personnel
8 involved and enable simpler checkups. This would also mean a more agile approach to the
9 routine QA, since device downtime would be reduced per measurement and the
10 corresponding time would be available for clinical use. The notion of the unnecessary
11 extensiveness of recommended routine QA tests and the subsequent reduction in the
12 protocols is shared in the literature (Dudley et al. 2001; Russell et al. 2010; Hangiandreou
13 et al. 2011). However, there are also some limited evidence of the value of the extensive
14 QA programs (Dudley et al. 2014).

15 **Conclusions**

16 A justified, timely, and an evidence based routine US QA program is an essential
17 requirement for preventive maintenance. It is a necessary condition to be able to declare
18 that the examinations are performed with adequate equipment and forecast cost of
19 equipment maintenance and replacement. With the presented five-step QA program the
20 most of the transducer faults were detected before they were spotted by the users. In light
21 of the obtained results, it is reasonable to reduce the repertoire of phantom tests included

1 in the routine QA protocol to air image and image uniformity, without compromising the
2 clinical image quality. Transducer electrical element sensitivity test provides additional
3 information on transducer fault that can be used to decide whether to repair or replace the
4 transducer.

5 **Acknowledgements**

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7 participating in the QA program over the years. This research received no specific grant
8 from any funding agency in the public, commercial, or not-for-profit sectors.

9

1 Appendices

2 *Table A.1: The outline of the individual measurements of our routine B-mode image quality*

3 *QA program.*

QA measure	Notes	Target	Essential	Advanced
The appearance of the reverberation bands.	The reverberation bands were assessed with the focus as close to the transducer surface as possible. The smoothness, continuity and symmetry of the bands in lateral direction were evaluated visually.	Free air	x	x
The lateral symmetry of the electronic noise.		Free air	x	x
The gain value at which electronic noise disappears.		Free air	x	x
Visualization depth	The visualization depth was judged as the depth middle between the depth where the background texture is clearly identifiable and the depth where the background texture is no longer visible (where the electronic noise is prominent). The two depths were measured using the US device's caliper and the visualization depth was calculated.	Phantom		
	Visualization depth in the 0.5 dB/cm/MHz attenuation region.			x
	Visualization depth in the 0.7 dB/cm/MHz attenuation region.		x	x
Homogeneity and uniformity of the image	With one focus, large image depth	Phantom	x	x
	With one focus, image depth 4 cm.		x	x

	With three focuses, large image depth.			x
Focus depth in the slice thickness plane	The transducer was positioned in 45° angle against the long side of the phantom and the vertical filaments were positioned in the central field of view of the transducer. The filament with the smallest lateral diameter was assessed to represent the focal depth.	Phantom		x
The visibility of anechoic targets at variable depth	The visibility was assessed as visible or not visible against the phantom background texture.	Phantom		x
The axial and lateral resolution determined with resolution groups within the visualization depth	Resolution groups were analysed within the visualisation depth of the transducer and thus only one or two resolution groups were analysed with high frequency probes.	Phantom		x
The visibility of contrast targets at two depths	The visibility was assessed as visible or not visible against the phantom background texture.	Phantom	x	x
The axial and lateral resolution determined with measurement of height and width of a selected filament.	The filament of the vertical distance group at 3 cm depth was measured. However, if the filament was not visible (for high frequency transducers) the filament at the 2 cm was measured instead.	Phantom	x	x
The axial and lateral measurement accuracy	The measurement accuracy was measured with vertical and horizontal distance groups. A distance of filaments namely 30 mm apart from each other were used. If the filaments 30 mm apart from each other were not visible in the transducer field of view of high frequency transducers, filaments 20 mm apart from each other were used instead.	Phantom	x	x
The depth of the dead zone	Evaluated with the filament group in the phantom.	Phantom	x	x

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1 **Figure Caption List**

2 **Figure 1.** The relative reason of documented transducer write-offs in 2012-2016

3 combined.

4 **Figure 2.** The relative reason of the write-off of all transducers each year.

5 **Figure 3.** The initial observer of verified faults leading to transducer write-off. "Other"

6 denotes a purchased service for transducer electrical element sensitivity tests in 2012.

7

1 Tables

2 *Table 1: The outline and scheduling of our routine QA program.*

Step	QA measure	Personnel	Scheduling
1	Advanced B-mode image quality ¹ Air image ² Physical condition of the US device ³	medical physicists	at acceptance, before guarantee expires
2	Essential B-mode image quality ¹ Air image ² Physical condition of the US device ³	medical physicists sonographers	annually during a multi-year guarantee annually after the expiration of the guarantee
3	Leakage current Transducer electrical element sensitivity ⁴ Physical condition of the US device ³	medical engineers	annually
4	Physical condition of the US device ³ , Air image ²	personnel at the departments	quarterly
5	Weight, physical condition and calibration of the phantoms and measuring equipment	medical physicists medical engineers	annually as instructed by manufacturers

3

4 ¹ For detailed information on the specific test included, see text and Supplementary

5 material.

6 ² An image taken when the transducer is clean and dry, and in free air.

7 ³ Physical condition covers the transducer, the device, all external cabling and connectors,

8 the console, maneuvering and ergonomics, and the dust filters.

- 1 ⁴ *Transducer element sensitivity is evaluated with the FirstCall aPerio™ device for those*
- 2 *transducers where the adapter is available.*
- 3

1 *Table 2. Categorization of transducer faults.*

Test	Minor fault	Major fault
Air image	One or few narrow low echoic streaks on reverberation bands. Phantom images are used to further analyse the effect of the fault on image uniformity.	Extensive unechoic streaks in reverberation bands. Phantom images are used to further analyse the effect of the fault on image uniformity.
B-mode phantom uniformity image	No visual effect on image uniformity or small effect at the edge of the image.	Strong unechoic beam in image.
Transducer electrical element sensitivity	Less than major condition.	More than four contiguous weak elements, or more than two dead elements, or two contiguous dead elements. ¹
Leakage current	-	Protective earth resistance over 0.3Ω, direct equipment leakage current over 500 μA, or direct patient leakage current over 5000 μA according to IEC 62353 ² .
Physical condition of the lens	Lens wearing or needle damage which is not penetrating lens nor having an effect on phantom image quality.	Lens damage exposing transducer emitting surface or major effect in phantom uniformity image.
Mechanical breakage	Small bend in device cabling or crack in housing which can be repaired by in-house medical engineers. No effect on image quality.	The use of device is limited due physical damage and/or major effect in phantom uniformity image.

2
3 ¹ *The overall categorization for the transducer to be renewed or replaced was as described*
4 *by Mårtensson et al. (2009).*

5 ² *IEC 62353. Medical electrical equipment - Recurrent test and test after repair of medical*

- 1 *electrical equipment. Geneva, Switzerland: International Electrotechnical Commission,*
- 2 *2014*
- 3