SPECIFICAȚIA TEHNICĂ COMPLETATĂ

Pentru Lotul 57 Servicii de mentenanță pentru Ecografe Logic

- 57.1 Mentenanță pentru Ecografe (USG) LOGIQ Fortis HDU Producător GE Healthcare , Corea.
- 57.2. Mentenanță pentru Ecografe (USG) Logiq P9, GE Healthcare
- 57.3. Mentenanță pentru Ecografe (USG) Logiq F8, GE Healthcare Inc.
- 57.4. Mentenanță pentru Ecografe (USG) Logiq S7, GE Healthcare Inc.
- 57.5. Mentenanță pentru Ecografe (USG) Logic P5 Premium BT 11/ GE Healthcare
- 57.6. Mentenanță pentru Ecografe (USG) Logiq C5, GE Healthcare Inc.

Specificarea tehnică deplină solicitată de către autoritatea contractantă	**Specificația tehnică propusă de operatorul economic**
Lucrări necesare de întreținere a dispozitivului conform manualului de service și recomandării producătorului dispozitivului medical.	**DA** Lucrări necesare de întreținere a dispozitivului conform manualului de service și recomandării producătorului dispozitivului medical.
1. Obligatoriu se va prezenta lista lucrărilor de mentenanță și numărul de intervenții planificate de mentenanță de la producător, care urmează să fie desfășurată.	1. **DA** Obligatoriu se va prezenta lista lucrărilor de mentenanță și numărul de intervenții planificate de mentenanță de la producător, care urmează să fie desfășurată. – **Vezi Service Manual Logiq Fortis** **Vezi Service Manual Logiq P9** **Vezi Service Manual Logiq F8** **Vezi Service Manual Logiq S7** **Vezi Service Manual Logiq P5** **Vezi Service Manual Logiq C5**
2.Prezentarea listei detaliate cu costul fiecărei activități întreprinse.	2.Prezentarea listei detaliate cu costul fiecărei activități întreprinse. -**În Formularul Anexa 23 este indicată pretul pentru vizita care include și serviciu de urgență.**
3.Prezentarea listei cu prețul piese de schimb, kit de mentenanță care urmează să fie inlocuite în procesul de mentenanță.,	3.Prezentarea listei cu prețul piese de schimb, kit de mentenanță care urmează să fie inlocuite în procesul de mentenanță. – **NU necesită și nu este kit de mentenanță.**
Numărul de intervenții tehnice asupra dispozitivului medical conform recomandării producătorului dar nu mai puțin decât numărul de intervenții solicitate.	**DA**umărul de intervenții tehnice asupra dispozitivului medical conform recomandării producătorului dar nu mai puțin decât numărul de intervenții solicitate.
Agentul economic v-a asigura lucrări de întreținere a dispozitivului medical solicitat și lucrări pentru toate dispozitivele aferente care sunt în legătură directă cu dispozitivul medical, sau accesorii. Înlăturarea tuturor defecțiunilor depistate, tehnice cât și cele de program.	**DA** Agentul economic v-a asigura lucrări de întreținere a dispozitivului medical solicitat și lucrări pentru toate dispozitivele aferente care sunt în legătură directă cu dispozitivul medical, sau accesorii. Înlăturarea tuturor defecțiunilor depistate, tehnice cât și cele de program.
Intervenții de urgență	**DA** Intervenții de urgență
Lucrări de diagnosticare, testare, reparație în cazul defecțiunilor minore neprevăzute (erori tehnice, calibrare, resetare).	**DA** Lucrări de diagnosticare, testare, reparație în cazul defecțiunilor minore neprevăzute (erori tehnice, calibrare, resetare).
Intervenții de urgență cu reacționarea în maxim 24 ore de la notificarea defecțiunii, problemei, timpul intervenției telefonică maxim 1 oră, soluționarea problemei nu mai mult de 72 ore de la notificare.	**DA** Intervenții de urgență cu reacționarea în maxim 24 ore de la notificarea defecțiunii, problemei, timpul intervenției telefonică maxim 1 ore, soluționarea problemei nu mai mult de 72 ore de la notificare.

Chemarea inginerului companiei poate fi în formă scrisă cât și telefonică. Numărul de intervenții la solicitarea beneficiarului nelimitate pe tot parcursul contractului încheiat. Intervenția trebuie să se soldeze cu dispozitivul reparat sau problema soluționată. Generarea din partea agentului economic a unui raport cu toate acțiunile de reparație, remediere interprinse și indicarea pieselor utilizate.	**DA** Chemarea inginerului companiei poate fi în formă scrisă cât și telefonică. **DA** Numărul de intervenții la solicitarea (**și cele de urgență**) beneficiarului 2 (două) pe tot parcursul contractului încheiat. **DA** Intervenția trebuie să se soldeze cu dispozitivul reparat (**în cazul că acest lucru poate fi efectuat cu piesele care le detine deja benificiarul final**) sau problema soluționată sau **recomandarile de piese sau aceesori care necesită a fi schimbate pentru o bună funcționare a dispoztivuluio medical**. Dacă însă, defecțiunea prezintă o complexitate avansată, fiind necesar să se înlocuiască eventuale piese, acestea vor face obiectul unei oferte ulterioare. Piesele de schimb normale si speciale ale sistemelor nu sunt incluse. Piesele de schimb se vor achiziționa separat, iar costurile aferente cad în sarcina Beneficiarului. **DA** Generarea din partea agentului economic a unui raport cu toate acțiunile de reparație, remediere interprinse și indicarea pieselor utilizate.
Controlul prin verificare a dispozitivelor medicale ▪ Verificare stare aparat (să nu aibă lovituri, crăpături, starea şuruburilor şi prinderilor roţilor, etc.); ▪ Verificare parametrii tensiune de alimentare (tensiune, împâmantare, verificare întrerupători, etc.); ▪ Verificarea protecţiilor interne care asigură funcţionarea în condiţii de siguranţă ale aparatului; ▪ Verificare conectori şi cabluri; ▪ Măsurarea tensiunii din sursa de alimentare şi din bateria de back up; ▪ Măsurarea rezistenţelor diferitelor ansamble ale aparatului; ▪ Verificare şi curăţare filtre; ▪ Verificare şi curăţare ventilatoare de răcire; ▪ Verificare si calibrare ecran; ▪ Descărcare fişiere de logurişi erori; ▪ Verificare parametrii de protecție electrică conform EN 60601; ▪ Evaluarea parametrilor definitorii de performanță, prin examinare și testare; ▪ Verificarea îndeplinirii setului de criterii de acceptabilitate pentru dispozitivul medical (valori impuse, limite specificate, accesorii etc.).	**Controlul prin verificare a dispozitivelor medicale** ▪ **DA** Verificare stare aparat (să nu aibă lovituri, crăpături, starea şuruburilor şi prinderilor roţilor, etc.); ▪ **DA** Verificare parametrii tensiune de alimentare (tensiune, împâmantare, verificare întrerupători, etc.); ▪ **DA** Verificarea protecţiilor interne care asigură funcţionarea în condiţii de siguranţă ale aparatului; ▪ **DA** Verificare conectori şi cabluri; ▪ **DA** Măsurarea tensiunii din sursa de alimentare şi din bateria de back up; ▪ **DA** Măsurarea rezistenţelor diferitelor ansamble ale aparatului; ▪ **DA** Verificare şi curăţare filtre; ▪ **DA** Verificare şi curăţare ventilatoare de răcire; ▪ **DA** Verificare si calibrare ecran; ▪ **DA** Descărcare fişiere de logurişi erori; ▪ **DA** Verificare parametrii de protecție electrică conform EN 60601; - **Doar dacă aceste lucru va fi necesar în urma diagnosticului efectual de către inginerul specializat.** ▪ **DA** Evaluarea parametrilor definitorii de performanță, prin examinare și testare; ▪ **DA** Verificarea îndeplinirii setului de criterii de acceptabilitate pentru dispozitivul medical (valori impuse, limite specificate, accesorii etc.).

▪ Verificarea și reglarea părților mecanice aflate în mișcare; ▪ Eliminarea jocurilor la părțile mecanice; ▪ Curățarea și gresarea părților mecanice aflate în mișcare; ▪ Curățarea plăcilor electronice (dacă este cazul), precum și a altor componente; ▪ Verificarea componentelor pneumatice (acolo unde este cazul).	▪ **DA** Verificarea și reglarea părților mecanice aflate în mișcare; ▪ **DA** Eliminarea jocurilor la părțile mecanice; ▪ **DA** Curățarea și gresarea părților mecanice aflate în mișcare; ▪ **DA** Curățarea plăcilor electronice (dacă este cazul), precum și a altor componente; ▪ **DA** Verificarea componentelor pneumatice (acolo unde este cazul). **DA** Vor fi asigurate lucrări de întreținere a dispozitivului medical solicitat și lucrări pentru toate dispozitivele aferente care sunt în legătură directă cu dispozitivul medical, sau accesorii. Înlăturarea tuturor defecțiunilor depistate, tehnice cât și cele de program. - Dacă însă, defecțiunea prezintă o complexitate avansată, fiind necesar să se înlocuiască eventuale piese, acestea vor face obiectul unei oferte ulterioare. Piesele de schimb normale si speciale ale sistemelor nu sunt incluse. Piesele de schimb se vor achiziționa separat, iar costurile aferente cad în sarcina Beneficiarului

Attendance Certificate

We certify

Ion Negru

attended the

European GE Healthcare Ultrasound

Distribution Partner Meeting
and Product training

Vienna, April 16th – 18th, 2018

Certificate of Completion

This certifies that

Ion Negru

has successfully completed

GE Healthcare Customer System Personal Information Privacy and Security Policy

Completed on 12/31/2020
(date format: mm/dd/yyyy)

Certificate of Completion

This certifies that

Ion Negru

has successfully completed

GE Healthcare Customer System Personal Information Privacy and Security Standard

Completed on 12/31/2020
(date format: mm/dd/yyyy)

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Certificate of Completion

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has successfully completed

Essentials of Digital Technology Lite (V2)

Completed on 4/1/2021
(date format: mm/dd/yyyy)

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Certificate of Completion

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Proficient_UL Exam (DL)

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Proficient_UL Service Training (DL)

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Certificate of Completion

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Protecting Customer Data Is Everyone's Business

Completed on 12/31/2020
(date format: mm/dd/yyyy)

_____

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Secure Service Access Training

Completed on 9/23/2020
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_____

GE Healthcare

LOGIQ C3/C5 Premium

Basic Service Manual

Part Number: 5341787-100
Revision: 8

Section 10-2
Why do Maintenance

10-2-1 Keeping Records

It is good business practice that ultrasound facilities maintain records of quality checks and corrective maintenance. The Ultrasound Inspection Certificate (provided on page 10-16) provides the customer with documentation that the ultrasound scanner is maintained on a periodic basis.

A copy of the Ultrasound Periodic Maintenance Inspection Certificate should be kept in the same room or near the scanner.

10-2-2 Quality Assurance

In order to gain accreditation from organizations such as the American College of Radiology (USA), it is the customer's responsibility to have a quality assurance program in place for each scanner. The program must be directed by a medical physicists, the supervising radiologist/physician or appropriate designee.

Routine quality control testing must occur regularly. The same tests are performed during each period so that changes can be monitored over time and effective corrective action can be taken.

Testing results, corrective action and the effects of corrective action must be documented and maintained on the site.

Your GE service representative can help you with establishing, performing and maintaining records for a quality assurance program. Please contact us for coverage information and/or price for service.

Section 10-3
Maintenance Task Schedule

10-3-1 How often should care & maintenance tasks be performed?

The Care & Maintenance Task Schedule (provided on page 10-3) specifies how often your LOGIQ C3/C5 Premium should be serviced and outlines items requiring special attention.

NOTE: It is the customer's responsibility to ensure the LOGIQ C3/C5 Premium care & maintenance is performed as scheduled in order to retain its high level of safety, dependability and performance.

Your GE Service Representative has an in-depth knowledge of your LOGIQ C3/C5 Premium ultrasound scanning system and can best provide competent, efficient service. Please contact us for coverage information and/or price for service.

The service procedures and recommended intervals shown in the Care & Maintenance Task Schedule assumes that you use your LOGIQ C3/C5 Premium for an average patient load (10-12 per day) and not use it as a primary mobile unit which is transported between diagnostic facilities.

NOTE: If conditions exist which exceed typical usage and patient load, then it is recommended to increase the maintenance frequencies.

Section 10-3 Maintenance Task Schedule (cont'd)

Table 10-2 Customer Care Schedule

Service at Indicated Time	Daily	Weekly	Monthly	Per Facilities QA Program	Notes
Clean Probe Holders	•				
Clean Air Filter		•			more frequently depending on your environment
Inspect AC Mains Cable			•		Mobile Unit Check Weekly
Inspect Cables and Connectors			•		
Clean Console			•		
Inspect Wheels, Casters, brakes and Swivel Locks			•		Mobile Unit Check Daily
Check Control Panel Movement			•		Mobile Unit Check Daily
Console Leakage Current Checks				•	also after corrective maintenance
Peripheral Leakage Current Checks				•	also after corrective maintenance
Surface Probe Leakage Current Checks				•	also after corrective maintenance
Endocavity Probe Leakage Current Checks				•	also after corrective maintenance
Transesphongeal Probe Leakage Current Checks				•	also after corrective maintenance
Surgical Probe Leakage Current Checks				•	also after corrective maintenance
Measurement Accuracy Checks				•	also after corrective maintenance
Functional Checks				•	also after corrective maintenance

NOTE: PMs are not mandatory, the table above is for reference only.

NOTE: May require specialized equipment to complete.

GE HealthCare

LOGIQ F

General Service Manual

5946504-1EN Rev. 7
General Service Documentation

Warnings

DANGER
BE SURE TO DISCONNECT THE ULTRASOUND SYSTEM POWER PLUG AND OPEN THE MAIN CIRCUIT BREAKER BEFORE YOU REMOVE ANY PARTS. BE CAUTIOUS WHENEVER POWER IS STILL ON AND COVERS ARE REMOVED.

CAUTION
Practice good ESD prevention. Wear an anti–static strap when handling electronic parts and even when disconnecting/connecting cables.

CAUTION
Do not pull out or insert circuit boards while power is on.

CAUTION
Do not operate this Ultrasound system unless all board covers and frame panels are securely in place. System performance and cooling require this.

Why do maintenance

Preventive maintenance inspections

It has been determined by engineering that your ultrasound system does not have any high wear components that fail with use, therefore no Preventive Maintenance inspections are mandatory.

However, some customers' Quality Assurance Programs may require additional tasks and or inspections at a different frequency than listed in this manual.

Quality assurance

In order to gain accreditation from organizations such as the American College of Radiology (USA), it is the customer's responsibility to have a quality assurance program in place for each Ultrasound system. The program must be directed by a medical physicists, the supervising radiologist/physician or appropriate designee.

Routine quality control testing must occur regularly. The same tests are performed during each period so that changes can be monitored over time and effective corrective action can be taken.

Testing results, corrective action and the effects of corrective action must be documented and maintained on the site.

Your GE HealthCare service representative can help you with establishing, performing and maintaining records for a quality assurance program. Contact GE HealthCare for coverage and/or price for service.

Maintenance task schedule

How often should maintenance tasks be performed?

It has been determined by engineering that your Ultrasound System does not have any high wear components that fail with use, therefore no Periodic Maintenance inspections are mandatory. However, some customers' Quality Assurance Programs may require additional tasks and or inspections at a different frequency than listed in this manual.

The Care and Maintenance task schedule (provided in *Table 10-1 Customer Care Schedule* on page 313) specifies how often your ultrasound system should be serviced and outlines items requiring special attention.

NOTE
It is the customer's responsibility to ensure the ultrasound system care and maintenance is performed as scheduled in order to retain its high level of safety, dependability and performance.

Your GE HealthCare Service Representative has an in-depth knowledge of your ultrasound system and can best provide competent, efficient service. Contact GE HealthCare for coverage information and/or price for service.

The service procedures and recommended intervals shown in the Care and Maintenance Task Schedule assumes that you use your ultrasound system for an average patient load (15 per day) and not use it as a primary mobile Ultrasound system which is transported between diagnostic facilities.

NOTE
If conditions exist which exceed typical usage and patient load, then it is recommended to increase the care and maintenance frequencies.

Table 10-1 Customer Care Schedule

Service at Indicated Time	Daily	Weekly	Monthly	Per Facilities QA Program	Notes
Clean Probes	•				* or before each use
Inspect AC Mains Cable			•		
Inspect Cables and Connectors			•		
Clean Console			•		
Clean Monitor			•		
Clean Filters			•		
Console Leakage Current Checks				See Notes	Twice Annually
Peripheral Leakage Current Checks				See Notes	Twice Annually
Surface Probe Leakage Current Checks				See Notes	Twice Annually
Endocavity Probe Leakage Current Checks				See Notes	Quarterly Annually
Surgical Probe Leakage Current Checks				See Notes	Quarterly Annually
Measurement Accuracy Checks				See Notes	Twice Annually
Functional Checks				See Notes	also after corrective maintenance

NOTE
The maintenance may require specialized equipment to complete.

NOTE
The care and maintenances are not mandatory. The table above is for reference only.

GE HealthCare

LOGIQ Fortis

General Service Manual

5874373 Rev. 8

General Service Documentation

The test verifies that the protective earth conductors in the power cord and console are intact.

The testing electrical safety analyzer is connected to parts of the equipment easily contacted by the user or patient.

The ground wire resistance should comply with the procedure used for the test.

- For IEC 60601-1, the expected result is less than 0.2 ohms.
- For IEC 62353, the expected result is less than 0.3 ohms.
- For NFPA 99, the expected result is less than 0.5 ohms.

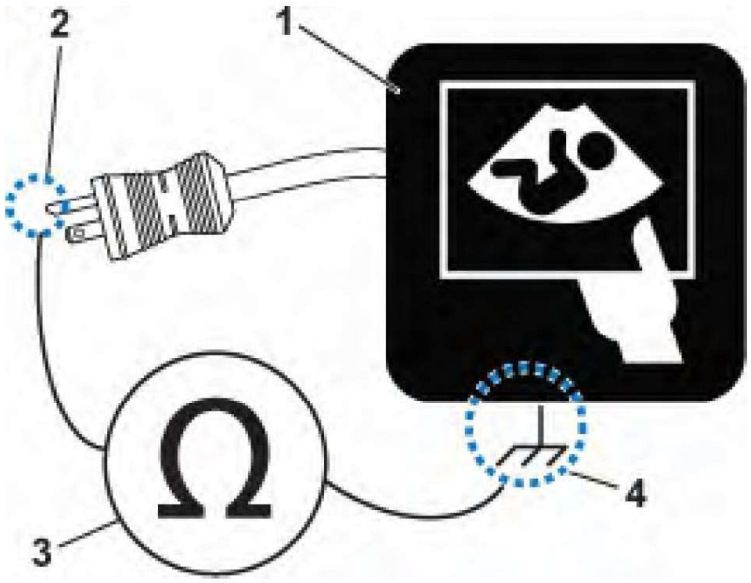
NOTE
In some countries/regions differing acceptance limits and differing test conditions may apply.

13.7.6.2 Generic procedure for the grounding continuity test

Measure the resistance from the third pin of the attachment plug to the exposed metal parts of the case.

Record the highest reading of current.

Figure 13-3 Ground Continuity Test



1. Ultrasound system	3. Ohmmeter or electrical safety analyzer
2. Ground pin	4. Accessible metal part such as: • Potential equilibrium connector • Monitor housing • Probe connector

13.7.6.3 Data sheet for the grounding continuity test

This table shows a typical format for recording the grounding continuity.

Record all data and keep the record of the results with other hard copies of maintenance data.

When filling out an electronic form (for example, an Ultrasound Equipment Quality Check (EQC and IQC)), record the highest reading from your results.

NOTE

Not all test procedures are applicable to all areas of the world. Reversed Polarity testing content satisfies regions following IEC 62353 and IEC 60601-1.

Table 13-9 Typical Data Format For Recording Grounding Continuity

Unit under test _____			**Date of test** __/__/____			
Test Conditions			**Measurement/Test Point Location**			
System Power	**Grounding/ PE**	**Limit µA**	**Third pin of the attachment plug**			
off	closed	For IEC 60601-1, the expected result is less than 0.2 ohms. For IEC 62353, the expected result is less than 0.3 ohms. For NFPA 99, the expected result is less than 0.5 ohms.				

13.7.7 Chassis leakage current test

DANGER

Electric Shock Hazard!
When the electrical safety analyzer's ground switch is OPEN, DO NOT touch the Ultrasound system!

CAUTION
Equipment damage possibility.

Never switch the Polarity and the status of Neutral when the Ultrasound system is powered ON.

Power off the Ultrasound system, allow the stored energy to bleed down, and turn the circuit breaker off BEFORE switching the "POLARITY" switch and/or the "NEUTRAL" switch on the Electrical Safety Analyzer to avoid possible power supply damage.

CAUTION
Lacquer is an isolation barrier! Measure only on blank accessible metal parts.

13.7.7.1 Definition of the chassis leakage current test

This test, also known as Enclosure Leakage current test, measures the current that would flow through a grounded person who touches the accessible conductive parts of the equipment during normal and fault conditions.

The test verifies the isolation of the power line from the chassis.

The testing electrical safety analyzer is connected to parts of the equipment easily contacted by the user or patient.

13.7.7.2 Generic procedure for the chassis leakage current test

The test verifies the isolation of the power line from the chassis. The testing electrical safety analyzer is connected from accessible metal parts of the case to ground. Measurements should be made under the test conditions specified in *Table 13-6 Leakage Current Limits for Ultrasound System Operation on 100-240 Volt Mains* on page 848, as applicable.

The maximum allowable limit for chassis source leakage is shown in *Table 13-6 Leakage Current Limits for Ultrasound System Operation on 100-240 Volt Mains* on page 848, as Chassis/Enclosure Leakage.

NOTE
Not all test procedures are applicable to all areas of the world. Reversed Polarity testing content satisfies regions following IEC 62353 and IEC 60601-1.

Record the highest reading of current.

1. Connect the safety analyzer to wall AC wall outlet.
2. Plug the equipment under test into the receptacle on the panel of the electrical safety analyzer.
3. Connect the electrical safety analyzer to an accessible metal surface of the Ultrasound system using the cable provided with the electrical safety analyzer.
4. Select the “Chassis” or “Enclosure Leakage” function on the electrical safety analyzer.
5. Test opening and closing the ground with the Ultrasound system on and off as indicated in *Table 13-6 Leakage Current Limits for Ultrasound System Operation on 100-240 Volt Mains* on page 848, as applicable.

NOTE
For more information, refer to the safety analyzer’s user manual that will be used to perform the tests.

13.7.7.3 Data sheet for the chassis leakage current test

Table 13-10 Typical Data Format For Recording Chassis Leakage (Touch Current) on page 855 shows a typical format for recording the enclosure/chassis leakage current. Measurements should be recorded from multiple locations for each set of test conditions. The actual location of the test probe may vary by Ultrasound system.

Record all data and keep the record of the results with other hard copies of maintenance data.

When filling out an electronic form (for example, an Ultrasound Equipment Quality Check (EQC and IQC)), record the highest reading from your results.

NOTE
Not all test procedures are applicable to all areas of the world. Reversed Polarity testing content satisfies regions following IEC 62353 and IEC 60601-1.

NOTE
Values in italics font are given as examples only.

Table 13-10 Typical Data Format For Recording Chassis Leakage (Touch Current)

Unit under test _____				**Date of test** __/__/____		
Test Conditions			**Measurement/Test Point Location**			
System Power	**Grounding/ PE**	**Limit µA**	***Potential equilibrium connector***	***Monitor housing***	***Probe connector***	
off	closed	100				
off	open	500				
on	closed	100				
on	open	500				
off	closed (reversed polarity)	100				
off	open (reversed polarity)	500				
on	closed (reversed polarity)	100				
on	open (reversed polarity)	500				

13.7.8 Isolated patient lead (source) leakage–lead to ground test (e.g. ECG)

CAUTION
Equipment damage possibility.

Never switch the Polarity and the status of Neutral when the Ultrasound system is powered ON.

Power off the Ultrasound system, allow the stored energy to bleed down, and turn the circuit breaker off BEFORE switching the "POLARITY" switch and/or the "NEUTRAL" switch on the electrical safety analyzer to avoid possible power supply damage.

13.7.8.1 Definition of the isolated patient lead (source) leakage–lead to ground test

This test measures the current which would flow to ground from any of the isolated ECG leads. The electrical safety analyzer simulates a patient who is connected to the monitoring equipment and is grounded by touching some other grounded surface.

Measurements should be made with the ground open and closed, with power line polarity normal and reversed, and with the Ultrasound system on and off (per IEC 62353 and/or IEC 60601-1).

For each combination the operating controls, such as the lead switch, should be operated to find the worst case condition.

13.7.8.2 Generic procedure for the isolated patient lead (source) leakage–lead to ground test

Measurements should be made under the test conditions specified in *Table 13-6 Leakage Current Limits for Ultrasound System Operation on 100-240 Volt Mains* on page 848, as applicable.

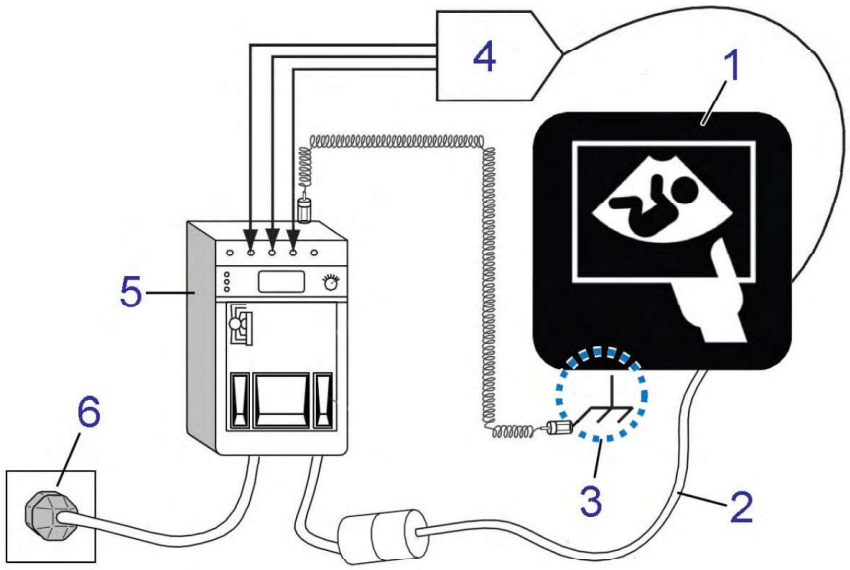
For each combination, the operating controls, such as the lead switch, should be operated to find the worst case condition.

Record the highest reading of current.

1. Connect the safety analyzer to wall AC power outlet.
2. Plug the equipment under test power cable into the receptacle on the panel of the electrical safety analyzer.
3. Connect the ECG cable to the Ultrasound system and the patient leads to the analyzer.
4. Select the “Patient Lead Leakage” function on the electrical safety analyzer.
5. Test opening and closing the ground with the Ultrasound system on and off.

NOTE
For more information, refer to the safety analyzer's user manual.

Figure 13-4 Set Up for Test of Earth Leakage Current, IEC 60601-1



1. Ultrasound system	4. ECG patient cable
2. Mains power cable	5. Electrical safety analyzer
3. Accessible metal parts (chassis - non-earth ground, unprotected surface)	6. AC wall outlet

13.7.8.3 Data sheet for the isolated patient lead (source) leakage–lead to ground test

This table shows a typical format for recording the isolated patient lead (source) leakage–lead to ground.

Record all data and keep the record of the results with other hard copies of maintenance data.

When filling out an electronic form (for example, an Ultrasound Equipment Quality Check (EQC and IQC)), record the highest reading from your results.

NOTE
Not all test procedures are applicable to all areas of the world. Reversed Polarity testing content satisfies regions following IEC 62353 and IEC 60601-1.

NOTE
Values in italics font are given as examples only.

Table 13-11 Typical Data Format For Recording Patient Lead To Ground (GND) Leakage for CF Type Applied Part (e.g. ECG)

Unit under test _____			**Date of test** __/__/____			
Test Conditions			**Patient Lead or Combination Measured**			
System Power	**Grounding/ PE**	**Limit µA**	***RA to GND***	***LA to GND***	***LL to GND***	***(RA+LA+LL) to GND***
off	closed	10				
off	open	50				
on	closed	10				
on	open	50				
off	closed (reversed polarity)	10				
off	open (reversed polarity)	50				
on	closed (reversed polarity)	10				
on	open (reversed polarity)	50				

13.7.9 Isolated patient lead (source) leakage–lead to lead test (e.g. ECG)

DANGER
Electric Shock Hazard!

When the electrical safety analyzer's ground switch is OPEN, DO NOT touch the Ultrasound system!

13.7.9.1 Definition of the isolated patient lead (source) leakage–lead to lead test

This test measures the current which would flow between ECG leads. The electrical safety analyzer simulates a patient who is connected to the monitoring equipment.

This test verifies that the separation between the patient connections is adequate to limit the patient leakage current to the allowed value when an external voltage is present.

The testing electrical safety analyzer is connected to parts of the equipment easily contacted by the user or patient.

Select and test each of the ECG lead positions (except ALL) on the LEAD selector, testing each to the power and ground condition combinations found in Table 4-6 on page 4-19, as applicable.

NOTE
This test is also known as the patient auxiliary current test.

13.7.9.2 Generic procedure for the lead to lead leakage test

Table 13-12 Typical Data Format For Recording Patient Lead To Lead Leakage for CF Type Applied Part (e.g. ECG) on page 860 shows a typical format for recording the patient lead to lead leakage current.

Measurements should be recorded from each lead combination under each set of test conditions specified in *Table 13-6 Leakage Current Limits for Ultrasound System Operation on 100-240 Volt Mains* on page 848, as applicable.

Record the highest reading of current.

1. Connect the safety analyzer to a wall AC power outlet.
2. Plug the equipment under test into the receptacle on the electrical safety analyzer's panel.
3. Connect the ECG cable to the Ultrasound system and the patient leads to the analyzer.
4. Select the “Patient Lead Leakage” function on the electrical safety analyzer.
5. Test opening and closing the ground with the Ultrasound system on and off.

NOTE
Refer to the safety analyzer’s user manual that will be used to perform the tests.

13.7.9.3 Data sheet for the lead to lead leakage test

This table shows a typical format for recording the lead to lead leakage test.

Record all data and keep the record of the results with other hard copies of maintenance data.

When filling out an electronic form (for example, an Ultrasound Equipment Quality Check (EQC and IQC)), record the highest reading from your results.

NOTE

Not all test procedures are applicable to all areas of the world. Reversed Polarity testing content satisfies regions following IEC 62353 and IEC 60601-1.

NOTE
Values in italics font are given as examples only.

Table 13-12 Typical Data Format For Recording Patient Lead To Lead Leakage for CF Type Applied Part (e.g. ECG)

Unit under test _____				**Date of test** __/__/____		
Test Conditions			**Patient Lead or Combination Measured**			
System Power	**Grounding/ PE**	**Limit µA**	***RA to LA***	***LA to LL***	***LL to RA***	***(RA+LA+ LL) to GND***
off	closed	10				
off	open	50				
on	closed	10				
on	open	50				
off	closed (reversed polarity)	10				
off	open (reversed polarity)	50				
on	closed (reversed polarity)	10				
on	open (reversed polarity)	50				

13.7.10 Isolated patient lead (sink) leakage-isolation test (e.g. ECG)

DANGER

Line voltage is applied to the ECG leads during this test. To avoid possible electric shock hazard, the Ultrasound system being tested must not be touched by patients, users or anyone while the ISO TEST switch is depressed.

13.7.10.1 Definition of the isolated patient lead (sink) leakage-isolation test

This test measures the current which would flow if mains voltage were connected to isolated ECG leads.

This test verifies that the separation between the patient connections and other parts is adequate to limit the patient leakage current to the allowed value when an external voltage is present.

The testing electrical safety analyzer is connected to parts of the equipment easily contacted by the user or patient.

Select the Individual Leads as well as All Lead position since the test is performed with mains applied to all ECG leads at the same time.

13.7.10.2 Generic procedure for the isolated lead (sink) leakage test

Table 13-13 Typical Data Format For Recording Isolated Patient Lead (Sink) Leakage for CF Type Applied Part (e.g. ECG) on page 861 shows a typical format for recording the isolated patient lead sink leakage current.

Measurements should be recorded for full lead combination under each set of test conditions specified in *Table 13-7 ISO and Mains Applied Limits** on page 849.

Record the highest reading of current.

1. Connect the safety analyzer to a wall AC power outlet.
2. Plug the equipment under test into the receptacle on the panel of the electrical safety analyzer.
3. Connect the ECG cable to the Ultrasound system and the patient leads to the analyzer.
4. Select the “Patient Lead Leakage” function on the electrical safety analyzer.
5. Test with closed ground with the Ultrasound system on and off.

NOTE
Refer to the electrical safety analyzer’s user manual that will be used to perform the tests.

13.7.10.3 Data sheet for the isolated lead (sink) leakage test

This table shows a typical format for recording the isolated lead (sink) leakage test.

Record all data and keep the record of the results with other hard copies of maintenance data.

When filling out an electronic form (for example, an Ultrasound Equipment Quality Check (EQC and IQC)), record the highest reading from your results.

NOTE
Not all test procedures are applicable to all areas of the world. Reversed Polarity testing content satisfies regions following IEC 62353 and IEC 60601-1.

NOTE
Values in italics font are given as examples only.

Table 13-13 Typical Data Format For Recording Isolated Patient Lead (Sink) Leakage for CF Type Applied Part (e.g. ECG)

Unit under test _____		**Date of test __/__/____**	
Test Conditions			**Patient Lead**
System Power	**Grounding/PE**	**Limit µA**	***RA+LA+LL***
off	closed	50	
on	closed	50	

Unit under test _____		Date of test __/__/____	
Test Conditions			**Patient Lead**
System Power	**Grounding/PE**	**Limit µA**	***RA+LA+LL***
off	closed (reversed polarity)	50	
on	closed (reversed polarity)	50	

13.7.11 Probe (source) leakage current test

DANGER
Do not use the probe if the insulating material has been punctured or otherwise compromised. Integrity of the insulation material and patient safety can be verified by safety testing according to IEC 60601-1.

13.7.11.1 Definition of probe (source) leakage current test

This test measures the current that would flow to ground from any of the probes through a patient who is being scanned and becomes grounded by touching some other grounded surface.

NOTE
Each probe will have some amount of leakage, dependent on its design. Small variations in probe leakage currents are normal from probe to probe. Other variations will result from differences in line voltage and test lead placement. It is abnormal if no leakage current is measured. If no leakage current is detected, check the configuration of the test equipment.

13.7.11.2 Generic procedure on probe leakage current

The most common method of measuring probe leakage is to partly immerse the probe into a saline bath while the probe is connected to the Ultrasound system and active. This method measures the actual leakage current resulting from the probe RF drive.

Measurements should be made under the test conditions specified in:

- *Table 13-6 Leakage Current Limits for Ultrasound System Operation on 100-240 Volt Mains* on page 848, as applicable for every probe.

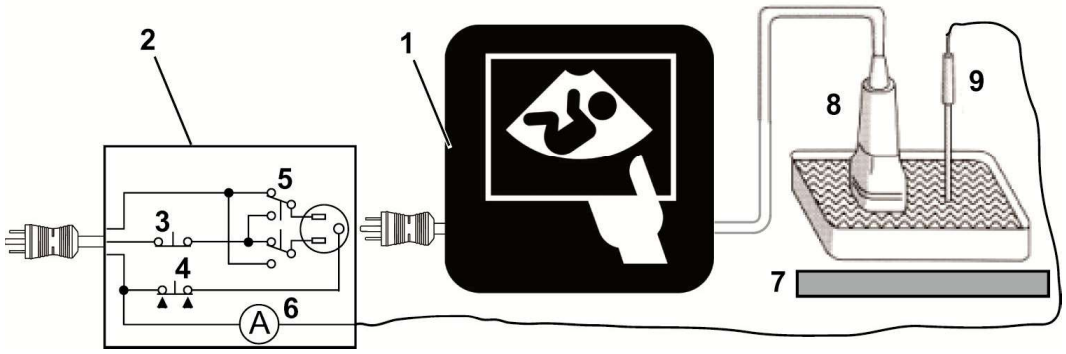
For each combination, the probe must be active to find the worst case condition.

Record the highest reading of current.

NOTE
Saline water pod should be insulated from floor and earth ground.

NOTE
The saline solution is a mixture of water and salt. The salt adds free ions to the water, making it conductive. Normal saline solution is 0.9% salt and 99.1% water. If ready-mixed saline solution is not available, a mixture of 1 quart or 1 liter water with 9 or more grams of table salt, mixed thoroughly, will substitute.

Figure 13-5 Set Up for Probe Leakage Current



1. Ultrasound system	6. Meter
2. Electrical safety analyzer	7. Isolator
3. Neutral switch	8. Ultrasound probe
4. Ground switch	9. Saline probe
5. Polarity reversing switch	

NOTE
Each probe will have some amount of leakage, dependent on its design. Small variations in probe leakage currents are normal from probe to probe. Other variations will result from differences in line voltage and test lead placement. It is abnormal if no leakage current is measured. If no leakage current is detected, check the configuration of the test equipment.

The Ultrasound probes imaging area is immersed in the saline solution along with a grounding probe from the electrical safety analyzer to complete the current path.

This test is also known as Patient Leakage Current.

1. Turn the Ultrasound system OFF
2. Connect the safety analyzer to AC wall outlet.
3. Set the safety analyzer's function switch to “Chassis” or “Enclosure Leakage.”
4. Plug the Ultrasound system’s power cord into the Electrical Safety Analyzer.
5. Plug the Chassis Ground Probe (saline probe) into the Electrical Safety Analyzer's “CHASSIS” connector.
6. Connect the Ultrasound probe to the Ultrasound system.
7. Immerse the Saline probe in the saline solution.
8. Immerse the Ultrasound probe’s face (imaging area of the probe) into the saline solution.

GE Healthcare

Technical Publication

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Revision 5

GE Healthcare
LOGIQ™P5 Service Manual

Operating Documentation

Section 10-2
Why do Maintenance

10-2-1 Keeping Records

It is good business practice that ultrasound facilities maintain records of quality checks and corrective maintenance. The Ultrasound Inspection Certificate (provided on page 10-29) provides the customer with documentation that the ultrasound scanner is maintained on a periodic basis.

A copy of the Ultrasound Periodic Maintenance Inspection Certificate should be kept in the same room or near the scanner.

10-2-2 Quality Assurance

In order to gain accreditation from organizations such as the American College of Radiology (USA), it is the customer's responsibility to have a quality assurance program in place for each scanner. The program must be directed by a medical physicists, the supervising radiologist/physician or appropriate designee.

Routine quality control testing must occur regularly. The same tests are performed during each period so that changes can be monitored over time and effective corrective action can be taken.

Testing results, corrective action and the effects of corrective action must be documented and maintained on the site.

Your GE service representative can help you with establishing, performing and maintaining records for a quality assurance program. Please contact us for coverage information and/or price for service.

Section 10-3
Maintenance Task Schedule

10-3-1 How often should care & maintenance tasks be performed?

The Care & Maintenance Task Schedule (provided on page 10-3) specifies how often your LOGIQ™ P5 should be serviced and outlines items requiring special attention.

NOTE: It is the customer's responsibility to ensure the LOGIQ™ P5 care & maintenance is performed as scheduled in order to retain its high level of safety, dependability and performance.

Your GE Service Representative has an in-depth knowledge of your LOGIQ™ P5 ultrasound scanning system and can best provide competent, efficient service. Please contact us for coverage information and/or price for service.

The service procedures and recommended intervals shown in the Care & Maintenance Task Schedule assumes that you use your LOGIQ™ P5 for an average patient load (10-12 per day) and not use it as a primary mobile unit which is transported between diagnostic facilities.

NOTE: If conditions exist which exceed typical usage and patient load, then it is recommended to increase the maintenance frequencies.

Table 10-2 Customer Care Schedule

Service at Indicated Time	Daily	Monthly	Quarterly	Per Facilities QA Program	Notes
Clean Probes	•*				* or before each use
Clean Probe Holders	•				
Clean Air Filter			•		more frequently depending on your environment
Inspect AC Mains Cable		•			Mobile Unit Check Weekly
Inspect Cables and Connectors		•			
Clean Console		•			
Clean Monitor and Touch Panel		•			
Inspect Wheels, Casters, brakes and Swivel Locks		•			Mobile Unit Check Daily
Check Control Panel Movement		•			Mobile Unit Check Daily
Console Leakage Current Checks				•	also after corrective maintenance
Peripheral Leakage Current Checks				•	also after corrective maintenance
Surface Probe Leakage Current Checks				•	also after corrective maintenance
Endocavity Probe Leakage Current Checks				•	also after corrective maintenance
Transesphongeal Probe Leakage Current Checks				•	also after corrective maintenance
Surgical Probe Leakage Current Checks				•	also after corrective maintenance
Measurement Accuracy Checks				•	also after corrective maintenance
Probe/Phantom Checks				•	also after corrective maintenance
Functional Checks				•	also after corrective maintenance

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10-3-1 How often should care & maintenance tasks be performed? (cont?)

Table 10-2 Customer Care Schedule

Item	Service at Indicated Time	D	W	M	A	Notes
Air Filter Grid	Remove the filter grid and clean the air filter.		•			Recommend to clean filter at least bi-weekly
AC Mains Cable	Inspect AC Mains Cable			•		Mobile Unit Check weekly
Cables and Connectors	Check if all cables are fixed well seated at the correct position and if there is no mechanical damage visible.				•	also after corrective maintenance
User Interface	Clean alphanumerical keyboard, Functional keys, Digital potentiometers, TGC-Shift potentiometers. (vacuum cleaner, lukewarm soap water on a soft, damp cloth)		•			Be careful not to get the cloth too wet so that moisture does not enter the loudspeakers, TGC-Slider, or other keys!
LCD Monitor, Touch Panel and Probe holder	Clean LCD Monitor surface and Probe holder with a fluid detergent in warm water on a soft, damp cloth.		•			Be careful not to get the cloth too wet so that moisture does not enter the entire system.
Mechanical parts	Clean and inspect the mechanical function of wheels, casters, brakes and swivel locks as well as side door, foot rest, front and rear handle, and monitor holder. Remove Dust and Coupling gel.			•		Mobile Unit Check Daily
Control Console movement	Check Translation/Rotation and Height Adjustment (Elevation)				•	more frequently at Mobile Units
Trackball Check	Check proper operation (Cursor movement X, Y direction)	•				If failure occurs go to trackball cleaning.
Trackball Cleaning	Remove trackball ring; open the trackball housing and take out the trackball to clean it with soft tissue and screwdriver shaft.				•	Please record it in the systems setup maintenance report
Disk Drives (Data Backup)	Test Image filing (Archive) Import and Export data capability (DVD/CD Drive)		•	•*		* save the image filing data weekly or at least monthly on DVD/CD depending on the number of examinations
Safe Probe Operation	Clean probes and probe cables and check acoustic lens housing (cracks) and probe cables. In case of mechanical damage, don't use them! **Danger:** Safety risk for operator and patient.	•*				* or before each use
Probe Air bubbles	To detect air bubbles in filling liquid, shake the probe carefully and check abnormal noise.					
Probe connectors	Remove dust/dirt of all probe connectors. Clean with vacuum cleaner if dust is visible.			•		
Console Leakage Current Checks					•	Also after corrective maintenance or as required by your facilities QA program.
Peripheral Leakage Current Checks					•	Also after corrective maintenance or as required by your facilities QA program.

Table 10-2 Customer Care Schedule

Item	Service at Indicated Time	D	W	M	A	Notes
Surface Probe Leakage Current Checks					•	Also after corrective maintenance or as required by your facilities QA program.
Endocavity Probe Leakage Current Checks					•	Also after corrective maintenance or as required by your facilities QA program.
Measurement Accuracy Checks					•	Also after corrective maintenance or as required by your facilities QA program.
Probe/Phantom Checks	Check axial and lateral resolution (see Basic User Manual Technical specifications). Check Gain and TGC changes, vary the focus and check reaction on screen.				•	Also after corrective maintenance or as required by your facilities QA program.
Functional Checks of all probes Section 10-5-2 on page 10-7					•	Also after corrective maintenance or as required by your facilities QA program.

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LOGIQ S8/LOGIQ E8/ LOGIQ S7 XDclear2.0

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Section 10-4
Maintenance task schedule

10-4-1 How often should maintenance tasks be performed?

The Care & Maintenance task schedule (Table 10-1 below) specifies how often your LOGIQ™ S8 should be serviced and outlines items requiring special attention.

NOTE: It is the customer's responsibility to ensure the LOGIQ™ S8 care & maintenance is performed as scheduled in order to retain its high level of safety, dependability and performance.

Your GE Service Representative has an in-depth knowledge of your LOGIQ™ S8 ultrasound scanning system and can best provide competent, efficient service. Please contact us for coverage information and/or price for service.

The service procedures and recommended intervals shown in the Care & Maintenance Task Schedule assumes that you use your LOGIQ™ S8 for an average patient load (10-12 per day) and not use it as a primary mobile unit which is transported between diagnostic facilities.

NOTE: If conditions exist which exceed typical usage and patient load, then it is recommended to increase the periodic maintenance frequencies.

Abbreviations used in the Customer Care Schedule 10-1:

D = Daily W = Weekly M = Monthly A = Annually

Table 10-1 Customer Care Schedule

Item	Service at Indicated Time	D	W	M	A	Notes
Air Filter Grid	Remove the filter grid and clean the air filter.		•			Recommend to clean filter at least bi-weekly
AC Mains Cable	Inspect AC Mains Cable			•		Mobile Unit Check weekly
Cables and Connectors	Check if all cables are fixed well seated at the correct position and if there is no mechanical damage visible.				•	also after corrective maintenance
User Interface	Clean alphanumerical keyboard, Functional keys, Digital potentiometers, TGC-Shift potentiometers. (vacuum cleaner, lukewarm soap water on a soft, damp cloth)		•			Be careful not to get the cloth too wet so that moisture does not enter the loudspeakers, TGC-Slider, or other keys!
LCD Monitor, Touch Panel and Probe holder	Clean LCD Monitor surface and Probe holder with a fluid detergent in warm water on a soft, damp cloth.		•			Be careful not to get the cloth too wet so that moisture does not enter the entire system.
Mechanical parts	Clean and inspect the mechanical function of wheels, casters, brakes and swivel locks as well as side door, foot rest, front and rear handle, and monitor holder. Remove Dust and Coupling gel.			•		Mobile Unit Check Daily
Control Console movement	Check Translation/Rotation and Height Adjustment (Elevation)				•	more frequently at Mobile Units
Trackball Check	Check proper operation (Cursor movement X, Y direction)	•				If failure occurs go to trackball cleaning.

Table 10-1 Customer Care Schedule

Item	Service at Indicated Time	D	W	M	A	Notes
Trackball Cleaning	Remove trackball ring; open the trackball housing and take out the trackball to clean it with soft tissue and screwdriver shaft.				•	Please record it in the systems setup maintenance report
Disk Drives (Data Backup)	Test Image filing (Archive) Import and Export data capability (DVD/CD Drive)		•	•*		* save the image filing data weekly or at least monthly on DVD/CD depending on the number of examinations
Safe Probe Operation	Clean probes and probe cables and check acoustic lens housing (cracks) and probe cables. In case of mechanical damage, don't use them! **Danger:** Safety risk for operator and patient.	•*				* or before each use
Probe Air bubbles	To detect air bubbles in filling liquid, shake the probe carefully and check abnormal noise.					
Probe connectors	Remove dust/dirt of all probe connectors. Clean with vacuum cleaner if dust is visible.			•		
Console Leakage Current Checks					•	Also after corrective maintenance or as required by your facilities QA program.
Peripheral Leakage Current Checks					•	Also after corrective maintenance or as required by your facilities QA program.
Surface Probe Leakage Current Checks					•	Also after corrective maintenance or as required by your facilities QA program.
Endocavity Probe Leakage Current Checks					•	Also after corrective maintenance or as required by your facilities QA program.
Measurement Accuracy Checks					•	Also after corrective maintenance or as required by your facilities QA program.
Probe/Phantom Checks	Check axial and lateral resolution (see Basic User Manual Technical specifications). Check Gain and TGC changes, vary the focus and check reaction on screen. Check deviation of brightness in the US-Image (missing elements / probe cable defect). Probe must be coupled as this test.				•	Also after corrective maintenance or as required by your facilities QA program.
Functional Checks of all probes section 10-6-2 on page 10-8	Check general functions and image appearance at human body with all available Modes.				•	Also after corrective maintenance or as required by your facilities QA program.

Table 10-1 Customer Care Schedule

Item	Service at Indicated Time	D	W	M	A	Notes
Battery	Battery deterioration When the system detects the battery deterioration, the “Battery deterioration” dialog displays. Replace the battery for proper function.				•	When “Battery deterioration” message will be displayed, call to GE Service.
Battery Refresh	If the user doesn’t maintain the battery as indicated in Basic User Manual Chapter 3 “Refreshing battery”, refresh the battery every 6 months for the user. Refresh procedure: 1. Turn on the system. 2. Wait until the battery is fully charged. it takes at least 1 hour to fully charge the battery. 3. Turn off the system. 4. Remove all probes. 5. Turn on the system. 6. Unplug the AC cable and wait until the system shuts down. It may take 30 minutes or more to complete shutdown. 7. Wait at least 5 hours. 8. Plug in the AC cable. 9. Turn on the system. 10. Wait until the battery is fully charged. It takes about 3 hours to fully charge the battery.				•	Every 6 months